



Chandrashekhar Kajagar <ckajagar@gmail.com>

FW: Regarding HMSC Decision

Shivaprasad Goudar <sgoudar@jnmc.edu>

8 May 2018 at 15:11

To: Robert L Goldenberg <rlg88@columbia.edu>, mcclure@rti.org, "Parlberg, Lindsay" <lparlberg@rti.org>, Norman Goco <ngoco@rti.org>, "Dhaded, S M" <drdhadedsm@gmail.com>, Manjunath Somannavar <manjunathsomannavar@gmail.com>, yogeshkumar23@gmail.com, Mahantesh Nagmoti <drmbnagmoti@yahoo.co.in>, Guruprasad G <dr_g_gp@yahoo.com>, Sunilkumar Byrnalli <drsuniilkb@gmail.com>, vardendrak@gmail.com, Babuji NICU <bapujinicu@gmail.com>

Cc: Chandrashekhar Kajagar <ckajagar@gmail.com>, Amit Revankar <amit@jnmc.edu>

ICMR HMSC approval for PURPOSE.

From: icmr@cdac.in [mailto:icmr@cdac.in]

Sent: Tuesday, May 8, 2018 3:01 PM

To: sgoudar@jnmc.edu

Subject: Regarding HMSC Decision

Dear DR. SHIVAPRASAD SADASHIVAPPA GOUDAR,

The proposal with proposal id **2018-0003** entitled **ASIA PREGNANCY OUTCOMES STUDY**, was considered during the HMSC meeting held on 01-05-2018 and the decision of the HMSC is as follows:

Approved .

You may now take necessary action at your end to initiate the project and let us know the date of initiation of the project. You are requested to kindly ensure submission of progress report of the project to ICMR.

You are also requested to upload the duly filled in and signed DST project summary sheet and DST check list by logging into your account at <http://icmrextramural.in/ICMR/> for onward transmission to DST by ICMR. For any further queries please contact the coordinator, ICMR at 011-26589492

With Regards
ICMR Team.

This is a system generated mail. Please do not reply to it. For Any Further Correspondence please contact only at "onlineicmrteam@gmail.com / 011-26588590".

[C-DAC is on Social-Media too. Kindly follow us at:

Facebook: <https://www.facebook.com/CDACINDIA> & Twitter: @cdacindia]

This e-mail is for the sole use of the intended recipient(s) and may contain confidential and privileged information. If you are not the intended recipient, please contact the sender by reply e-mail and destroy all copies and the original message. Any unauthorized review, use, disclosure, dissemination, forwarding, printing or copying of this email is strictly prohibited and appropriate legal action will be taken.

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

**KLE University's
Women's and Children's Health Research Unit
J N Medical College
COST REIMBURSABLE RESEARCH SUBCONTRACT
"PRETERM COD"**

This contract Agreement for "**Cause of Death among Preterm Births**" in Karnataka Sub-site, India hereafter referred to as the "**PRETERM COD**" is entered into in order to specify the terms and conditions under which the KLE University's, Women's and Children's Health Research Unit, JN Medical College, (hereinafter referred to as "JNMC") and JJM Medical College Davangere, Karnataka (hereinafter referred to as "JJMMC") will participate in the conduct of a project supported by the RTI International (RTI) (hereinafter referred to as "Sponsor").

General Information:

Title: Research Subcontract in between Jawaharlal Nehru Medical College, Belgaum and JJM Medical College, Davangere, Karnataka for the "**PRETERM COD**"

Award Title: This Hospital-based Trial Contract (the "Contract"), effective as of Dec 15, 2017 (the "Effective Date") is by and between RTI and Jawaharlal Nehru Medical College located at Belgaum 590010 in Karnataka, India ("JNMC"), represented by its employee Dr Shivaprasad Goudar, MD (the "Principal Investigator").

Prime Award : Between RTI & Bill & Melinda Gates Foundation: Grant No OPP1169824

Sub Award : Between RTI & JNMC Sub Award No: 3-312-0216193-65162L

Purchase Order Number of RTI: 65162L

Principal Investigator Name: Dr Shivaprasad S Goudar (JNMC)

Site Co- Principal Investigator Name: Dr G Guruprasad (JJMMC)

WHEREAS, JNMC and Sponsor entered into an agreement on 15 June 2017, attached hereto (Attachment A) and incorporated by this reference, wherein JNMC was to provide certain services to Sponsor for the "**PRETERM COD**"

WHEREAS, JNMC and JJMMC wish to enter into a subcontract wherein JJMMC will provide certain services to JNMC in JNMC's performance of the contract with RTI International (RTI);


WHEREAS, JJMMC agrees to abide by all of the terms and conditions of the Sponsor- RTI International (RTI) agreement;

WHEREAS, the Agreement is for work approved by Sponsor as a portion of the statement of work shown in Attachment A & Attachment B;

NOW, THEREFORE, the parties agree that the foregoing statements of fact are true and correct and are incorporated herein by this reference. In consideration of the covenants and conditions contained in this Agreement ("the Agreement"), and other good and valuable consideration, the adequacy and receipt of which are acknowledged, JNMC and JJMMC agree as follows:

1

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Definitions:

1. "JNMC" means the Jawaharlal Nehru Medical College, which has its principal office in Belgaum, India
2. "RTI" means RTI International.
3. "JJMMC" means Jagadguru Jayadeva Murugarajendra Medical College, Davanegere, Karnataka which has its principal office in Davangere, Karnataka, India, and which pursuant to the Protocol, agrees to provide data entry, data management, and data quality control services and to dedicate an employee to serve as a Co-Investigator (as defined below) for the Hospital-based Trial. JJMMC has legal Administrative and operative control of the below listed Hospital.
 1. Bapuji Child Health Institute Davangere (herein after referred to as BCHID as the context Permits)
 2. Chigateri General Hospital Davangere (herein after referred to as CGHD as the context Permits- (Attachment D-)
 3. Women's and Children's Hospital Davangere (herein after referred to as W&CHD as the Context permits (Attachment D)

Article I. Scope of Work provided in Attachment A

JJMMC, as a Sub-Contractor of JNMC, agrees to provide all the necessary qualified personnel, equipment, materials (except as otherwise may be provided herein), and facilities to perform the work as described in its proposal, which by this reference is incorporated into this Agreement, Attachment A & Attachment B.

JJMMC will facilitate the implementation of research protocol (Attachment B) at

1. Bapuji Child Health Institute Davangere (herein after referred to as BCHID as the context Permits)
2. Chigateri General Hospital Davangere (herein after referred to as CGHD as the context Permits- (Attachment D-)
3. Women's and Children's Hospital Davangere (herein after referred to as W&CHD as the Context permits) (Attachment D)

JJMMC will provide designated places for storage and administration of the research protocol at the above said facilities. JJMMC will ensure that the study documents will be stored at the above designated facilities under lock and key.

Article II. Period of Performance

The period of this Agreement shall be from Jan 1, 2018 to June 30, 2020 unless extended by written amendment to this Agreement.

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Article III. Estimated Cost

JNMC agrees to pay JJMMC an amount not to exceed Rs. 1,82,15,781 for the work described in Article I which includes 15% Indirect costs payable to JJMMC.

JNMC will provide equipment to JJMMC for the implementation of the project costing up to Rs. 32,00,000/-

JNMC will also reimburse JJMMC towards cost of investigations related to the study like cost of USG, Cost of Investigations, Autopsy cost & collection of cord and tissue samples that are specifically related to the study. Payment will be made upon receipt of Invoices from JJMMC's maximum up to Rs.1,63,50,000 /-.

JJMMC will extend credit facility to the site investigators towards expenditures by investigations and sample collection as requested by the Site Principal Investigator until reimbursement is processed by JNMC. JNMC will process all Invoices within 45 days of receipt of the Invoices.

JJMMC's budget is incorporated into this Agreement as Attachment C. The allowance of costs will be determined in accordance with JNMC's methods of determining costs under its grants and contracts with the Sponsor, and with the Sponsor's policies applicable to research projects as in effect on the beginning date of the budget period of this Agreement. Where JJMMC is normally required by these current policies to seek prior approval for actions from the Sponsor, JJMMC shall direct its request to the Administrative Representative of JNMC

JNMC will pay remuneration to the faculty and consultants from JJMMC working on this project directly. Indirect costs associated with these remuneration will be transferred to the administrative account of JJMMC on a monthly basis (Attachment C) in adherence to the Scope of Work (SOW). JJMMC will submit audited statement of expenses to JNMC every six months. Required supporting documentation, to be submitted with invoices, is clearly detailed and incorporated into this agreement as Attachment A.

The Project funds will be transferred to JJMMC

INSTITUTION ACCOUNT DETAILS

Name of Institution : JJM Medical College, Davangere
Address of Institution : JJM, Medical College, Campus,
Davangere Karnataka
Bank Account Holder's Name/Beneficiary Name : Dean and Principal
Bank Account No. (For NEFT/RTGS/E-Payment) :
Type of Account (Current A/c) :
Bank IFSC Code :
Bank MICR Code :
Bank Code :

3

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

JJMMC is to submit monthly invoice to JNMC on a cost reimbursable basis. Required supporting documentation, to be submitted with invoices, is clearly detailed and incorporated into this Agreement as Attachment A

The indirect costs provide for institutional costs that benefit and support research. These costs are included in budget build research capacity at JJMMC. These funds may be utilized for the following Activities.

- Use, maintenance and upgrading of building space, utilities and libraries;
- central technical support of labs, offices, core and other facilities;
- management and administration of research, finances, regulatory requirements and research compliance (i.e. research ethics, biohazards certification, animal care etc.);
- hazardous waste disposal;
- radiation and occupational safety and security; and
- liability insurance.

The utilization of funds received as indirect costs towards strengthening of research capacity at JJMMC will be in consultation between the site Principal Investigator and Administration of JJMMC.

Article IV. Authorized Representatives

The authorized representatives of JNMC and JJMMC for technical and administrative matters shall be:

JJM Medical College, Davangere, Karnataka

Technical Representative:

Dr Gowdar Guruprasad,

Administrative Representative:

Dr S B Murugesh

Dean & Principal

J N Medical College, Belgaum

Technical Representative:

Dr Shivaprasad S Goudar

Administrative Representative:

Dr. N S Mahantshetti

Principal

ATTESTED

Dr V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Article V. Reports

As stated in Article VII Section C paragraph 3, JJMMC must submit its most recent audit report to the JNMC Audit Representative.

Quarterly financial reports are required by JJMMC if it is not required under Article VII, entitled "Additional General Provisions", Section C paragraph 3, to submit its most recent audit report. The financial reports must be submitted to the JNMC Audit Representative.

Final Progress Report - A Final Progress Report shall be submitted to the JNMC Technical Representative within sixty (60) days of the close of the final project period for inclusion in the Principal Investigator's Final Progress Report.

Article VI. General Provisions

The work to be performed under this Agreement is being supported by the Sponsor under Agreement Attachment B. Therefore, wherever applicable, the rules and regulations governing the award to JNMC are by this reference hereby incorporated into this Agreement, including, but not limited to, provisions governing care and treatment of laboratory animals, civil rights and equal employment opportunity, protection of human subjects, patents and inventions, publications and rights in data.

Article VII. Additional General Provisions

The following general provisions shall apply to this Agreement:

A. Allowable Costs

Allowable costs shall be determined by JNMC in accordance with cost principles generally accepted by, or required to be used by, similar institutions or organizations, that are in effect as of the effective date of this Agreement.

B. Billing

JNMC shall reimburse the JJMMC's payment within forty (40) days after receipt of an acceptable invoice and after inspection and acceptance of the research deliverables provided in accordance with the terms and conditions of this Agreement.

JJMMC agrees that bills and invoices for fees or other compensation for services or expenses shall cite the Title: "PRETERM COD"

The performance of JNMC of any of its obligations under this Agreement shall be subject to and

ATTESTED
/

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

contingent upon the availability of funds, and the obligation of funds by the prime funding agency (Sponsor), or otherwise lawfully expendable for the purposes of this Agreement for the current and future periods. JNMC shall give notice to JJMMC of the non-availability of such funds when JNMC has knowledge of such fact. Upon receipt of such notice by JJMMC, JJMMC shall be entitled to payment only for those services performed and expenses incurred prior to the date notice is received.

If this Agreement includes travel expenditures, any such expenditure, including reimbursement, must comply with University or JNMC rules and itemized in detail.

JJMMC shall submit invoices based on the payment schedule specified in Article III, Cost. A final invoice must be received within 30 days after the budget period end date. Please forward all invoices to the following address:

Dr Shivaprasad S Goudar
Principal Investigator, "Preterm COD",
KLE University's Women's and Children's Health Research Unit
J N Medical College
Nehru Nagar,
Belgaum, 590010
sgoudar@jnmc.edu

C. Audit

JJMMC shall maintain and have available for audit and inspection all administrative and financial documents, and all other records, pertinent to the financial costs allocated to this agreement for a period of three years following the termination date except that, if an audit is initiated before the expiration of the three year period, the records shall be retained until audit findings have been resolved. The above records are subject to inspection and audit by JNMC, its designated representatives or representatives of Sponsor at all reasonable times during the life of the grant and for three years thereafter.

Any costs reimbursed by JNMC which are subsequently found to be disallowed under audit shall be refunded to JNMC by JJMMC. JJMMC agrees to comply with the requirements. In cases of non-compliance with Indian laws and regulations, JJMMC will also provide copies of responses to auditor's reports and a plan for corrective action. All records and reports prepared in accordance with the requirements shall be available for inspection by JNMC, its designated representatives or representatives of Sponsor at all reasonable times during the life of the grant and for three years thereafter.

If JJMMC is required to perform an Audit, JJMMC must provide JNMC with a copy of its most recent audit report.

D. Equipment

JNMC and JJMMC agree that if JJMMC purchases permanent equipment under this Agreement, title to such equipment will vest in the JNMC under the same conditions as apply under JNMC's grant with the Sponsor and that JNMC shall have the same rights to require transfer of equipment as the Sponsor has.

E. Indemnification

Each party hereby assumes any and all risk of personal injury and property damage attributable to the negligent acts or omissions of that party and the officers, employees and agents thereof. JJMMC will assure

ATTESTED

Dr. V.A.Kothiwale
Registrar

that persons subcontracting with or otherwise acting or engaged to act at the instance of JJMMC in furtherance of JJMMC fulfilling its obligations under this Agreement will assume such risk with respect to the willful or negligent acts or omissions of their personnel. JJMMC shall provide professional liability coverage for its employees discharging services as per the provisions of this contract and accident insurance coverage for all equipment/material procured for conducting the trial as specified in Attachment B.

F. Amendments

Any amendments, including renewals, alterations or modifications to the Agreement must be signed by the signatories to this Agreement.

G. Governance

The validity, construction and effect of this Agreement shall be governed by the prevailing laws. In the event either party is required to obtain from any governmental authority any permit, license or authorization as a prerequisite to perform its obligations under this Agreement, the cost shall be borne by the party required to obtain such permit, license or authorization.

JJMMC shall allow access to all documents, papers, letters or other material subject to the provisions of this Contract, and made or received by JJMMC in conjunction with this Agreement to JNMC or its representatives, the regulatory authorities or the representatives of the sponsor as specified in Attachment B. Refusal by JJMMC to allow such access shall be grounds for cancellation of this Agreement by JNMC.

JJMMC may not, without the advance written approval of JNMC, assign any right or delegate any duties under this Agreement nor may it transfer, pledge, surrender or otherwise encumber or dispose of its interest in any portion of this Agreement

It is understood and agreed that nothing contained in this Agreement is intended, or should be construed, as creating or establishing the relationship of partners between the parties, or as constituting JJMMC as the agent or representative of JNMC for any purpose in any manner whatsoever. JJMMC is not authorized to bind JNMC to any contracts or other obligations. JJMMC shall not expressly or impliedly represent to any party that RTI and JNMC are partners or that JNMC is the agent or representative of RTI International (RTI) for any purpose or in any manner whatsoever.

H. Termination

JNMC or JJMMC may terminate this Agreement upon thirty (30) days written notice to the other party. However, in the event that the Sponsor terminates the Agreement with JNMC prior to the period end date, this Agreement will be immediately terminated. In the event of termination JNMC will pay for costs incurred and non-cancelable commitments through the date of termination, contingent upon JNMC having received sufficient funds from Sponsor. JJMMC will furnish all necessary reports of research completed or in progress through the date of termination.

I. Publications

Any publications resulting from this Agreement shall be governed by the policies laid out in Attachment B.

J. Arbitration

7

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

This Contract includes the following Appendices (incorporated herein):


Attachment A:

Attachment B:

Attachment C:

IN WITNESS WHEREOF, JNMC and JJMMC have executed and delivered this Contract by and through their duly authorized representatives below

Jawaharlal Medical College (JNMC)

By: 

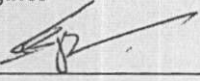
Name: Dr (Mrs) N S Mahantshetti

Title: Principal

Date:

DD /MM /YYYY

Principal Investigator

By: 

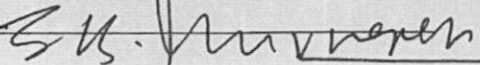
Name: Dr Shivaprasad S Goudar

Title: Professor Department of
PHYSIOLOGY

Date:

16/01/2018
DD /MM /YYYY

JJM Medical College, Davangere, Karnataka (JJMMC)

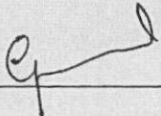
By: 

Name: Dr. S B Murugesh

Title: Dean & Principal

Date:

DD /MM /YYYY

By: 


Name: Dr. Guruprasad Gowdar

Title: Professor and Head, Neonatology

Date:

16/02/2018
DD /MM /YYYY

ATTESTED


Dr. V.A. Kothiwale
Registrar



SUBCONTRACT RESEARCH AGREEMENT (the "Agreement") between the President and Fellows of Harvard College hereinafter referred to as "Harvard," and Jawaharlal Nehru Medical College, hereinafter referred to as "Subcontractor" Harvard and Subcontractor may hereinafter be referred to individually as a "Party," and/or collectively as the "Parties."

This Agreement is entered into as of 01 November, 2018, the "Effective Date."

WHEREAS, Harvard has received funding from Bill and Melinda Gates Foundation ("Prime Sponsor") in accordance with an agreement dated 10/22/2018 (the "Prime Agreement") for a research project entitled "Low Birth-Weight Infant Feeding Exploration (LIFE)", conducted under the direction of Professor Katherine Semrau (the "Harvard Investigator") herein incorporated by reference and attached hereto as Exhibit A;

WHEREAS, Harvard has received funding under the Prime Agreement and wishes to enter into this Agreement with Subcontractor to perform research as defined herein;

WHEREAS, Subcontractor is willing to perform such research in accordance with the terms and conditions set forth below:

WHEREAS, the research program contemplated by this Agreement is of mutual interest and benefit to Harvard and to the Subcontractor, and will further the instructional and research objectives of Harvard in a manner consistent with its status as a non-profit, tax-exempt, educational institution.

NOW, THEREFORE, the Parties hereto agree as follows:

- 1. STATEMENT OF WORK.** Subcontractor agrees to use reasonable efforts to perform the research program as described in Exhibit B (the "Research").
- 2. PRINCIPAL INVESTIGATOR.** Subcontractor's performance of the Research will be supervised by Dr. Shivaprasad Goudar (the "Subcontractor Investigator"). The Subcontractor Investigator may not be changed, nor may his/her effort be substantially reduced or redirected without written approval from a duly authorized representative of Harvard. If the Subcontractor Investigator should become unavailable to perform the Research for a period exceeding three (3) months, Subcontractor shall appoint a replacement upon written approval from a duly authorized representative of Harvard.
- 3. PERIOD OF PERFORMANCE.** The Research shall be conducted during the period 01 November 2018 (the "Starting Date") through 31 October 2019 (the "Completion Date"). The Completion Date may be extended only by mutual written agreement of the Parties. It is understood that Harvard may need to obtain authorization from the Prime Sponsor in order to grant Subcontractor an extension.
- 4. REIMBURSEMENT OF COSTS.** In consideration for this Agreement and the Research performed by Subcontractor hereunder, Harvard shall pay to the Subcontractor as per the agreed upon budget contained in Exhibit C (the "Budget") an amount not to exceed USD \$347,018. Harvard assumes no obligation to reimburse costs in excess of the Budget. Subcontractor shall not be obligated to continue performance once it has expended the funds allotted provided it has exerted its good faith efforts to

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

complete the Research within the Budget.

5. **PAYMENT.** Subcontractor shall submit invoices to the Harvard Investigator no more frequently than monthly and no less frequently than quarterly. Invoices must be sent within 30 days of the period covered by the invoice. Invoices shall detail current and cumulative charges by each of the line items set forth in the Budget. The invoice shall be emailed to the Harvard Financial Contact named in Exhibit D. All invoices shall be signed by a duly authorized representative of the Subcontractor, shall include a certification by a duly authorized representative of Subcontractor that costs reported are for appropriate purposes and in accordance with the terms of this Agreement, and shall reference Agreement Number 5111046-261426. The final invoice shall be submitted to the Harvard Financial Contact within forty-five (45) days after the Agreement End Date and must clearly be marked "Final." The Subcontractor shall inform Harvard if the final invoice cannot be submitted within forty-five (45) days of expiration of this Agreement in order to arrive at a mutually agreeable due date for the final invoice. If the final invoice is submitted after the forty-five (45) day period, and the Parties fail to agree upon an alternative due date, the final invoice may not be paid.

Payment to Subcontractor shall be contingent upon the availability of funding from the Prime Sponsor under the Prime Agreement and upon Subcontractor's spending funds in accordance with the Budget. For the avoidance of doubt, changes or rebudgeting that exceed 10% of any Budget category must be approved in writing by a duly authorized representative of Harvard.
6. **AUDIT.** All costs incurred in the performance of the Research will be subject to audit by Harvard, and the Subcontractor agrees to allow authorized representative of Harvard access to records necessary to support the reported costs. Any amounts disallowed upon audit will be repayable to Harvard within ninety (90) days following termination or expiration of this Agreement.
7. **REPORTS.** The Subcontractor Investigator shall make period reports to the Harvard Investigator regarding the progress of the Research; and prepare a final written report to the Harvard Investigator summarizing the results of the Research including a summary of information and materials developed in the course of Research hereunder, including any inventions within forty-five (45) days after termination or expiration of this Agreement.
8. **EQUIPMENT.** Unless included in the Budget, Subcontractor may not purchase equipment without written approval from Harvard. Subcontractor shall submit a final report of equipment purchased under this Agreement to Harvard within thirty (30) days of the Completion Date.
9. **CONFIDENTIALITY.** If, during the term of this Agreement, either Party chooses to disclose to another Party any information that is confidential or proprietary, the obligations and rights of such Parties with respect to that information will be governed by the terms and conditions set forth in a separate and duly authorized agreement.
10. **PUBLICATIONS.** Subcontractor has the right to publish and otherwise publicly disclose information derived from Research conducted under this Agreement. Subcontractor shall provide drafts of any such publications to the Harvard Investigator 60 days in advance of submission for publication to review for confidential information, material which would affect pending patents, and to forward to Prime Sponsor, if applicable.

ATTESTED

2



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

11. **COPYRIGHTS.** The author(s) is free to arrange for copyright without approval when publications or similar materials are developed from the Research. Any such copyrighted materials shall be subject to a royalty-free, non-exclusive, and irrevocable license to Harvard to reproduce, translate, publish, use and dispose of them, and to authorize others to do so.
12. **LABORATORY ANIMALS.** No research involving animals is planned or authorized under this Agreement.
13. **HUMAN SUBJECTS.** The use of human subjects in the Research shall comply with Department of Health and Human Services (DHHS) policies and regulations on the protection of human subjects (45 CFR 46, as amended) and with any terms of approval imposed by Harvard's Committee on the Use of Humans as Experimental Subjects ("Harvard IRB"). In all cases, Subcontractor agrees to adhere to the study protocol approved by Harvard IRB, to assure that any legal or IRB requirements for the informed consent process are met and are appropriately documented, and to report to Harvard any adverse events or unexpected problems and any proposed changes to the study protocol or informed consent process. If Subcontractor has its own approved Institutional Review Board, then the Research shall also be submitted to that board for approval and Subcontractor shall provide verification to the Harvard that the approval has been granted. If applicable, the verification shall state the date when the Research must be resubmitted for continuing review.
14. **USE OF NAME.** Except as provided below, Subcontractor shall not use or register the name "Harvard" (alone or as part of another name) or any logos, seals, insignia or other words, names, symbols or devices that identify Harvard or any Harvard school, unit, division or affiliate ("Harvard Names") for any purpose except with the prior written approval of, and in accordance with restrictions required by, Harvard. Without limiting the foregoing, Subcontractor shall cease all use of Harvard Names on the termination or expiration of this Agreement except as otherwise approved by Harvard. This restriction shall not apply to any information required by law to be disclosed to any governmental entity.
15. **TERMINATION.** Harvard may terminate this Agreement for any reason upon sixty (60) day prior written notice to Subcontractor. Either Party may terminate this Agreement upon material breach of the Agreement by the other party if such breach has not been cured within thirty (30) days after written notice of the breach has been given.
16. **LIMITATION OF LIABILITY.** The Parties to this Agreement each agree that they will be solely liable for their own acts or omissions and the acts or omissions of their employees, officers and agents. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER for any INDIRECT, PUNITIVE, consequential, or special damages, including lost REVENUES OR profits, ARISING FROM BREACH OF THE TERMS IN THIS AGREEMENT, NEGLIGENCE, STRICT LIABILITY OR OTHER TORT.
17. **GOVERNING LAW.** This Agreement will be governed by, and construed in accordance with, the substantive laws of the Commonwealth of Massachusetts, without giving effect to any choice or conflict of law provision, except that questions affecting the construction and effect of any patent shall be determined by the law of the country in which the patent shall have been granted. Any action, suit or other proceeding arising under or relating to this Agreement (a "Suit") shall be brought in a court of competent jurisdiction in the Commonwealth of Massachusetts, and the parties hereby consent to the sole jurisdiction of the state and federal courts sitting in the Commonwealth of Massachusetts. Each

ATTESTED

3


Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Party agrees not to raise any objection at any time to the laying or maintaining of the venue of any Suit in any of the specified courts, irrevocably waives any claim that Suit has been brought in any inconvenient forum and further irrevocably waives the right to object, with respect to any Suit, that such court does not have any jurisdiction over such party. The Subcontractor will also abide by all applicable local laws in the country where the Statement of Work will be conducted.

18. **GOVERNING LANGUAGE.** The English language version of this Agreement shall be the official version. The Agreement may be translated, if necessary, but the English language version shall govern in the event of any inconsistencies or conflicts between the two versions. All disputes under this Agreement shall be resolved and conducted in the English language.
19. **COMPLIANCE WITH LAW.** Subcontractor will cause the Research performed hereunder to conform with all requirements of all applicable federal, state and local laws, rules and regulations, including but not limited to, laws relating to equal employment opportunity, as well as all standards applicable to such research. Additionally, Subcontractor agrees to comply with U.S. export laws and regulations pertaining to the export of technical data, services and commodities, including the International Traffic in Arms Regulations (22 C.F.R. § 120 et seq.), the Export Administration Regulations (15 C.F.R. § 730 et seq.), the regulations administered by the Treasury Department's Office of Foreign Assets Control (31 C.F.R. § 500, et seq.), and the Anti-Boycott Regulations (15 C.F.R. § 760). The Parties shall cooperate with each other to facilitate compliance with these laws and regulations.
20. **ARBITRATION.** In the event of any controversy or claim arising out of or relating to any provision of this Agreement or the breach thereof, the Parties shall try to settle such conflicts amicably between themselves. Subject to the limitation stated herein, any such conflict which the Parties are unable to resolve shall be settled through arbitration conducted as set forth in this paragraph and otherwise in accordance with the Rules of Conciliation and Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with said rules. The demand for arbitration shall be filed within a reasonable time after the controversy or claim has arisen, and in no event after the date upon which institution of legal proceedings based on such controversy or claim would be barred by applicable statute of limitations periods.
21. **RESEARCH MISCONDUCT.** Subcontractor hereby certifies that it has established administrative procedures to review allegations of scientific misconduct and to evaluate and process real or potential Conflict of Interest situations and that such procedures conform to federal regulations. Additionally, Subcontractor agrees to cooperate fully with any proceedings, inquiries or investigations as requested by Harvard or Prime Sponsor.
22. **NOTICES.** Any notices to be given hereunder shall be sufficient if signed by the Party giving same and delivered in one of the following manners to the appropriate addresses listed on **Exhibit D (Notices)**: (a) mailed certified mail, return receipt requested; (b) sent by expedited delivery via a nationally recognized courier service; (c) delivered via e-mail to other Party if the sender retains evidence of successful transmission; or (d) faxed to other Party if the sender retains evidence of successful transmission and if the sender promptly sends the original by ordinary mail, in any event to the following addresses:

By such notice, either Party may change its address for future notices. Notices mailed shall be deemed given on the date postmarked on the envelope. Notices sent by expedited delivery shall be deemed

4

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

given on the date received by the courier, as indicated on the shipping documents. Notices sent by e-mail with receipt acknowledged shall be deemed given on the date transmitted. Notices sent by fax shall be deemed given on the date faxed.

23. **INDEPENDENT CONTRACTOR.** For the purposes of this Agreement, each Party shall be, and shall be deemed to be, an independent contractor and not an agent or employee of the other Party. Neither Party shall have authority to make any statements, representations or commitments of any kind, or to take any action which shall be binding on the other Party, except as may be explicitly provided for herein or authorized by the other Party in writing
24. **ASSIGNMENT.** This Agreement and all rights and obligations hereunder shall not be assigned (whether through merger or consolidation, by operation of law, or otherwise), without the written consent of the other Party and any attempt to assign without such consent shall be void.
25. **MODIFICATION.** No modification or waiver of this Agreement or of any covenant, condition or limitation herein contained shall be valid unless in writing and executed by duly-authorized representatives of both Parties. A failure by one of the Parties to this Agreement to assert its rights under, including upon any breach or default of, this Agreement shall not be deemed a waiver of such rights. No such failure or waiver in writing by any one of the Parties hereto with respect to any rights shall extend to or affect any subsequent breach or impair any right consequent thereon.
26. **SEVERABILITY.** If any provision of this Agreement is or becomes invalid or is ruled invalid by any court of competent jurisdiction or is deemed unenforceable, it is the intention of the parties that the remainder of this Agreement shall not be affected.
27. **ORDER OF PRECEDENCE/ RELATION TO OTHER AGREEMENTS.** The Agreement is subject to all the terms and conditions of the Prime Agreement, and other special terms and conditions attached and incorporated by reference herein. In the event of any inconsistent or incompatible provisions, this Agreement, shall take precedence, followed by the terms of the Prime Agreement. For the avoidance of doubt, Subcontractor hereby acknowledges and agrees to be, to the fullest extent, bound by any and all of the applicable terms and conditions set forth in the aforementioned agreements.
28. **COUNTERPARTS.** This Agreement may be executed in two or more counterparts, and by facsimile or electronic transmission, each of which will be deemed to be an original, but all of which together constitute one and the same instrument.
29. **ENTIRE AGREEMENT.** Unless otherwise specified, this Agreement and its Attachments embody the entire understanding between Harvard and Subcontractor for the Research, and any prior or contemporaneous representations, either oral or written, are hereby superseded. No amendments or changes to this Agreement, including without limitation, changes in the statement of work, total estimated cost, and period of performance, shall be effective unless made in writing and signed by authorized representatives of the Parties.

[SIGNATURES ON FOLLOWING PAGE]

ATTESTED

5

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

IN WITNESS WHEREOF, Harvard and Subcontractor have executed this Agreement as of the Effective Date.

THE PRESIDENT AND FELLOWS OF HARVARD COLLEGE

By: *Elaine Kiley*
Elaine Kiley,
Title: Associate Director of Research Administration

Date: *10 Jan 2019*

Agreement No. : 5111046-261426

SUBCONTRACTOR

By: Dr N S Mahantashetti
NS
Principal
JNMC BELAGAVI

Title: Principal, J N Medical College, Belagavi

Date: January 3, 2019

ATTESTED

6

↓
Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

**KLE Academy of Higher Education and Research
Women's and Children's Health Research Unit
J N Medical College
COST REIMBURSABLE RESEARCH SUBCONTRACT
"Low birthweight Infant Feeding Exploration (LIFE)"**

This contract Agreement for "Low birthweight Infant Feeding Exploration (LIFE)" in Karnataka Sub-site, India hereafter referred to as the "LIFE" is entered into in order to specify the terms and conditions under which the KLE Academy of Higher Education and Research, Women's and Children's Health Research Unit, J N Medical College, (hereinafter referred to as "JNMC") and JJM Medical College Davangere, Karnataka (hereinafter referred to as "JJMMC") will participate in the conduct of a project supported by the Harvard School of Public Health, USA (HSPH) (hereinafter referred to as "Sponsor").

General Information:

Title: Research Subcontract in between Jawaharlal Nehru Medical College, Belgaum and JJM Medical College, Davangere, Karnataka for the "LIFE"

Award Title: This Hospital & Community based Observational Cohort Contract (the "Contract"), effective as of Nov 1, 2018 (the "Effective Date") is by and between President and Fellows of Harvard College and Jawaharlal Nehru Medical College located at Belgaum 590010 in Karnataka, India ("JNMC"), represented by its employee Dr Shivaprasad Goudar, MD (the "Principal Investigator").

Prime Award: Between President and Fellows of Harvard College & Bill & Melinda Gates Foundation: Agreement. Investment ID - OPP1192260
Sub Award: Between President and Fellows of Harvard College & JNMC Sub Award - Agreement. 5111046-261426

Principal Investigator Name: Dr Shivaprasad S Goudar (JNMC)
Site Co- Principal Investigator Name: Dr G Guruprasad (JJMMC)

WHEREAS, JNMC and Sponsor entered into an agreement on 15 June 2017, attached hereto (Attachment A) and incorporated by this reference, wherein JNMC was to provide certain services to Sponsor for the "LIFE"

WHEREAS, JNMC and JJMMC wish to enter into a subcontract wherein JJMMC will provide certain services to JNMC in JNMC's performance of the contract with Harvard School of Public Health, USA (HSPH);

WHEREAS, JJMMC agrees to abide by all of the terms and conditions of the Sponsor- Harvard School of Public Health, USA (HSPH) agreement;

WHEREAS, the Agreement is for work approved by Sponsor as a portion of the statement of work shown in Attachment A & Attachment B;

NOW, THEREFORE, the parties agree that the foregoing statements of fact are true and correct and are

1

ATTESTED

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

JNMC will provide equipment to JJMMC for the implementation of the project costing up to Rs. 11,19,825/-

JNMC will also reimburse JJMMC towards Screening, reimbursements of data captions, cost of IDI, FGD & transcription of IDI and FGDs will be directly paid by JNMC .

JJMMC will extend credit facility to the site investigators towards expenditures by investigations and sample collection as requested by the Site Principal Investigator until reimbursement is processed by JNMC. JNMC will process all Invoices within 45 days of receipt of the Invoices.

JJMMC's budget is incorporated into this Agreement as Attachment C. The allowance of costs will be determined in accordance with JNMC's methods of determining costs under its grants and contracts with the Sponsor, and with the Sponsor's policies applicable to research projects as in effect on the beginning date of the budget period of this Agreement. Where JJMMC is normally required by these current policies to seek prior approval for actions from the Sponsor, JJMMC shall direct its request to the Administrative Representative of JNMC

JNMC will pay remuneration to the faculty and consultants from JJMMC working on this project directly. Indirect costs associated with these remunerations will be transferred to the administrative account of JJMMC on a monthly basis (Attachment C) in adherence to the Scope of Work (SOW). JJMMC will submit audited statement of expenses to JNMC every six months. Required supporting documentation, to be submitted with invoices, is clearly detailed and incorporated into this agreement as Attachment A.

The Project funds will be transferred to JJMMC

INSTITUTION ACCOUNT DETAILS

Name of Institution : JJM Medical College, Davangere
Address of Institution : JJM, Medical College, Campus,
Davangere Karnataka
Bank Account Holder's Name/Beneficiary Name : Dean and Principal
Bank Account No. (For NEFT/RTGS/E-Payment) :
Type of Account (Current A/c) :
Bank IFSC Code :
Bank MICR Code :
Bank Code :

JJMMC is to submit monthly invoice to JNMC on a cost reimbursable basis. Required supporting documentation, to be submitted with invoices, is clearly detailed and incorporated into this Agreement as Attachment A

ATTESTED



Dr. V.A. Kothiwale
Registrar

The indirect costs provide for institutional costs that benefit and support research. These costs are included in budget build research capacity at JJMMC. These funds may be utilized for the following Activities.

- Use, maintenance and upgrading of building space, utilities and libraries;
- central technical support of labs, offices, core and other facilities;
- management and administration of research, finances, regulatory requirements and research compliance (i.e. research ethics, biohazards certification, animal care etc.);
- hazardous waste disposal;
- radiation and occupational safety and security; and
- liability insurance.

The utilization of funds received as indirect costs towards strengthening of research capacity at JJMMC will be in consultation between the site Principal Investigator and Administration of JJMMC.

Article IV. Authorized Representatives

The authorized representatives of JNMC and JJMMC for technical and administrative matters shall be:

JJM Medical College, Davangere, Karnataka J N Medical College, Belgaum

Technical Representative:

Dr Gowdar Guruprasad,

Administrative Representative:

Dr S B Murugesh

Dean & Principal

Technical Representative:

Dr Shivaprasad S Goudar

Administrative Representative:

Dr. N S Mahantshetti

Principal

Article V. Reports

As stated in Article VII Section C paragraph 3, JJMMC must submit its most recent audit report to the JNMC Audit Representative.

Quarterly financial reports are required by JJMMC if it is not required under Article VII, entitled "Additional General Provisions", Section C paragraph 3, to submit its most recent audit report. The financial reports must be submitted to the JNMC Audit Representative.

Final Progress Report - A Final Progress Report shall be submitted to the JNMC Technical Representative within sixty (60) days of the close of the final project period for inclusion in the Principal Investigator's Final Progress Report.

ATTESTED

Dr V.A. Kothiwale
Registrar

Article VI. General Provisions

The work to be performed under this Agreement is being supported by the Sponsor under Agreement Attachment B. Therefore, wherever applicable, the rules and regulations governing the award to JNMC are by this reference hereby incorporated into this Agreement, including, but not limited to, provisions governing care and treatment of laboratory animals, civil rights and equal employment opportunity, protection of human subjects, patents and inventions, publications and rights in data.

Article VII. Additional General Provisions

The following general provisions shall apply to this Agreement:

A. Allowable Costs

Allowable costs shall be determined by JNMC in accordance with cost principles generally accepted by, or required to be used by, similar institutions or organizations, that are in effect as of the effective date of this Agreement.

B. Billing

JNMC shall reimburse the JJMMC's payment within forty (40) days after receipt of an acceptable invoice and after inspection and acceptance of the research deliverables provided in accordance with the terms and conditions of this Agreement.

JJMMC agrees that bills and invoices for fees or other compensation for services or expenses shall cite the Title: "LIFE"

The performance of JNMC of any of its obligations under this Agreement shall be subject to and contingent upon the availability of funds, and the obligation of funds by the prime funding agency (Sponsor), or otherwise lawfully expendable for the purposes of this Agreement for the current and future periods. JNMC shall give notice to JJMMC of the non-availability of such funds when JNMC has knowledge of such fact. Upon receipt of such notice by JJMMC, JJMMC shall be entitled to payment only for those services performed and expenses incurred prior to the date notice is received.


If this Agreement includes travel expenditures, any such expenditure, including reimbursement, must comply with University or JNMC rules and itemized in detail.

JJMMC shall submit invoices based on the payment schedule specified in Article III, Cost. A final invoice must be received within 30 days after the budget period end date. Please forward all invoices to the following address:

Dr Shivaprasad S Goudar
Principal Investigator
Women's and Children's Health Research Unit
KLE Academy of Higher Education and Research
J N Medical College
Nehru Nagar,
Belgaum, 590010
sgoudar@jnmc.edu

5

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

C. Audit

JJMMC shall maintain and have available for audit and inspection all administrative and financial documents, and all other records, pertinent to the financial costs allocated to this agreement for a period of three years following the termination date except that, if an audit is initiated before the expiration of the three year period, the records shall be retained until audit findings have been resolved. The above records are subject to inspection and audit by JNMC, its designated representatives or representatives of Sponsor at all reasonable times during the life of the grant and for three years thereafter.

Any costs reimbursed by JNMC which are subsequently found to be disallowed under audit shall be refunded to JNMC by JJMMC. JJMMC agrees to comply with the requirements. In cases of non-compliance with Indian laws and regulations, JJMMC will also provide copies of responses to auditor's reports and a plan for corrective action. All records and reports prepared in accordance with the requirements shall be available for inspection by JNMC, its designated representatives or representatives of Sponsor at all reasonable times during the life of the grant and for three years thereafter.

If JJMMC is required to perform an Audit, JJMMC must provide JNMC with a copy of its most recent audit report.

D. Equipment

JNMC and JJMMC agree that if JJMMC purchases permanent equipment under this Agreement, title to such equipment will vest in the JNMC under the same conditions as apply under JNMC's grant with the Sponsor and that JNMC shall have the same rights to require transfer of equipment as the Sponsor has.

E. Indemnification

Each party hereby assumes any and all risk of personal injury and property damage attributable to the negligent acts or omissions of that party and the officers, employees and agents thereof. JJMMC will assure that persons subcontracting with or otherwise acting or engaged to act at the instance of JJMMC in furtherance of JJMMC fulfilling its obligations under this Agreement will assume such risk with respect to the willful or negligent acts or omissions of their personnel. JJMMC shall provide professional liability coverage for its employees discharging services as per the provisions of this contract and accident insurance coverage for all equipment/material procured for conducting the trial as specified in Attachment B.

F. Amendments


Any amendments, including renewals, alterations or modifications to the Agreement must be signed by the signatories to this Agreement.

G. Governance

The validity, construction and effect of this Agreement shall be governed by the prevailing laws. In the event either party is required to obtain from any governmental authority any permit, license or authorization as a prerequisite to perform its obligations under this Agreement, the cost shall be borne by the party required to obtain such permit, license or authorization.

JJMMC shall allow access to all documents, papers, letters or other material subject to the provisions of this Contract, and made or received by JJMMC in conjunction with this Agreement to JNMC or its

ATTESTED


Dr. V.A. Kothiwale
Registrar

representatives, the regulatory authorities or the representatives of the sponsor as specified in Attachment B. Refusal by JJMMC to allow such access shall be grounds for cancellation of this Agreement by JNMC.

JJMMC may not, without the advance written approval of JNMC, assign any right or delegate any duties under this Agreement nor may it transfer, pledge, surrender or otherwise encumber or dispose of its interest in any portion of this Agreement

It is understood and agreed that nothing contained in this Agreement is intended, or should be construed, as creating or establishing the relationship of partners between the parties, or as constituting JJMMC as the agent or representative of JNMC for any purpose in any manner whatsoever. JJMMC is not authorized to bind JNMC to any contracts or other obligations. JJMMC shall not expressly or impliedly represent to any party that HSPH and JNMC are partners or that JNMC is the agent or representative of Harvard School of Public Health, USA (HSPH) for any purpose or in any manner whatsoever.

H. Termination

JNMC or JJMMC may terminate this Agreement upon thirty (30) days written notice to the other party. However, in the event that the Sponsor terminates the Agreement with JNMC prior to the period end date, this Agreement will be immediately terminated. In the event of termination JNMC will pay for costs incurred and non-cancelable commitments through the date of termination, contingent upon JNMC having received sufficient funds from Sponsor. JJMMC will furnish all necessary reports of research completed or in progress through the date of termination.

I. Publications

Any publications resulting from this Agreement shall be governed by the policies laid out in Attachment B.

J. Arbitration

If any dispute arises in between JNMC and JJMMC the same should be referred to Chancellor, KLE University and Chairman, KLE Society, Belgaum and Honorable Chairman, BEA Davangere, Karnataka and the decision of the Arbitrators shall be final and the same shall be binding on the both the parties.

JJMMC certifies that to the best of its knowledge and belief that it and its principals will abide by the payment Standard Operating Procedures in Attachment A and Attachment B.

7

ATTESTED



Dr. V.A. Kothiwale
Registrar

This Contract includes the following Appendices (incorporated herein):

Attachment A:

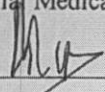
Attachment B:

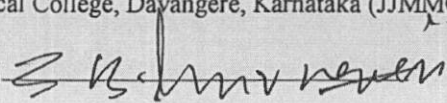
Attachment C:

IN WITNESS WHEREOF, JNMC and JJMMC have executed and delivered this Contract by and through their duly authorized representatives below

Jawaharlal Medical College (JNMC)

JJM Medical College, Dayangere, Karnataka (JJMMC)

By: 

By: 

Name: Dr. N S Mahantshetti

Name: Dr. S B Murugesh

Title: Principal

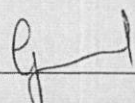
Title: Dean & Principal

Date: 01/02/2019
DD/MM/YYYY

Date: 31/01/2019
DD/MM/YYYY

Principal Investigator

By: 

By: 

Name: Dr Shivaprasad S Goudar

Name: Gowdar Guruprasad

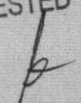
Title: Professor Department of
PHYSIOLOGY

Title: Professor and Head, Neonatology

Date: 01/02/2019
DD/MM/YYYY

Date: 31/01/2019
DD/MM/YYYY

ATTESTED


Dr. V.A. Kothiwale
Registrar



Bapuji Educational Association®

J.J.M. MEDICAL COLLEGE

(Recognised by the Medical Council of India, New Delhi, Vide No. MCI-34(1)87-Med./12101 dt. 6-8-1987)

DAVANGERE-577 004, KARNATAKA, INDIA.

To, Ref. No: JJMMC/5289/2018-19

Date: 03.01.2019

Dr. Shamanur Shivashankarappa M.L.A.
Chairman,
Bapuji Educational Association,
Davangere

Respected sir,

Sub: Research Study programme "Low-birth weight Infant Feeding Exploration (LIFE) project" in Collaboration with JNMC Belagavi.

With Respect to the above subject, we would like to bring to your kind notice that collaborative study "Low-birth weight Infant Feeding Exploration (LIFE) project" With the financial funding support from 'BILL AND MELINDA GATES FOUNDATION', is planned to undertake in our both esteemed medical colleges JJMMC & SSIMS.

The study Period is around 2 years starting from Jan 2019 to Dec 2020. We request you to kindly approve this proposal. For the conduct of this study, there will be no financial expenditure from our side.

It is one of the prestigious research study that our institute is under taking, and it is headed by Dr. G. Guruprasad Prof & HOD Department Of Neonatology.

We are glad to inform that Sri S.S. Mallikarjun, Chairman, Bapuji Child Health Institute & Research Centre, has approved for implementation of the project after thorough discussion.

We seek your kind Permission and Guidance for the same.

Kindly oblige and do the needful.

Thanking You

Yours Faithfully

Yes Permitted
Good Sir
Dr. G. Guruprasad
Co-Principal Investigator
Prof & HOD Dept of Neonatology
JJMMC Davangere

S. B. Murugesu
Dr. S. B. Murugesu
Principal
JJMMC
Davangere

Dr. V. A. Kothiwale
Registrar

Research Subaward Agreement Amendment

Prime Recipient		Subrecipient	
Institution/Organization ("Prime Recipient") Name: The University of North Carolina at Chapel Hill Address: Office of Sponsored Research 104 Airport Drive, Suite 2200, CB# 1350 Chapel Hill, NC 27599-1350 Email: ResAdminOSR@unc.edu		Institution/Organization ("Subrecipient") Name: K L E Society's Jawaharlal Nehru Medical College Address: Nehru Nagar Belagavi-590010, Karnataka INDIA	
Prime Award No. OPP1192462	Prime Recipient Principal Investigator Jeff Stringer	Subaward No. 5116269	Subrecipient Principal Investigator Shivaprasad Goudar
Effective Date of Amendment January 1, 2020		Amendment No. 1	

Amendment(s) to Original Terms and Conditions

Action:

- 1) Period of Performance: To extend the period of performance to October 31, 2020.
- 2) Compensation: To authorize incremental funding in the amount of US \$724,613. The total amount of the Agreement per Amendment 1 is not to exceed US \$889,818.

The following documents are incorporated into this Subaward Agreement Amendment as noted:

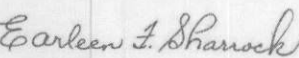
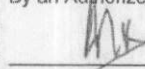
Attachments:

Attachment A: Notice of Award
Attachment B: Budget

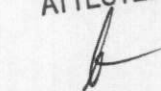
Administrative Contact Information:

Contact Name: Chester Williams
 The University of North Carolina at Chapel Hill
 Office of Sponsored Research
 104 Airport Drive, Suite 2200, CB#1350
 Chapel Hill NC 27599-1350
 Email: resadminosr@unc.edu
 Fax: (919) 962-5011/3352
 Phone: (919) 966-3411

All other terms and conditions of this Subaward Agreement remain in full force and effect.

By an Authorized Official of Prime Recipient:  Digitally signed by Earleen F. Sharrock Date: 2020.06.17 12:17:13 -04'00'	By an Authorized Official of Subrecipient:  Name: Dr. N.S. Mahantashetti Title: Principal, J.N. Medical College, Belagavi Date: 8/6/2020
Name: on behalf of Terry Magnuson Title: Vice Chancellor for Research	Name: Dr. N.S. Mahantashetti Title: Principal, J.N. Medical College, Belagavi

ATTESTED


 Dr. V.A. Kothiwale
 Registrar

KLE Academy of Higher Education and Research,
 (Deemed-to-be-University u/s 3 of the UGC Act, 1956)
 Belagavi-590 010, Karnataka

UNC date last updated: July 18, 2016

BILL & MELINDA GATES foundation

GRANT AGREEMENT Investment ID OPP1192462

AGREEMENT SUMMARY & SIGNATURE PAGE

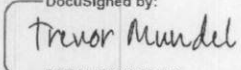
GRANTEE INFORMATION	
Name:	University of North Carolina at Chapel Hill
Tax Status:	Public Charity pursuant to U.S. IRC § 509(a)(1) You confirm that Your receipt of the Grant Funds will not affect Your classification as a public charity under Section 501(c)(3) of the United States Internal Revenue Code of 1986, as amended and agree to notify the Foundation immediately of any change to this classification.
Mailing Address:	104 Airport Drive, Suite 2200 Campus Box 1350 Chapel Hill, NC, 27517
Primary Contact:	Jeffrey Stringer, Ph.D, Dept of OB/GYN, jeffrey_stringer@med.unc.edu

FOUNDATION INFORMATION	
Mailing Address:	P. O. Box 23350, Seattle, WA 98102
Primary Contact:	Megan Carey, Program Officer, Enteric Diarrheal Diseases, Megan.Carey@gatesfoundation.org

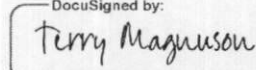
AGREEMENT INFORMATION	
Title:	Limiting Adverse Birth Outcomes in Resource-Limited Settings (LABOR) Trial
"Charitable Purpose":	to produce a low-cost device that can be deployed in developing world labor wards to substantially improve outcomes through better risk assessment and early diagnosis.
"Start Date":	Date of last signature.
"End Date":	October 31, 2021
This Agreement includes and incorporates by this reference:	This Agreement Summary & Signature Page and: <ul style="list-style-type: none"> • Grant Amount and Reporting & Payment Schedule (Attachment A) • Terms and Conditions (Attachment B) • Proposal Narrative (date submitted October 2, 2018) • Results Framework and Tracker (date submitted September 20, 2018) • Budget (date submitted September 24, 2018)

THIS AGREEMENT is between University of North Carolina at Chapel Hill ("*UNC*" "*You*" or "*Grantee*") and the Bill & Melinda Gates Foundation ("*Foundation*"), and is effective as of the date of last signature. Each party to this Agreement may be referred to individually as a "*Party*" and together as the "*Parties*." As a condition of this grant, the Parties enter into this Agreement by having their authorized representatives sign below.

BILL & MELINDA GATES FOUNDATION

DocuSigned by:

 DD5444F322CE4A9...
 By: Trevor Mundel
 Title: president of Global Health
 Date: October 25, 2018

UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL

DocuSigned by:

 81549B4C22C1460...
 By: Terry Magnuson
 Title: vice Chancellor for Research
 Date: November 1, 2018

ATTESTED


 Dr. V.A. Kothiwale
 Registrar

KLE Academy of Higher Education and Research,
 (Deemed-to-be-University u/s 3 of the UGC Act, 1956)
 Belagavi-590 010, Karnataka

GRANT AGREEMENT
Investment ID OPP1192462

ATTACHMENT A
GRANT AMOUNT AND REPORTING & PAYMENT SCHEDULE

GRANT AMOUNT

The Foundation will pay You up to the total grant amount specified in the Reporting & Payment Schedule below. The Foundation's Primary Contact must approve in writing any Budget cost category change of more than 10%.

REPORTING & PAYMENT SCHEDULE

Payments are subject to Your compliance with this Agreement, including Your achievement, and the Foundation's approval, of any applicable targets, milestones, and reporting deliverables required under this Agreement. The Foundation may, in its reasonable discretion, modify payment dates or amounts and will notify You of any such changes in writing.

REPORTING

You will submit reports according to the Reporting & Payment Schedule using the Foundation's templates or forms, which the Foundation will make available to You and which may be modified from time to time. For a progress or final report to be considered satisfactory, it must demonstrate meaningful progress against the targets or milestones for that investment period. If meaningful progress has not been made, the report should explain why not and what adjustments You are making to get back on track. Please notify the Foundation's Primary Contact if You need to add or modify any targets or milestones. The Foundation must approve any such changes in writing. You agree to submit other reports the Foundation may reasonably request.

REPORTING & PAYMENT SCHEDULE				
<i>Investment Period</i>	<i>Target, Milestone, or Reporting Deliverable</i>	<i>Due By</i>	<i>Payment Date</i>	<i>Payment Amount (U.S.\$)</i>
	Countersigned Agreement	November 15, 2018	Within 15 days after receipt of countersigned Agreement	\$2,500,000.00
	Milestone: Submission of Sub-Award Budgets	March 31, 2019	April 2019	\$3,000,000.00
Start Date - 10/31/19	Progress report	December 31, 2019	January 2020	\$6,000,000.00
11/1/19 - 10/31/20	Progress report	December 31, 2020	January 2021	\$1,064,320.00
Start Date - End Date	Final report	November 30, 2021		
Total Grant Amount				\$12,564,320.00

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

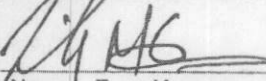
NON FEDERAL Foreign **Research Subaward Agreement**

Prime Recipient	Subrecipient
Institution/Organization ("Prime Recipient") Name: <u>The University of North Carolina at Chapel Hill</u>	Institution/Organization ("Subrecipient") Name: <u>K L E Society's Jawaharlal Nehru Medical College</u>
Prime Award No. <u>OPP1192462</u>	Subaward No. <u>5116269</u>
Awarding Agency <u>Bill & Melinda Gates Foundation</u>	Amount Funded This Action <u>\$165,205US</u>
Prime Recipient PI <u>Jeff Stringer</u>	Subrecipient PI <u>Shivaprasad Goudar</u>
Subaward Period of Performance: Budget Period From: <u>January 1, 2020</u> To: <u>August 31, 2020</u>	Estimated Project Period (if incrementally funded): From: <u>January 1, 2020</u> To: <u>September 30, 2021</u>
Project Title <u>Limiting Adverse Birth Outcomes in Resource-Limited Settings (LABOR) Trial</u>	
Reporting Requirements <input checked="" type="checkbox"/> See Attachment 4	

Terms & Conditions

- 1) Prime Recipient hereby awards a cost reimbursable subaward, as described above, to Subrecipient. The statement of work and budget for this subaward are (check one): As specified in Subrecipient's proposal dated _____; or as shown in Attachment 5. In its performance of the subaward work, Subrecipient shall be an independent entity and not an employee or agent of Prime Recipient.
- 2) Prime Recipient shall reimburse Subrecipient not more often than monthly for allowable costs. All invoices shall be submitted using Subrecipient's standard invoice, but at a minimum shall include current and cumulative costs (including cost-sharing), subaward number, and certification as to truth and accuracy of invoice. *Invoices that do not reference Prime Recipient's Subaward Number shall be returned to Subrecipient.* Invoices and questions concerning invoice receipt or payment should be directed to appropriate party's Financial Contact as shown in Attachments 3A & 3B.
- 3) A final statement of cumulative costs incurred, including cost-sharing, marked "FINAL" must be submitted to the Prime Recipient's Financial Contact, as shown in Attachments 3A & 3B, NO LATER THAN 30 days after the subaward end date. The final statement of costs shall constitute Subrecipient's final financial report.
- 4) All payments shall be considered provisional and subject to adjustment within the total estimated cost in the event such adjustment is necessary as a result of an adverse audit finding against Subrecipient.
- 5) Matters concerning the technical performance of this subaward should be directed to the appropriate party's Principal Investigator, as shown in Attachments 3A & 3B. Technical reports are required as shown below. "Reporting Requirements."
- 6) Matters concerning the request or negotiation of any changes in the terms conditions or amounts cited in this subaward agreement, and any changes required prior approval, should be directed to the appropriate party's Administrative Contact, as shown in Attachments 3A & 3B.
- 7) Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, or directs, to the extent allowed by law.
- 8) Either party may terminate this subaward with thirty days written notice to the appropriate party's Administrative Contact as shown in Attachments 3A & 3B. Prime Recipient shall pay Subrecipient for termination costs as allowable under Prime Award.
- 9) No Cost Extensions require the approval of the Prime Recipient. Any request for a no cost extension should be addressed to and received by the Administrative Contact, as shown in Attachments 3A & 3B, not less than thirty (30) days prior to the desired effective date of the requested change.
- 10) The Subaward is subject to the terms and conditions of the Prime Award (Attachment 6) and other special terms and conditions, as identified in Attachment 2.
- 11) By Signing below Subrecipient makes the certifications and assurances shown in Attachment 1. Subrecipient also assures that it will comply with applicable regulatory requirements specified in the Prime Award and Attachment 2.

By and Authorized Official of Prime Recipient:


Name: Terry Magnuson
Title: Vice Chancellor for Research

Date: March 3, 2020

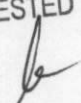
By an Authorized Official of Subrecipient:



Name: Dr. N.S. Mahantachetty
Title: _____
Date: 27/2/2020

UNC date last updated: July 18, 2016

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Attachment 3B
Research Subaward Agreement

Subaward Number:
5116269

Subrecipient Contacts

Institutional/Organization ("Subrecipient")

Name: KLE Society's Jawaharlal Nehru Medical College
Address: JNMC Campus
Nehru Nagar
City: Belgaum State: Karnataka ZipCode: 590010
EIN No.: Institution Type: Non-Profit Organization SAM.gov Reg Yes No
Performance Site Same Address as Above? Yes No DUNS No.:
If no, is the performance site the same as PI address below? Yes No 650251213

Administrative Contact

Name: Dr Shivaprasad S Goudar
Address: Professor of Physiology and Research Coordinator
Women's and Children's Health Research Unit
KLE Academy of Higher Education and Research (Deemed-to-be-University) Jawahar
City: Belgaum State: Karnataka ZipCode: 590010
Telephone: +91-94481 26371; +91-831-24 Fax: +91-831-2472891
Email: sgoudar@jnmc.edu

Principal Investigator

Name: Dr Mrutyunjaya B Bellad
Address: Professor of OBGYN
KLE Academy of Higher Education and Research
Jawaharlal Nehru Medical College, Nehru Nagar
City: Belgaum State: Karnataka ZipCode: 590010
Telephone: +91-9481 24893 Fax: +91-831-2472891
Email: mbbellad@hotmail.com

Financial Contact

Name: Mr Amit P Revankar
Address: Network Manager and Data Coordinator
Women's and Children's Health Research Unit
KLE Academy of Higher Education and Research (Deemed-to-be-University) Jawahar
City: Belgaum State: Karnataka ZipCode: 590010
Telephone: +91-98441 74337 Fax: +91-831-2472891
Email: amit@jnmc.edu

Authorized Official

Name: Dr Niranjana S Mahantashetti
Address: Principal
KLE Academy of Higher Education and Research (Deemed-to-be-University)
Jawaharlal Nehru Medical College, Nehru Nagar
City: Belgaum State: Karnataka ZipCode: 590010
Telephone: +91-94481 57237 Fax: +91-831-2472891
Email: niranjanasn@yahoo.com; principal@jnmc.edu

UNC date last updated: July 18, 2016

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



FIXED AMOUNT AWARD AGREEMENT

Between

Research Triangle Institute (RTI)


And

KLE SOCIETY'S JAWAHARLAL NEHRU MEDICAL COLLEGE, BELAGAVI

Agreement Summary:

1. Agreement Number	
2. Type of Agreement	Fixed Amount Award
3. Agreement Activity Title	To promote MITS activities to determine cause of death among neonatals and stillbirths in tertiary care teaching hospital
4. Agreement Administrator	US Address: Research Triangle Institute (RTI) 36040 Cornwallis Road - P. O. Box 12194 Research Triangle Park, NC 27709-2194 – USA
5. RTI Agreement Officer	
6. Recipient Organization	<u>KLE SOCIETY'S JAWAHARLAL NEHRU MEDICAL COLLEGE, BELAGAVI</u>
7. Recipient Organization's 's Point-of-Contact	Niranjana Mahantashetti principal@jnmc.edu <u>+918312471350</u>
8. Prime Award Number	OPP-1180554
9. Project Title	<u>MITS Surveillance Alliance</u>
10. RTI Project No	0216178
11. Period of Performance	Start Date: July 1, 2019 End Date: September 30, 2020
12. Agreement Ceiling	<u>\$80,000</u>
13. RTI Technical Monitor	<u>Norman Goco</u>
14. Incorporated Documents	Attachments A-B
ATTACHMENTS:	
Attachment A: Project Description	
Attachment B Standard Provisions	

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



This Agreement is awarded to **KLE SOCIETY'S JAWAHARLAL NEHRU MEDICAL COLLEGE, BELAGAVI** (hereinafter called "Awardee") and administered by **Research Triangle Institute** (hereinafter called "RTI"), a not-for-profit corporation existing under the laws of the State of North Carolina, USA and having its principal place of business at 3040 Cornwallis Road, Research Triangle Park 27709-2194, under above mentioned award between Gates Foundation and RTI to support implementation of the **To promote MITS activities to determine cause of death among neonatals and stillbirths in tertiary care teaching hospital**

(hereinafter called "Project").

Whereas:

- A. This Grant will implement specific activities that will contribute to achievement of the overall Project Objectives.
- B. This Agreement shall not (i) create the relationship of principal and agent, employer and employee, joint venture, or business partnership between RTI and the Awardee; and (ii) establish privity of contract between Gates Foundation and the Awardee.
- C. Authority of Agent: Designated agents on behalf of the Awardee and RTI are the sole authority authorized to make amendments and any other substantive changes to the Agreement Terms.

Now, therefore, in consideration of the promises and of the mutual covenants and Agreements contained herein, and intending to be legally bound, RTI and the Awardee hereby agree to the following terms and conditions of this Agreement.

Article 1. PROGRAM DESCRIPTION

The purpose of this Agreement is to provide support for the activities described in the Program Description in **Attachment A** of this Agreement.

Article 2. PERIOD OF PERFORMANCE

The period of performance for the Agreement activities is July 1, 2019 to September 30, 2020.

All activities financed with Agreement funds will not commence prior to the Agreement Activity Start date, and will be completed and will cease no later than the Agreement Activity Completion Date; unless RTI provides approval of a time extension in writing prior to the specified Agreement Activity Completion Date. No award will provide for retroactive funding.

Article 3. CEILING AMOUNT OF AWARD AND BUDGET

RTI hereby awards the amount of \$30,000 for the purposes of this Agreement. A potential increase of \$50,000 is possible if acceptable progress is made, allowing for a ceiling of \$80,000.

Payments will be made to the Awardee upon presentation to RTI a properly prepared invoice, with a certification that the Milestone being billed has been completed and providing any other documentation required by RTI specified for that Milestone in the chart below. An invoice format may be provided upon award of this Agreement. Each invoice shall include the following: Agreement Number, Milestone being billed and fixed amount associated with that Milestone.

On submission of the invoice for the final Milestone, the Awardee shall certify that the Agreement is completed and the Awardee will make no further claim against RTI after final payment.

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Article 4. PAYMENT MILESTONES AND DISBURSEMENT SCHEDULE

The approved Payment Milestones and disbursement schedule:

Milestone	Description of Milestone	Required Deliverable	Completion Date (if applicable)	Amount (Local Currency or USD)
1	Organization IRB Approval of the program	IRB Approval Letter	TBD	25% of total award value - \$7,500
2	Recipient organization staff trained*	Training certificate	TBD	25% of total award value - 7,500
3	50% of MITS utilized	Documentation of MITS used and corresponding QC process complete	TBD	25% of total award value - \$7,500
4	Program completion report	Program completion report	TBD	25% of total award value - \$7,500
Total				\$ 30,000

*The Awardee may proceed with training, however the second milestone for training completion cannot be paid until the first milestone for IRB approval is complete.

Article 5. PROGRAM REPORTING

Awardee

The Awardee will be responsive to requests for programmatic information and results by the Technical Monitor. RTI will conduct monitoring of the program activities, including site visits as appropriate.

Article 6. TITLE TO PROPERTY


Title to all property purchased under this Agreement shall be vested in the Awardee.

Article 7. RECORDKEEPING, RIGHT OF INSPECTION AND AUDIT

Right of inspection: RTI reserves the right to review all program related documentation, and any documents related to proper compliance during the implementation of the Agreement and up to a period of 3 years after the end-date of this Agreement. Therefore, Awardee agrees to maintain records funded by this Agreement for the period above.

The Awardee will commit to eliminate all the deficiencies or refund RTI for any unallowable costs found in resulting Inspection Report within 60 days.

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



Article 8. TERMINATION AND SUSPENSION

This Agreement may be terminated by RTI at a date earlier than the proposed end-date under the following conditions:

- 1) Significant change in the scope of work: If the requirements of the donor or the program change such that the work to be completed varies significantly from the proposed activities.
- 2) Reduction or termination of donor funding.
- 3) As a requirement of the donor: In the event the donor requests early termination of the Agreement.
- 4) Significant delays or external or internal challenges which have a material impact on the ability of the Awardee to implement the activities.

The Awardee will be notified in writing of proposed termination or suspension and outline close out procedures of the Agreement.

Article 10. LIABILITY

RTI does not assume liability for any third-party claims for damages arising out of this Agreement.

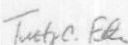

Article 11. DISPUTES

Any dispute under or relating to this Agreement shall be decided by the RTI Agreement Officer.


Article 12. SPECIAL PROVISIONS

The Awardee should comply with the Standard Provisions contained in Attachment B.

IN WITNESS OF THEIR AGREEMENT and their acceptance of its terms and conditions, RTI and the Awardee hereby execute this Agreement.

RTI International	KLE SOCIETY'S JAWAHARLAL NEHRU MEDICAL COLLEGE, BELAGAVI
Signature:  <small>Digitally signed by Tim Fetner DN: cn=Tim Fetner, o=RTI, ou=Global Supply Chain, email=timfetner@rti.org, c=US Date: 2019.07.02 13:26:22 -0400</small>	Signature: 
Name: Tim Fetner	Name: Dr. N.S. Mahantashetti
Title: Sr. Strategic Sourcing Officer	Title: Principal, J.N. Medical college.
Date: July 2, 2019	Date: July 17, 2019

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



ATTACHMENT B

STANDARD PROVISIONS

GLOBAL ACCESS TO INTELLECTUAL PROPERTY

GLOBAL ACCESS COMMITMENT

You will conduct and manage the Project and the Funded Developments in a manner that ensures Global Access. Your Global Access commitments will survive the term of this Agreement. "Funded Developments" means the products, services, processes, technologies, materials, software, data, other innovations, and intellectual property resulting from the Project (including modifications, improvements, and further developments to Background Technology). "Background Technology" means any and all products, services, processes, technologies, materials, software, data, or other innovations, and intellectual property created by You or a third party prior to or outside of the Project used as part of the Project. "Global Access" means: (a) the knowledge and information gained from the Project will be promptly and broadly disseminated; and (b) the Funded Developments will be made available and accessible at an affordable price (i) to people most in need within developing countries, or (ii) in support of the U.S. educational system and public libraries, as applicable to the Project.

LICENSE TO RTI-

For the purpose of achieving Global Access, You grant the RTI a nonexclusive, perpetual, irrevocable, worldwide, royalty-free, fully paid up, sublicensable license to: make, use, sell, offer to sell, import, distribute, copy, modify, create derivative works, publicly perform and display the Funded Developments and any Background Technology incorporated into a Funded Development or required to use a Funded Development. In the event You demonstrate to the satisfaction of RTI that Global Access can best be achieved without such a license (or a license of different scope) RTI and You will make good faith efforts to modify or terminate this license, as appropriate.

PUBLICATION

Consistent with Your Global Access commitments, if the Project description specifies Publication or Publication is otherwise requested by RTI, You will seek prompt Publication of any Funded Developments consisting of data and results. "Publication" means publication in a peer-reviewed journal or other method of public dissemination specified in the Project description or otherwise approved by RTI in writing. Publication may be delayed for a reasonable period for the sole purpose of seeking patent protection, provided the patent application is drafted, filed, and managed in a manner that best furthers Global Access. If You seek Publication in a peer-reviewed journal, such Publication shall be under "open access" terms and conditions consistent with RTI's Open Access Policy available at: www.gatesfoundation.org/How-We-Work/General-Information/Open-Access-Policy, which may be modified from time to time. Nothing in this section shall be construed as requiring Publication in contravention of any applicable ethical, legal, or regulatory requirements. You will mark any Funded Development subject to this clause with the appropriate notice or attribution, including author, date and copyright (e.g., © 20<> <Name>).

PUBLICITY

PUBLICITY BY YOU

You must obtain the RTI's prior written approval before: (a) issuing a press release or other public announcement regarding this grant; and (b) any other public use of the Gates Foundation's name or logo. Please email Your request to the Technical Monitor. Detailed guidelines are available at:

www.gatesfoundation.org/grantseeker/documents/guidelines_communications_for_grantees.doc.

PROHIBITED ACTIVITIES

ANTI-TERRORISM

ATTESTED

Dr. V.A. Kothiwale

Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



You will not use funds provided under this Agreement, directly or indirectly, in support of activities (a) prohibited by U.S. laws relating to combating terrorism; (b) with persons on the List of Specially Designated Nationals (www.treasury.gov/sdn) or entities owned or controlled by such persons; or (c) in or with countries or territories against which the U.S. maintains comprehensive sanctions (currently, Cuba, Iran, (North) Sudan, Syria, North Korea, and the Crimea Region of Ukraine), including paying or reimbursing the expenses of persons from such countries or territories, unless such activities are fully authorized by the U.S. government under applicable law and specifically approved by RTI in its sole discretion.

ANTI-CORRUPTION; ANTI-BRIBERY You will not offer or provide money, gifts, or any other things of value directly or indirectly to anyone in order to improperly influence any act or decision relating to RTI or the Project, including by assisting any party to secure an improper advantage. Training and information on compliance with these requirements are available at www.learnfoundationlaw.org.


LOBBYING AND ELECTIONEERING PROHIBITION

You may not use Grant Funds to influence the outcome of any election for public office or to carry on any voter registration drive. You acknowledge that RTI has not earmarked Grant Funds to support lobbying activities or to otherwise support attempts to influence legislation. Activities will be conducted consistent with the private foundation lobbying rules and exceptions under Internal Revenue Code Section 4945 and related regulations. You confirm that the Budget (or the combined project budget if there are multiple funders) accurately reflects that You will expend at least the amount of the Grant Funds on (a) non-lobbying activities in the project year, or (b) for multiple year projects, the total non-lobbying portion of the project.

OTHER LOBBYING, GIFT, AND ETHICS RULES

You agree to comply with any national, state, local, or other lobbying, gift, and ethics rules applicable to the Project. RTI is not retaining or employing You to engage in lobbying activities.

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



FIXED AMOUNT AWARD AGREEMENT

Between

Research Triangle Institute (RTI)


And

KLE SOCIETY'S JAWAHARLAL NEHRU MEDICAL COLLEGE, BELAGAVI

Agreement Summary:

1. Agreement Number	
2. Type of Agreement	Fixed Amount Award
3. Agreement Activity Title	To promote MITS activities to determine cause of death among neonatals and stillbirths in tertiary care teaching hospital
4. Agreement Administrator	US Address: Research Triangle Institute (RTI) 36040 Cornwallis Road - P. O. Box 12194 Research Triangle Park, NC 27709-2194 – USA
5. RTI Agreement Officer	
6. Recipient Organization	<u>KLE SOCIETY'S JAWAHARLAL NEHRU MEDICAL COLLEGE, BELAGAVI</u>
7. Recipient Organization's 's Point-of-Contact	Niranjana Mahantashetti principal@jnmc.edu <u>+918312471350</u>
8. Prime Award Number	OPP-1180554
9. Project Title	<u>MITS Surveillance Alliance</u>
10. RTI Project No	0216178
11. Period of Performance	Start Date: July 1, 2019 End Date: September 30, 2020
12. Agreement Ceiling	<u>\$80,000</u>
13. RTI Technical Monitor	<u>Norman Goco</u>
14. Incorporated Documents	Attachments A-B
ATTACHMENTS:	
Attachment A: Project Description	
Attachment B Standard Provisions	

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



This Agreement is awarded to **KLE SOCIETY'S JAWAHARLAL NEHRU MEDICAL COLLEGE, BELAGAVI** (hereinafter called "Awardee") and administered by **Research Triangle Institute** (hereinafter called "RTI"), a not-for-profit corporation existing under the laws of the State of North Carolina, USA and having its principal place of business at 3040 Cornwallis Road, Research Triangle Park 27709-2194, under above mentioned award between Gates Foundation and RTI to support implementation of the **To promote MITS activities to determine cause of death among neonatals and stillbirths in tertiary care teaching hospital**

(hereinafter called "Project").

Whereas:

- A. This Grant will implement specific activities that will contribute to achievement of the overall Project Objectives.
- B. This Agreement shall not (i) create the relationship of principal and agent, employer and employee, joint venture, or business partnership between RTI and the Awardee; and (ii) establish privity of contract between Gates Foundation and the Awardee.
- C. Authority of Agent: Designated agents on behalf of the Awardee and RTI are the sole authority authorized to make amendments and any other substantive changes to the Agreement Terms.

Now, therefore, in consideration of the promises and of the mutual covenants and Agreements contained herein, and intending to be legally bound, RTI and the Awardee hereby agree to the following terms and conditions of this Agreement.

Article 1. PROGRAM DESCRIPTION

The purpose of this Agreement is to provide support for the activities described in the Program Description in **Attachment A** of this Agreement.

Article 2. PERIOD OF PERFORMANCE

The period of performance for the Agreement activities is July 1, 2019 to September 30, 2020.

All activities financed with Agreement funds will not commence prior to the Agreement Activity Start date, and will be completed and will cease no later than the Agreement Activity Completion Date; unless RTI provides approval of a time extension in writing prior to the specified Agreement Activity Completion Date. No award will provide for retroactive funding.


Article 3. CEILING AMOUNT OF AWARD AND BUDGET

RTI hereby awards the amount of \$30,000 for the purposes of this Agreement. A potential increase of \$50,000 is possible if acceptable progress is made, allowing for a ceiling of \$80,000.

Payments will be made to the Awardee upon presentation to RTI a properly prepared invoice, with a certification that the Milestone being billed has been completed and providing any other documentation required by RTI specified for that Milestone in the chart below. An invoice format may be provided upon award of this Agreement. Each invoice shall include the following: Agreement Number, Milestone being billed and fixed amount associated with that Milestone.

On submission of the invoice for the final Milestone, the Awardee shall certify that the Agreement is completed and the Awardee will make no further claim against RTI after final payment.

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Article 4. PAYMENT MILESTONES AND DISBURSEMENT SCHEDULE

The approved Payment Milestones and disbursement schedule:

Milestone	Description of Milestone	Required Deliverable	Completion Date (if applicable)	Amount (Local Currency or USD)
1	Organization IRB Approval of the program	IRB Approval Letter	TBD	25% of total award value - \$7,500
2	Recipient organization staff trained*	Training certificate	TBD	25% of total award value - 7,500
3	50% of MITS utilized	Documentation of MITS used and corresponding QC process complete	TBD	25% of total award value - \$7,500
4	Program completion report	Program completion report	TBD	25% of total award value - \$7,500
Total				\$ 30,000

*The Awardee may proceed with training, however the second milestone for training completion cannot be paid until the first milestone for IRB approval is complete.

Article 5. PROGRAM REPORTING

Awardee

The Awardee will be responsive to requests for programmatic information and results by the Technical Monitor. RTI will conduct monitoring of the program activities, including site visits as appropriate.

Article 6. TITLE TO PROPERTY

Title to all property purchased under this Agreement shall be vested in the Awardee.

Article 7. RECORDKEEPING, RIGHT OF INSPECTION AND AUDIT

Right of inspection: RTI reserves the right to review all program related documentation, and any documents related to proper compliance during the implementation of the Agreement and up to a period of 3 years after the end-date of this Agreement. Therefore, Awardee agrees to maintain records funded by this Agreement for the period above.

The Awardee will commit to eliminate all the deficiencies or refund RTI for any unallowable costs found in resulting Inspection Report within 60 days.

ATTESTED

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka



Article 8. TERMINATION AND SUSPENSION

This Agreement may be terminated by RTI at a date earlier than the proposed end-date under the following conditions:

- 1) Significant change in the scope of work: If the requirements of the donor or the program change such that the work to be completed varies significantly from the proposed activities.
- 2) Reduction or termination of donor funding.
- 3) As a requirement of the donor: In the event the donor requests early termination of the Agreement.
- 4) Significant delays or external or internal challenges which have a material impact on the ability of the Awardee to implement the activities.

The Awardee will be notified in writing of proposed termination or suspension and outline close out procedures of the Agreement.

Article 10. LIABILITY

RTI does not assume liability for any third-party claims for damages arising out of this Agreement.

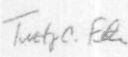

Article 11. DISPUTES

Any dispute under or relating to this Agreement shall be decided by the RTI Agreement Officer.

Article 12. SPECIAL PROVISIONS

The Awardee should comply with the Standard Provisions contained in Attachment B.

IN WITNESS OF THEIR AGREEMENT and their acceptance of its terms and conditions, RTI and the Awardee hereby execute this Agreement.

RTI International	KLE SOCIETY'S JAWAHARLAL NEHRU MEDICAL COLLEGE, BELAGAVI
Signature:  <small>Digitally signed by Tim Fetner DN: cn=Tim Fetner, o=PS, ou=Global Supply Chain, email=timfetner@rti.org Date: 2019.07.02 13:36:22 -0400</small>	Signature: 
Name: Tim Fetner	Name: Dr. N.S. Mahantashetti
Title: Sr. Strategic Sourcing Officer	Title: Principal, J.N. Medical college.
Date: July 2, 2019	Date: July 17, 2019

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



ATTACHMENT B

STANDARD PROVISIONS

GLOBAL ACCESS TO INTELLECTUAL PROPERTY

GLOBAL ACCESS COMMITMENT

You will conduct and manage the Project and the Funded Developments in a manner that ensures Global Access. Your Global Access commitments will survive the term of this Agreement. "*Funded Developments*" means the products, services, processes, technologies, materials, software, data, other innovations, and intellectual property resulting from the Project (including modifications, improvements, and further developments to Background Technology). "*Background Technology*" means any and all products, services, processes, technologies, materials, software, data, or other innovations, and intellectual property created by You or a third party prior to or outside of the Project used as part of the Project. "*Global Access*" means: (a) the knowledge and information gained from the Project will be promptly and broadly disseminated; and (b) the Funded Developments will be made available and accessible at an affordable price (i) to people most in need within developing countries, or (ii) in support of the U.S. educational system and public libraries, as applicable to the Project.

LICENSE TO RTI-

For the purpose of achieving Global Access, You grant the RTI a nonexclusive, perpetual, irrevocable, worldwide, royalty-free, fully paid up, sublicensable license to: make, use, sell, offer to sell, import, distribute, copy, modify, create derivative works, publicly perform and display the Funded Developments and any Background Technology incorporated into a Funded Development or required to use a Funded Development. In the event You demonstrate to the satisfaction of RTI that Global Access can best be achieved without such a license (or a license of different scope) RTI and You will make good faith efforts to modify or terminate this license, as appropriate.

PUBLICATION

Consistent with Your Global Access commitments, if the Project description specifies Publication or Publication is otherwise requested by RTI, You will seek prompt Publication of any Funded Developments consisting of data and results. "*Publication*" means publication in a peer-reviewed journal or other method of public dissemination specified in the Project description or otherwise approved by RTI in writing. Publication may be delayed for a reasonable period for the sole purpose of seeking patent protection, provided the patent application is drafted, filed, and managed in a manner that best furthers Global Access. If You seek Publication in a peer-reviewed journal, such Publication shall be under "open access" terms and conditions consistent with RTI's Open Access Policy available at: www.gatesfoundation.org/How-We-Work/General-Information/Open-Access-Policy, which may be modified from time to time. Nothing in this section shall be construed as requiring Publication in contravention of any applicable ethical, legal, or regulatory requirements. You will mark any Funded Development subject to this clause with the appropriate notice or attribution, including author, date and copyright (e.g., © 20<> <Name>).

PUBLICITY

PUBLICITY BY YOU

You must obtain the RTI's prior written approval before: (a) issuing a press release or other public announcement regarding this grant; and (b) any other public use of the Gates Foundation's name or logo. Please email Your request to the Technical Monitor. Detailed guidelines are available at:

www.gatesfoundation.org/grantseeker/documents/guidelines_communications_for_grantees.doc.

PROHIBITED ACTIVITIES

ANTI-TERRORISM

ATTESTED

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka



You will not use funds provided under this Agreement, directly or indirectly, in support of activities (a) prohibited by U.S. laws relating to combating terrorism; (b) with persons on the List of Specially Designated Nationals (www.treasury.gov/sdn) or entities owned or controlled by such persons; or (c) in or with countries or territories against which the U.S. maintains comprehensive sanctions (currently, Cuba, Iran, (North) Sudan, Syria, North Korea, and the Crimea Region of Ukraine), including paying or reimbursing the expenses of persons from such countries or territories, unless such activities are fully authorized by the U.S. government under applicable law and specifically approved by RTI in its sole discretion.

ANTI-CORRUPTION; ANTI-BRIBERY You will not offer or provide money, gifts, or any other things of value directly or indirectly to anyone in order to improperly influence any act or decision relating to RTI or the Project, including by assisting any party to secure an improper advantage. Training and information on compliance with these requirements are available at www.learnfoundationlaw.org.

LOBBYING AND ELECTIONEERING PROHIBITION

You may not use Grant Funds to influence the outcome of any election for public office or to carry on any voter registration drive. You acknowledge that RTI has not earmarked Grant Funds to support lobbying activities or to otherwise support attempts to influence legislation. Activities will be conducted consistent with the private foundation lobbying rules and exceptions under Internal Revenue Code Section 4945 and related regulations. You confirm that the Budget (or the combined project budget if there are multiple funders) accurately reflects that You will expend at least the amount of the Grant Funds on (a) non-lobbying activities in the project year, or (b) for multiple year projects, the total non-lobbying portion of the project.

OTHER LOBBYING, GIFT, AND ETHICS RULES

You agree to comply with any national, state, local, or other lobbying, gift, and ethics rules applicable to the Project. RTI is not retaining or employing You to engage in lobbying activities.

ATTESTED

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka



FIXED AMOUNT AWARD AGREEMENT

Between

Research Triangle Institute (RTI)


And

KLE SOCIETY'S JAWAHARLAL NEHRU MEDICAL COLLEGE, BELAGAVI

Agreement Summary:

1. Agreement Number	
2. Type of Agreement	Fixed Amount Award
3. Agreement Activity Title	To promote MITS activities to determine cause of death among neonatals and stillbirths in tertiary care teaching hospital
4. Agreement Administrator	US Address: Research Triangle Institute (RTI) 36040 Cornwallis Road - P. O. Box 12194 Research Triangle Park, NC 27709-2194 – USA
5. RTI Agreement Officer	
6. Recipient Organization	<u>KLE SOCIETY'S JAWAHARLAL NEHRU MEDICAL COLLEGE, BELAGAVI</u>
7. Recipient Organization's 's Point-of-Contact	Niranjana Mahantashetti principal@jnmc.edu <u>+918312471350</u>
8. Prime Award Number	OPP-1180554
9. Project Title	<u>MITS Surveillance Alliance</u>
10. RTI Project No	0216178
11. Period of Performance	Start Date: July 1, 2019 End Date: September 30, 2020
12. Agreement Ceiling	<u>\$80,000</u>
13. RTI Technical Monitor	<u>Norman Goco</u>
14. Incorporated Documents	Attachments A-B
ATTACHMENTS:	
Attachment A: Project Description	
Attachment B Standard Provisions	

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



This Agreement is awarded to **KLE SOCIETY'S JAWAHARLAL NEHRU MEDICAL COLLEGE, BELAGAVI** (hereinafter called "Awardee") and administered by **Research Triangle Institute** (hereinafter called "RTI"), a not-for-profit corporation existing under the laws of the State of North Carolina, USA and having its principal place of business at 3040 Cornwallis Road, Research Triangle Park 27709-2194, under above mentioned award between Gates Foundation and RTI to support implementation of the **To promote MITS activities to determine cause of death among neonatals and stillbirths in tertiary care teaching hospital**

(hereinafter called "Project").

Whereas:

- A. This Grant will implement specific activities that will contribute to achievement of the overall Project Objectives.
- B. This Agreement shall not (i) create the relationship of principal and agent, employer and employee, joint venture, or business partnership between RTI and the Awardee; and (ii) establish privity of contract between Gates Foundation and the Awardee.
- C. Authority of Agent: Designated agents on behalf of the Awardee and RTI are the sole authority authorized to make amendments and any other substantive changes to the Agreement Terms.

Now, therefore, in consideration of the promises and of the mutual covenants and Agreements contained herein, and intending to be legally bound, RTI and the Awardee hereby agree to the following terms and conditions of this Agreement.

Article 1. PROGRAM DESCRIPTION

The purpose of this Agreement is to provide support for the activities described in the Program Description in **Attachment A** of this Agreement.

Article 2. PERIOD OF PERFORMANCE

The period of performance for the Agreement activities is July 1, 2019 to September 30, 2020.

All activities financed with Agreement funds will not commence prior to the Agreement Activity Start date, and will be completed and will cease no later than the Agreement Activity Completion Date; unless RTI provides approval of a time extension in writing prior to the specified Agreement Activity Completion Date. No award will provide for retroactive funding.


Article 3. CEILING AMOUNT OF AWARD AND BUDGET

RTI hereby awards the amount of \$30,000 for the purposes of this Agreement. A potential increase of \$50,000 is possible if acceptable progress is made, allowing for a ceiling of \$80,000.

Payments will be made to the Awardee upon presentation to RTI a properly prepared invoice, with a certification that the Milestone being billed has been completed and providing any other documentation required by RTI specified for that Milestone in the chart below. An invoice format may be provided upon award of this Agreement. Each invoice shall include the following: Agreement Number, Milestone being billed and fixed amount associated with that Milestone.

On submission of the invoice for the final Milestone, the Awardee shall certify that the Agreement is completed and the Awardee will make no further claim against RTI after final payment.

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



Article 4. PAYMENT MILESTONES AND DISBURSEMENT SCHEDULE

The approved Payment Milestones and disbursement schedule:

Milestone	Description of Milestone	Required Deliverable	Completion Date (if applicable)	Amount (Local Currency or USD)
1	Organization IRB Approval of the program	IRB Approval Letter	TBD	25% of total award value - \$7,500
2	Recipient organization staff trained*	Training certificate	TBD	25% of total award value - 7,500
3	50% of MITS utilized	Documentation of MITS used and corresponding QC process complete	TBD	25% of total award value - \$7,500
4	Program completion report	Program completion report	TBD	25% of total award value - \$7,500
Total				\$ 30,000

*The Awardee may proceed with training, however the second milestone for training completion cannot be paid until the first milestone for IRB approval is complete.

Article 5. PROGRAM REPORTING

Awardee

The Awardee will be responsive to requests for programmatic information and results by the Technical Monitor. RTI will conduct monitoring of the program activities, including site visits as appropriate.

Article 6. TITLE TO PROPERTY

Title to all property purchased under this Agreement shall be vested in the Awardee.

Article 7. RECORDKEEPING, RIGHT OF INSPECTION AND AUDIT

Right of inspection: RTI reserves the right to review all program related documentation, and any documents related to proper compliance during the implementation of the Agreement and up to a period of 3 years after the end-date of this Agreement. Therefore, Awardee agrees to maintain records funded by this Agreement for the period above.

The Awardee will commit to eliminate all the deficiencies or refund RTI for any unallowable costs found in resulting Inspection Report within 60 days.

ATTESTED

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka



Article 8. TERMINATION AND SUSPENSION

This Agreement may be terminated by RTI at a date earlier than the proposed end-date under the following conditions:

- 1) Significant change in the scope of work: If the requirements of the donor or the program change such that the work to be completed varies significantly from the proposed activities.
- 2) Reduction or termination of donor funding.
- 3) As a requirement of the donor: In the event the donor requests early termination of the Agreement.
- 4) Significant delays or external or internal challenges which have a material impact on the ability of the Awardee to implement the activities.

The Awardee will be notified in writing of proposed termination or suspension and outline close out procedures of the Agreement.

Article 10. LIABILITY

RTI does not assume liability for any third-party claims for damages arising out of this Agreement.

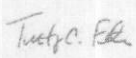

Article 11. DISPUTES

Any dispute under or relating to this Agreement shall be decided by the RTI Agreement Officer.

Article 12. SPECIAL PROVISIONS

The Awardee should comply with the Standard Provisions contained in Attachment B.

IN WITNESS OF THEIR AGREEMENT and their acceptance of its terms and conditions, RTI and the Awardee hereby execute this Agreement.

RTI International	KLE SOCIETY'S JAWAHARLAL NEHRU MEDICAL COLLEGE, BELAGAVI
Signature:  <small>Digitally signed by Tim Fetner DN: cn=Tim Fetner, o=RTI, ou=Global Supply Chain, email=timf@rti.org, c=US Date: 2019.07.02 13:36:22 -0400</small>	Signature: 
Name: Tim Fetner	Name: Dr. N.S. Mahantashetti
Title: Sr. Strategic Sourcing Officer	Title: Principal, J.N. Medical College.
Date: July 2, 2019	Date: July 17, 2019

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



ATTACHMENT B

STANDARD PROVISIONS

GLOBAL ACCESS TO INTELLECTUAL PROPERTY

GLOBAL ACCESS COMMITMENT

You will conduct and manage the Project and the Funded Developments in a manner that ensures Global Access. Your Global Access commitments will survive the term of this Agreement. "Funded Developments" means the products, services, processes, technologies, materials, software, data, other innovations, and intellectual property resulting from the Project (including modifications, improvements, and further developments to Background Technology). "Background Technology" means any and all products, services, processes, technologies, materials, software, data, or other innovations, and intellectual property created by You or a third party prior to or outside of the Project used as part of the Project. "Global Access" means: (a) the knowledge and information gained from the Project will be promptly and broadly disseminated; and (b) the Funded Developments will be made available and accessible at an affordable price (i) to people most in need within developing countries, or (ii) in support of the U.S. educational system and public libraries, as applicable to the Project.

LICENSE TO RTI-

For the purpose of achieving Global Access, You grant the RTI a nonexclusive, perpetual, irrevocable, worldwide, royalty-free, fully paid up, sublicensable license to: make, use, sell, offer to sell, import, distribute, copy, modify, create derivative works, publicly perform and display the Funded Developments and any Background Technology incorporated into a Funded Development or required to use a Funded Development. In the event You demonstrate to the satisfaction of RTI that Global Access can best be achieved without such a license (or a license of different scope) RTI and You will make good faith efforts to modify or terminate this license, as appropriate.

PUBLICATION

Consistent with Your Global Access commitments, if the Project description specifies Publication or Publication is otherwise requested by RTI, You will seek prompt Publication of any Funded Developments consisting of data and results. "Publication" means publication in a peer-reviewed journal or other method of public dissemination specified in the Project description or otherwise approved by RTI in writing. Publication may be delayed for a reasonable period for the sole purpose of seeking patent protection, provided the patent application is drafted, filed, and managed in a manner that best furthers Global Access. If You seek Publication in a peer-reviewed journal, such Publication shall be under "open access" terms and conditions consistent with RTI's Open Access Policy available at: www.gatesfoundation.org/How-We-Work/General-Information/Open-Access-Policy, which may be modified from time to time. Nothing in this section shall be construed as requiring Publication in contravention of any applicable ethical, legal, or regulatory requirements. You will mark any Funded Development subject to this clause with the appropriate notice or attribution, including author, date and copyright (e.g., © 20<> <Name>).

PUBLICITY

PUBLICITY BY YOU

You must obtain the RTI's prior written approval before: (a) issuing a press release or other public announcement regarding this grant; and (b) any other public use of the Gates Foundation's name or logo. Please email Your request to the Technical Monitor. Detailed guidelines are available at:

www.gatesfoundation.org/grantseeker/documents/guidelines_communications_for_grantees.doc.

PROHIBITED ACTIVITIES

ANTI-TERRORISM

ATTESTED

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



You will not use funds provided under this Agreement, directly or indirectly, in support of activities (a) prohibited by U.S. laws relating to combating terrorism; (b) with persons on the List of Specially Designated Nationals (www.treasury.gov/sdn) or entities owned or controlled by such persons; or (c) in or with countries or territories against which the U.S. maintains comprehensive sanctions (currently, Cuba, Iran, (North) Sudan, Syria, North Korea, and the Crimea Region of Ukraine), including paying or reimbursing the expenses of persons from such countries or territories, unless such activities are fully authorized by the U.S. government under applicable law and specifically approved by RTI in its sole discretion.

ANTI-CORRUPTION; ANTI-BRIBERY You will not offer or provide money, gifts, or any other things of value directly or indirectly to anyone in order to improperly influence any act or decision relating to RTI or the Project, including by assisting any party to secure an improper advantage. Training and information on compliance with these requirements are available at www.learnfoundationlaw.org.


LOBBYING AND ELECTIONEERING PROHIBITION

You may not use Grant Funds to influence the outcome of any election for public office or to carry on any voter registration drive. You acknowledge that RTI has not earmarked Grant Funds to support lobbying activities or to otherwise support attempts to influence legislation. Activities will be conducted consistent with the private foundation lobbying rules and exceptions under Internal Revenue Code Section 4945 and related regulations. You confirm that the Budget (or the combined project budget if there are multiple funders) accurately reflects that You will expend at least the amount of the Grant Funds on (a) non-lobbying activities in the project year, or (b) for multiple year projects, the total non-lobbying portion of the project.

OTHER LOBBYING, GIFT, AND ETHICS RULES

You agree to comply with any national, state, local, or other lobbying, gift, and ethics rules applicable to the Project. RTI is not retaining or employing You to engage in lobbying activities.

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



KLE Academy of Higher Education and Research
Jawaharlal Nehru Medical College, Belagavi
Women's and Children's Health Research Unit

September 2, 2020

Research Project Title:

Reducing Anemia in Pregnancy in India: The RAPIDIRON Trial

International Collaborating Institutions:

- Thomas Jefferson University, Philadelphia, USA
- Georgetown University School of Medicine, Baltimore, Maryland USA
- University of Minnesota, Minneapolis, Minnesota USA
- University of Alabama at Birmingham, Birmingham, Alabama USA

National Collaborating Institute:

Sawai Man Singh Medical College (SMSMC), Jaipur, Rajasthan

Sponsor:

The Children's Investment Fund Foundation, London, UK

Duration: April 2019 – July 2023

Preparatory Activities

Funding Contribution by Thomas Jefferson University, Philadelphia, USA

S.No.	Activity	Funding
1	April 24-29, 2019 Participated in Anemia in Pregnancy Investigators' Meeting <ul style="list-style-type: none">• Dr Shivaprasad S Goudar, Professor of Physiology & Senior Foreign Investigator, JNMC Women's & Children's Health Research Unit, KAHER's J N Medical College, Belagavi• Dr M B Bellad, Professor of OBGYN, KAHER's J N Medical College, Belagavi• Mr Amit Revankar, Data Management and IT Support, Women's and Children's Health Research Unit, KAHER's J N Medical College, Belagavi	Rs.6,36,004.32/-
2	June 3-5, 2019 June 11-13, 2019 November 10-13, 2019 Visited to Sawai Man Singh Medical College (SMSMC), Jaipur, Rajasthan <ul style="list-style-type: none">• Dr M B Bellad, Professor of OBGYN, KAHER's J N Medical College, Belagavi	Rs.5,60,504.00/-

ATTESTED

Dr. V.A.Kothiwale
Registrar

Address for Correspondence:

KLE Academy of Higher Education and Research, J.N. Medical College,
Nehru Nagar, Belagavi-590 010, Karnataka
Phone: +91-831-2474200 / +91 831 244 4190

Fax: +91-831-2472891
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



KLE Academy of Higher Education and Research
Jawaharlal Nehru Medical College, Belagavi
Women's and Children's Health Research Unit

	<ul style="list-style-type: none">• Dr Manjunath Somannavar, Associate Professor of Biochemistry, KAHER's J N Medical College, Belagavi• Dr Yogesh Kumar S, Associate Professor of Community Medicine, KAHER's J N Medical College, Belagavi• Mr Amit Revankar, Data Management and IT Support, Women's and Children's Health Research Unit, KAHER's J N Medical College, Belagavi	
	Total Contribution	Rs.11,96,508.32/-

Funding Contribution by KLE Academy of Higher Education and Research, Belagavi

S.No.	Activity	Funding
1	June 3-5, 2019 June 11-13, 2019 November 10-13, 2019 Visited to Sawai Man Singh Medical College (SMSMC), Jaipur, Rajasthan <ul style="list-style-type: none">• Dr Shivaprasad S Goudar, Professor of Physiology & Senior Foreign Investigator, JNMC Women's & Children's Health Research Unit, KAHER's J N Medical College, Belagavi	Rs.1,19,772.10/-
	Total Contribution	Rs.1,19,772.10/-

Total Funding: Rs.13,16,280.42/-

Dr Shivaprasad S Goudar

Professor of Physiology &

Director - Research, KLE Academy of Higher Education and Research (Deemed-to-be-University);

Senior Foreign Investigator, NICHD Global Network for Women's and Children's Health Research Site 08

KAHER's J N Medical College

Nehru Nagar, Belagavi-590010

Mobile: +91-94481 26371

Email: sgoudar@jnmc.edu



ATTESTED

Dr. V.A.Kothiwale

Registrar

Address for Correspondence:

KLE Academy of Higher Education and Research, J.N. Medical College,

Nehru Nagar, Belagavi-590 010, Karnataka

Phone: +91-831-2474200 / +91 831 244 4190

Fax: +91-831-2472891
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Attachment 3B
Subrecipient Contacts

Subaward Number:
080-70000-U25902

Subrecipient Information for FFATA reporting

Entity's DUNS Name: KLE Society's Jawaharlal Nehru Medical College

EIN No.: [] Institution Type: []

DUNS: 650251213 Currently registered in SAM.gov: Yes No
Exempt from reporting executive compensation: Yes No (if no, complete 3Bpg2)

Parent DUNS: [] This section for U.S. Entities: Zip Code Look-up

Place of Performance Address Congressional District: [] Zip Code+4: []

KLE Society's Jawaharlal Nehru Medical College
JNMC Campus, Nehru Nagar
Belagavi 590010, Karnataka, India

Subrecipient Contacts

Central Email: principal@jnmc.edu

Website: https://kledeemeduniversity.edu.in/jnmc-womens-childs-research-unit/#1561969809031-00231286-619d

Principal Investigator Name: Dr Mrutyunjaya B. Bellad

Email: mbbellad@hotmail.com Telephone Number: +91-9448124893

Administrative Contact Name: Dr Shivaprasad S Goudar

Email: sgoudar@jnmc.edu Telephone Number: +91-9448126371

Financial Contact Name: Mr Basavaraj Killedar

Email: bkilledar@jnmc.edu Telephone Number: +91-9448091205

Invoice Email: bkilledar@jnmc.edu; amit@jnmc.edu

Authorized Official Name: Dr Niranjana S Mahantashetti

Email: principal@jnmc.edu; niranjanasn@yahoo.com Telephone Number: +91-8312471350

Legal Address:

KLE Society's Jawaharlal Nehru Medical College
JNMC Campus, Nehru Nagar
Belagavi 590010, Karnataka, India

Administrative Address:

Women's and Children's Health Research Unit
KLE Society's Jawaharlal Nehru Medical College
JNMC Campus, Nehru Nagar
Belagavi 590010, Karnataka, India

Payment Address:

Account Name: THE REGISTRAR, KLE UNIVERSITY FCRA; Account Number: 05042010135011
Beneficiary Bank Name: e-SYNDICATE BANK; Bank Address: J N MEDICAL COLLEGE CAMPUS, NEHRU NAGAR, BELAGAVI
Routing Number (SWIFT Code): SYNBINBB155; Banking Currency: INDIAN RUPEES
Intermediary Bank Name: STANDARD CHARTERED BANK; Account Number: 3582089604001; Routing Number (SWIFT Code) SCBLUS33

ATTESTED

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Attachment 4
Reporting and Prior Approval Terms

Subaward Number:
080-70000-U25902

Subrecipient agrees to submit the following reports (PTE contacts are identified in Attachment 3A):

Technical Reports:

- Monthly technical/progress reports will be submitted to the PTE's Administrative Contact within 15 days of the end of the month.
- Quarterly technical/progress reports will be submitted within 30 days after the end of each project quarter to the PTE's Administrative Contact
- Annual technical / progress reports will be submitted 60 days prior to the end of each budget period to the PTE's Principal Investigator. Such report shall also include a detailed budget for the next Budget Period, updated other support for key personnel, certification of appropriate education in the conduct of human subject research of any new key personnel, and annual IRB or IACUC approval, if applicable.
- A Final technical/progress report will be submitted to the PTE's Principal Investigator within 60 days of the end of the Project Period or after termination of this award, whichever comes first.
- Technical/progress reports on the project as may be required by PTE's Administrative Contact in order for the PTE to satisfy its reporting obligations to the Federal Awarding Agency.

Prior Approvals:

Carryover:

Carryover is restricted for this subaward by the:

See restrictions detailed within the Sponsor's Grant Agreement, Attachment 6.

Other Reports:

- In accordance with 37 CFR 401.14, Subrecipient agrees to notify PTE's Administrative Contact 60 days after Subrecipient's inventor discloses invention(s) in writing to Subrecipient's personnel responsible for patent matters. The Subrecipient will submit a final invention report using Federal Awarding Agency specific forms to the PTE's Administrative Contact within 60 days of the end of the Project Period to be included as part of the PTE's final invention report to the Federal Awarding Agency.
A negative report is required: Upon Request
- Property Inventory Report (only when required by Federal Awarding Agency), specific requirements below.
- Each invoice must be accompanied by a brief technical report, and: (i) be sequentially numbered; (ii) indicate the date(s) of performance by the Subrecipient; (iii) state the Purchase Order number, the title of the project and the name of the PTE Principal Investigator; (iv) itemize costs in detail, in accordance with the Subaward budget; (v) include both current costs and cumulative costs; (vi) include the Subrecipient certification, with authorized official's signature, that costs are appropriate and accurate and that payment has not yet been received; and (vii) be supported by a general ledger report originating directly from the Subrecipient's financial record keeping system. PTE may request supporting documentation in certain categories prior to or subsequent to approving the invoice. Supporting documentation includes, but is not limited to, travel receipts, purchase orders, invoices for services or supplies, or time records, Property Inventory Report; frequency, type, and submission instructions listed here and only to be used when required by PTE Federal Award.

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Attachment 6



GRANT AGREEMENT

This Key Grant Information sheet, the attached Grant Conditions and the Annexes referred to on this page form the Grant Agreement between you and The Children's Investment Fund Foundation (UK) ("us", "we" or "CIFF").

By countersigning this Grant Agreement, you are agreeing to comply with its terms and conditions. The Grant Agreement will become effective as of the date of the last signature below.

<u>GRANTEE DETAILS</u>	
Grantee	Thomas Jefferson University, registered in the USA as a charitable organisation with registration number 23-1352651 (" you " or " your ")
Grantee Address	XXXXXXXXXXXX 833 Chestnut Street, Suite 900 1020 Walnut Street Philadelphia PA 19107 United States
Key Personnel	Richard Derman or such persons as notified to us by you from time to time.
<u>GRANT DETAILS & DEFINITIONS</u>	
Grant Title	IV Iron
Grant Reference Number	1811-03347 Investment approval date: October 2019
Grant Purpose	The purpose of this project is to conduct a 3-arm, randomized-controlled, trial known as " <i>Reducing Anemia in Pregnancy in India: RAPIDIRON TRIAL</i> " This research will be conducted in India in selected primary and community health centers of Karnataka and Rajasthan to determine if a single dose (up to 1 gram) of intravenous (IV) iron (ferric carboxymaltose in intervention arm 1 or iron isomaltoside in intervention arm 2), administered early in the second trimester of pregnancy to pregnant women with moderate anemia (haemoglobin of 7-9.9 g/dL) and confirmed iron deficiency will result in a greater percentage of pregnant women in the IV iron arms achieving a normal for pregnancy haemoglobin concentration of ≥ 11 g/dL prior to delivery compared to the percentage of pregnant women with iron deficiency anemia that were randomized to a control arm (arm 3) that received oral iron for treatment. The study will also assess if treatment of anemia in pregnancy with a single-dose of IV iron is more effective than oral iron for reducing other adverse pregnancy outcomes, including the primary outcome of interest--low birth weight rate (<2500 grams) (the Project)
Grant Activities	To carry out the activities set out at Annex 1 and the Deliverables in Annex 4 as amended from time to time in accordance with this Grant Agreement.
Grant Amount	inclusive of all value added taxes (or equivalent sales taxes), other taxes and charges (the Grant).
Grant Term	1 August 2020 (Start Date) to 30 June 2023 (End Date), subject to the terms of this Grant Agreement. For the purposes of this Grant Agreement, " year " means the following years: Year 1: 1 August 2020 – 28 February 2021 Year 2: 1 March 2021 – 28 February 2022 Year 3: 1 March 2022 – 28 February 2023

ATTESTED

Page 1 of 24

Dr. V.A.Kothiwale
Registrar


KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

CIFF CHILDREN'S
INVESTMENT FUND
FOUNDATION

	Year 4: 1 March 2023 – 30 June 2023
CIFF Key Contact	Hemang Shah, or as otherwise notified to you from time-to-time.
Party	You or CIFF (each a Party and together the Parties)

ATTESTED

Page 2 of 24


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



**CHILDREN'S
INVESTMENT FUND
FOUNDATION**

GRANT CONDITIONS

1 Use of Grant

- 1.1 We are awarding you this Grant to carry out the Grant Activities and grant monies may only be used for those Grant Activities.
- 1.2 All Grant Activities must be carried out in accordance with this Grant Agreement (including the budget set out at Annex 2 (**Budget**)).
- 1.3 The Grant monies will be paid in accordance with the payment schedule in Annex 4 subject to the provision of the related Deliverables (if any).
- 1.4 You must inform us if you intend to engage any third-party (**Third Parties**) in relation to the Grant and provide details of any payments to Third Parties in the Budget. You are responsible for the acts and omissions of any Third Parties and ensuring their compliance with the terms of this Grant Agreement. If any Third Party loses the consents, licences or permissions required to receive the Grant or undertake Grant Activities under any applicable laws, you must immediately cease to make any further Grant payments to such Third Party and inform us of such without delay.

2 Compliance

- 2.1 In connection with the Grant Activities, you agree:
 - a. to comply with and ensure any Third Parties comply with all applicable laws and regulations;
 - b. to ensure that any necessary licenses and approvals have been obtained and are valid for the duration of the Grant;
 - c. not to offer, give or agree to offer or give (either alone or in agreement with others) any payment, gift or other advantage which could be interpreted as an inducement or a reward for any act or failure to act related to the Grant. You shall comply with and ensure that anybody employed or engaged or acting on your behalf complies with the Bribery Act 2010 and any other anti-bribery or anti-corruption legislation applicable in any jurisdiction;
 - d. to ensure that slavery and human trafficking is not taking place in any part of your business or your supply chain;
 - e. to ensure that Grant monies are not used directly or indirectly in support of any activities (i) prohibited by any laws related to terrorism; (ii) with or related to parties on the Financial Sanctions Target list of the UK Office of Financial Sanctions Implementation or the US Office of Foreign Asset Control's list of Specially Designated Nationals; or (iii) with or related to countries against which there are comprehensive embargos; and
 - f. to ensure that the Grants are never used for, and you shall not engage in, (i) any party-political activity, (ii) any activity that would require you or us to register with the UK Electoral Commission or any similar body in any other country, or (iii) any activity to carry out religious conversions.
- 2.2 You shall notify us immediately upon becoming aware of any actual or suspected activity that could constitute a breach of this Condition 2 and you shall cooperate with us (including by providing any information or assistance) in order to enable us to comply with any obligations that we may have in respect of such breaches.

ATTESTED

Page 3 of 24

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



**CHILDREN'S
INVESTMENT FUND
FOUNDATION**

3 Management of the Grant and Reporting

- 3.1 Before the initial tranche of the Grant is paid, we must be satisfied with the items set out in paragraph 1.1 of Annex 4.
- 3.2 Where applicable, before any subsequent tranche of the Grant is paid, we must be satisfied with the items set out in paragraph 2.1 of Annex 4.
- 3.3 You will promptly repay us any amount we notify you has been paid incorrectly, including any amount paid before all the conditions to payment have been complied with.
- 3.4 In relation to the Grant, you must provide us with:
 - a. the reports set out in paragraph 1 of Annex 3 by the relevant reporting dates; and
 - b. any other information relating to any of the Grant Activities that we may reasonably require.
- 3.5 During the Grant Term we shall have update calls and meetings to discuss the progress of the Grant Activities with your Key Personnel (or such other persons as agreed by the Parties) at such intervals as we may specify from time-to-time.
- 3.6 In relation to the Grant, you shall:
 - a. tell us immediately if there has been or may be:
 - (i) any adverse effect or significant delay to the Grant Activities;
 - (ii) a change to any of the Key Personnel;
 - (iii) any suspicion of or actual fraud, corruption, financial impropriety, conflict of interest or other actual or suspected misuse of Grant funds; or
 - (iv) any actual or proposed material change to your finances, business or operations;
 - b. notify the CIFF Key Contact in advance of any change of more than 10% in any cost category for each year's Budget up to and including a change of 20%;
 - c. ensure that any change in a cost category for a year's Budget does not exceed 20%;
 - d. ensure that the Budget, if amended in relation to a particular year, does not exceed the total amount of the Grant; and
 - e. following any request by us, provide timely access to data for the Grant.

4 Annual Programme Review

- 4.1 You agree that we may carry out an annual programme review of the Grant (APR) prior to each anniversary of the Start Date of the Grant to assess progress against the Grant objectives.
- 4.2 You agree to provide such information as we reasonably request and make available the Key Personnel for the purposes of the APR.
- 4.3 Following the APR, we will notify of one of the following outcomes:
 - a. the relevant objectives have been met for the Grant;

ATTESTED

Page 4 of 24

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



**CHILDREN'S
INVESTMENT FUND
FOUNDATION**

- b. the relevant objectives have not been met and the amendments set out in the notice are required to the Grant Activities and Budget; or
- c. the relevant objectives have not been met and the Grant will be terminated in accordance with Condition 17.

4.4 You acknowledge and agree that a condition to payment of any tranche of the Grant due after an anniversary of the Start Date will be subject to provision by us of a notice under Condition 4.3a or 4.3b and, in relation to 4.3b, your acceptance of the amendments in the manner set out in Condition 5.2.

5 Amendments

5.1 Save as set out in Condition 5.2, amendments to this Grant Agreement may only be made in writing between the parties.

5.2 In the case of a notification under Condition 4.3b, your continued performance of the related Grant Activities shall constitute your acceptance of and agreement to the amendments set out in the relevant notice and the Grant Agreement will be deemed to be amended on those terms. If you do not agree to the amendments in the notice you must notify us in writing within five London business days, in which case the Grant Agreement will be terminated in accordance with Condition 17.

6 Audit and Financial Administration

6.1 You shall comply, and facilitate our compliance with, all statutory requirements as regards accounts, audit or examination of accounts, annual reports and annual returns, as well as other regulatory requirements or requests applicable to you and us.

6.2 You must accurately account for all income and expenditure relating to the Grant (including any disbursements to or expenditures by Third Parties and interest earned on bank deposits) through separate cost centres. We reserve the right, acting reasonably, to require you to open a separate bank account for the Grant.

6.3 You must allow us, or any firm of accountants retained by us, at our expense and on reasonable notice, to audit your accounts, records, systems and facilities in relation to the Grant and you agree to make available your personnel for that purpose.

6.4 If there are, or you suspect that there are, circumstances or incidents that may affect the financial administration of this Grant, you shall report to us promptly, and in any event, within two London business days of becoming aware of such circumstances or incidents.

6.5 You must keep all invoices, receipts, accounts and other relevant documents relating to the Grant for six years after the end of the Grant Term and provide these to us promptly on request.

7 Evaluation

7.1 You shall permit us or any person authorised by us, on reasonable notice, to visit you and any sites relating to the Grant and to access your employees, agents, any other third parties working on the Grant Activities, records and auditors for the purpose of monitoring and evaluating the Grant Activities. You will use your best endeavours to facilitate such visits.

8 Withholding and Repayment

8.1 Without prejudice to our other remedies under this Grant Agreement, we may withhold or suspend payment of the Grant, or require prompt repayment of all or part of the Grant if:

ATTESTED

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

CIFF CHILDREN'S
INVESTMENT FUND
FOUNDATION

- a. you use the Grant for purposes other than those for which it has been awarded;
- b. delivery of the Grant Activities does not start within three months of the relevant Start Date and you do not provide us with a reasonable explanation for the delay;
- c. we provide you with a notice under Condition 4.3c;
- d. you do not accept amendments to the Grant specified in a notice under Condition 4.3b;
- e. you provide us with any materially misleading or inaccurate information;
- f. you or any of your directors, trustees, employees, representatives or agents takes any actions which, in our reasonable opinion brings or is likely to bring our reputation into disrepute;
- g. you cease to operate for any reason, or pass a resolution (or any court of competent jurisdiction makes an order) that you be wound up or dissolved (other than for the purpose of a bona fide and solvent reconstruction or amalgamation);
- h. you become insolvent, or are declared bankrupt, or are placed into receivership, administration or liquidation, or a petition has been presented for your winding up, or enter into any arrangement or composition for the benefit of your creditors, or are unable to pay your debts as they fall due;
- i. you fail to comply with any of the Conditions set out in this Grant Agreement and you fail to rectify any such failure within 30 days of receiving written notice detailing the failure;
- j. at any time, we are not reasonably satisfied with your progress under this Grant Agreement or we determine that this Grant Agreement ceases to be in line with our charitable objects or any laws applicable to us; or
- k. at any time, there is a change in the tax, charitable or regulatory status applicable to you or the Grant or the Grant Activities.

8.2 You agree that any amount of the Grant that remains unspent at the end of the Grant Term shall be promptly repaid to us (including any interest earned on such amount), save where we notify you in writing that such amounts may be used for another purpose.

9 Equipment and goods

9.1 Any equipment or goods purchased using the Grant must only be used for the Grant Activities, save where we expressly permit otherwise.

9.2 Prior to the end of the Grant Term you will notify us of any equipment or goods which were purchased using the Grant and you agree to comply with our reasonable directions in relation to the further use or disposal of such equipment and goods, including the use of any proceeds.

10 Insurance

10.1 You shall procure and maintain with a reputable insurance company a policy or policies in respect of all risks arising out of your performance of all Grant Activities, including death or personal injury, loss of or damage to property or any other loss.

11 Intellectual Property

11.1 All Intellectual Property Rights owned by either Party before the Start Date or developed by either party in relation to each Grant, shall remain the property of that Party.

11.2 Unless otherwise agreed with us in writing, you agree to comply with our "Transparency Policy, Implementation Guide for Grantees" available on here: <https://ciff.org/about-us/transparency-accountability/> (as the same may be amended from time-to-time) (**Grantee Transparency Guide**).

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka



11.3 You agree to grant us a non-exclusive, world-wide, irrevocable, royalty-free licence, with the right to sub-licence, any Intellectual Property Rights developed by you as part of the Grant Activities which are not made available on open licence in accordance with the Grantee Transparency Guide.

11.4 In this Grant Agreement, "**Intellectual Property Rights**" means all patents, copyrights and design rights (whether registered or not) and all applications for any of the foregoing and all rights of confidence and know-how however arising for their full term and any renewals or extensions.

12 Publication and Publicity

12.1 You must not at any time refer to or make use of our name, logo or brand without our prior written consent save that any written or spoken public presentation made by you in relation to the Grant shall acknowledge the provision of the Grant.

12.2 You acknowledge that we may, at our discretion, make the provision of the Grant and the Grant Activities public in accordance with our "Transparency Policy" available here: https://ciff.org/about-us/transparency_accountability/ (as amended from time-to-time).

12.3 You agree to notify us immediately if you become aware of anything related to the Grant or otherwise that may have an adverse reputational impact on you or us.

13 Confidentiality

13.1 No Party shall disclose any Confidential Information (as defined below) to any person other than those employees, officers, trustees, corporate members, representatives, or advisors who need to know such information in connection with the Grant.

13.2 The Parties to this Agreement shall not use such Confidential Information except as reasonably required in relation to the Grant.

13.3 The Parties must ensure that any person to whom any Confidential Information is disclosed complies with the restrictions contained in this condition as if such person were a party to this Grant Agreement.


13.4 Notwithstanding the other provisions of this condition, the Parties may disclose Confidential Information to the extent required by law, by any governmental or other regulatory authority or by a court or other authority of competent jurisdiction or arbitration.

13.5 For the purposes of this Agreement, Confidential Information means any information that is provided by one Party to the other in connection with the Grant which relates to the business, affairs, finances, properties, assets, trading practices, developments, personnel, personal data, trade secrets, intellectual property rights (including business and brand names, domain names, devices and logos) and know-how of either Party, save where such information is already in the public domain or becomes public or otherwise comes into the possession of the receiving Party, other than as a result of a breach of confidentiality.

14 Data Protection

14.1 Both Parties will comply with all applicable requirements of and all their obligations under the Data Protection Legislation which arise in connection with the Agreement.

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

CIFE
**CHILDREN'S
INVESTMENT FUND
FOUNDATION**

14.2 Each Party will promptly notify the other party of any actual or potential breach of the Data Protection Legislation.

14.3 In this Grant Agreement, "**Data Protection Legislation**" means all applicable data protection legislation and privacy legislation in force from time-to-time in the UK including the General Data Protection Regulation ((EU) 2016/679); the Data Protection Act 2018; the Privacy and Electronic Communications Directive 2002/58/EC (as updated by Directive 2009/136/EC) and the Privacy and Electronic Communications Regulations 2003 (SI 2003/2426); any other directly applicable European Union regulation relating to privacy; and all other legislation and regulatory requirements in force from time-to-time which apply to a Party relating to the use of Personal Data and the privacy of electronic communications.

15 Safeguarding and Child Protection

15.1 You confirm that you will comply with our Safeguarding and Child Protection requirements set out in Annex 6 and save only as expressly agreed otherwise, you must have in place a safeguarding and child protection policy acceptable to us prior to the Grant being paid to you.

15.2 At any time during the term of this Grant Agreement we may require you to update your safeguarding and child protection policy if we deem it necessary in our sole discretion in connection with the Grant.

15.3 You shall ensure that all Third Parties have their own safeguarding policy prior to making any payments to them using the Grant.

15.4 You shall notify us promptly of becoming aware of any concerns, disclosures or allegations relating to safeguarding or child protection and provide us with all information and assistance we may require in relation to the same.

15.5 You agree that we may at any time carry out a review or independent audit of your safeguarding and child protection policies and procedures and you will ensure that either we or any relevant auditor we appoint have access to all relevant information, personnel and assistance in this regard.

16 Liability

16.1 We do not accept any liability for any consequences (whether direct or indirect) that may arise out of this Grant Agreement, the use of the Grant or from withdrawal of the Grant.

16.2 Our sole liability under this Grant Agreement is limited to payment of the Grant.

17 Term and Termination

17.1 This Grant Agreement shall commence on the Effective Date and may be terminated by either party at any time on one month's written notice.

17.2 The Grant Agreement may be terminated by us if:

- a. you do not accept amendments notified to you in accordance with Condition 4.3b;
- b. we notify you that the Grant objectives are not being met in accordance with Condition 4.3c;
or
- c. we request repayment of the Grant for any other reason in accordance with Condition 8.1.

ATTESTED

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka



**CHILDREN'S
INVESTMENT FUND
FOUNDATION**

17.3 If we require repayment of the Grant or terminate the Grant prior to its End Date, we will consider your reasonable requests for reimbursement of expenses incurred prior to the relevant termination date. Any request will be determined in our sole discretion.

18 Survival

A Party's obligations under this Grant Agreement will be continuous and survive expiration or termination of this Grant Agreement save as expressly provided or otherwise required by law or intended by their nature.

19 Notices and Approvals

Written notices, requests and approvals under this Grant Agreement shall be delivered in writing to one of your Key Personnel or the CIFF Key Contact (as the case may be) or to any other person as notified to the other Party from time-to-time.

20 No assignment

Save as otherwise permitted by this Grant Agreement in respect of sub-contracting to approved Third Parties, you may not assign, transfer or sub-contract any of your rights or obligations under this Grant Agreement.

21 Relationship

This Grant Agreement shall not create any legal partnership or joint venture between us, nor any relationships of employment, principal and agent, nor authorise you to make or enter into any commitments for or on our behalf.

22 Counterparts

This Grant Agreement may be signed in counterparts each of which will be deemed an original and both of which, when taken together, will constitute one agreement.

23 Contracts (Rights of Third Parties) Act 1999

This Grant Agreement does not and is not intended to confer any contractual benefit on any person pursuant to the terms of the Contracts (Rights of Third Parties) Act 1999.

24 Governing law and jurisdiction

This Grant Agreement and any dispute or claim arising out of or in connection with it shall be governed by and construed in accordance with the law of England and Wales. The Parties irrevocably agree that the courts of England and Wales shall have non-exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this Agreement.

25 Entire Agreement

This Grant Agreement constitutes the entire agreement between the Parties and supersedes and extinguishes all previous agreements, promises, assurances, warranties, representations and understandings between them, whether written or oral, relating to its subject matter.

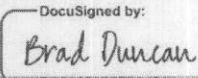
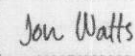
This Grant Agreement will become effective as of the date of the last signature below (**Effective Date**).

ATTESTED

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

CIF CHILDREN'S
INVESTMENT FUND
FOUNDATION

THE CHILDREN'S INVESTMENT FUND FOUNDATION (UK)		THOMAS JEFFERSON UNIVERSITY	
Signature 1: 	DocuSigned by: Brad Duncan	Signature: Margaret Burwell	Digitally signed by Margaret Burwell DN: cn=Margaret Burwell, o=Thomas Jefferson University, ou=Office of Research Administration, email=margaret.burwell@jefferson.edu, c=US Date: 2020.09.13 20:59:10 -04'00'
Name: Brad Duncan	Date: 04-09-2020	Name: Margaret Burwell	Date: 9/13/2020
Title: General Counsel		Title: Associate Director, Pre-Award	
Signature 2: 	DocuSigned by: Jon Watts		
Name: Jon Watts	Date: 04-09-2020		
Title: CFO			

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

BT/IN/DBT-MRC/DFID/SSG/16/2018-19

Government of India
Ministry of Science & Technology
Department of Biotechnology

Block 2, 7th Floor
CGO Complex, Lodhi Road
New Delhi 110 003
Dated: 09.05.2019

Admin Order

Sanction of the President is hereby accorded under Rule 18 of the Delegation of Financial Power Rules, 1978 for the implementation of the UK-India Global Research Partnership (GRP) joint research project titled "**CRADLE-4: Can Reduction of Adverse pregnancy outcomes occur with planned DeDelivery vs. Expectant management in pre-eclampsia?**" by **Dr. Shivaprasad S Goudar**, KLE Academy of Higher Education and Research, JN Medical College, Belgaum-590 010, Karnataka for a period of **3 years** at a total cost of **Rs.168.80 Lakhs (Rupees One Crore Sixty Eight Lakhs Eighty Thousand Only)** for the Indian component of the project on the terms and conditions as detailed hereunder:

2.0 PROJECT TITLE :

"CRADLE-4: Can Reduction of Adverse pregnancy outcomes occur with planned DeDelivery vs. Expectant management in pre-eclampsia?"

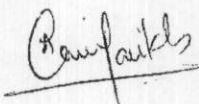
2.1 Investigators :

Indian Investigators:

Principal Investigator	Dr. Shivaprasad S Goudar , KLE Academy of Higher Education and Research, JN Medical College, Belgaum-590 010, Karnataka
Co-Principal Investigators	Dr. Mrutyunjaya Bellad , JN Medical College, KLE Academy of Higher Education and Research, Belgaum-590 010, Karnataka
	Dr. Mrityunjay Metgud , JN Medical College, KLE Academy of Higher Education and Research, Belgaum-590 010, Karnataka
	Dr. Sangappa Dhaded , JN Medical College, KLE Academy of Higher Education and Research, Belgaum-590 010, Karnataka
	Dr. Manjunath Somannavar , JN Medical College, KLE Academy of Higher Education and Research, Belgaum-590 010, Karnataka
	Dr. Umesh Charantimath , JN Medical College, KLE Academy of Higher Education and Research, Belgaum-590 010, Karnataka

UK Investigator:

Principal Investigator	Professor Andrew Shennan , Women's Health, King's College London
Co-Principal Investigators	Prof. Lucy Chappell , Women's Health, King's College London
	Prof. Jane Sandall , Women's Health, King's College London
	Mr. Paul Seed , Women's Health, King's College London
LIC PI:	Prof. Bellington Vwalika , MRC/UVRI Unit, Uganda



ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

2.2 Project Aims & Objectives:

- i) To determine whether in low and middle income country populations (LMIC) planned early delivery for women with pre-eclampsia after 34 weeks of gestation will reduce a composite outcome of maternal morbidity and mortality without increasing adverse neonatal outcomes compared to current practice.
- ii) To determine the impact to the intervention on short-term perinatal outcomes including adverse events related to planned delivery (e.g. increased NNU admission from RDS) and expectant management (e.g. stillbirths and NNU admissions related to growth restriction/asphyxia).
- iii) The impact of the intervention on other secondary short-term outcomes for the mother will also be determined such as the number of women that are referred to hospital for delivery, the length of hospital stay and the mode of delivery.
- iv) To determine how the intervention is influenced by context including political and cultural environment in each setting and explore the experiences of women and their families. The development work in Phase 1 will identify potential barriers to the intervention in each context and potential solutions.

2.3 Project Duration:

The duration of the project is **three years** from the date of this Admin order.

2.4 Project Cost:

The estimated cost for the Indian component of the project for three years is as under:

		(Rs. in Lakhs)			
S. No.	Head	Year I	Year II	Year III	Total
A.	Non-recurring				
1.	Equipment Desktop (Nos. 2)	1.50	0.00	0.00	1.50
	Total (A)	1.50	0.00	0.00	1.50
B.	Recurring				
1.	Consumables	1.15	0.35	0.35	1.85
2.	Manpower				
a.	Project Administrator (Sr. RS) - Consultant (Administration) and Consultant (Finance & Accounts) @ Rs. 60,000/- fixed per month	5.40	7.20	5.40	18.00
b.	Data Coordinator (RO)- Consultant (Scientific Technical/Medical/Non Medical) @ Rs. 1,00,000/- fixed per month (will work only 15% in the month)	1.35	1.80	1.35	4.50
c.	Data Manager & Network Manager- Consultant (Scientific technical/Medical/Non Medical) @ Rs. 1,00,000/- fixed per month (will work only 20% in the month)	1.80	2.40	1.80	6.00

Rampal

ATTESTED

k
Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

d.	Data Entry Operator – Grade C @ Rs. 31000/- fixed per month	2.79	3.72	2.79	9.30
e.	Field Monitoring (LHV) – Junior Medical Officer (2 Nos.) @ Rs. 60000/- in the 1 st and 2 nd year and Rs. 75000/- in the 3 rd year (will work only 50% in the month)	5.40	7.20	6.75	19.35
f.	Training Coordinator (Sr. SN) - Consultant (Administration) and Consultant (Finance & Accounts) @ Rs. 1,00,000/- fixed per month (will work only 20% in the month)	1.80	2.40	1.80	6.00
g.	Officer Secretary (LDC) – Data Entry Operator – Grade C @ Rs. 31000/- fixed per month	2.79	3.72	2.79	9.30
h.	Budget Manager - Consultant (Administration) and Consultant (Finance & Accounts) @ Rs. 60000/- fixed per month (will work only 15% in the month)	0.81	1.08	0.81	2.70
i.	Field Assistant - Data Entry Operator – Grade C (4 Nos.) @ Rs. 31000/- fixed per month	11.16	14.88	11.16	37.20
Total Manpower		33.30	44.40	34.65	112.35
3.	Travel				
	Domestic	3.35	3.10	1.80	8.25
	International	2.50	4.00	3.50	10.00
	Local Hospitality for visiting Scientist	1.00	1.00	1.00	3.00
	Total	6.85	8.10	6.30	21.25
4.	Contingency	0.25	0.25	0.25	0.75
5.	Overhead	2.00	2.00	2.00	6.00
6.	Other Expenses	3.10	5.90	3.10	12.10
7.	Training & FGD & Expenditure	9.00	2.00	2.00	13.00
Total (B) (1+2+3+4+5+6+7)		55.65	63.00	48.65	167.30
Total (A+B)		57.15	63.00	48.65	168.80

3. HEAD OF ACCOUNT:

Non-Recurring expenditure involved is debitable to:

Demand No.85	:	Department of Biotechnology
3425	:	Other Scientific Research (Major Head)
60	:	Others (Sub Major Head)
60.200	:	Assistance to other scientific bodies
60.200.29	:	Biotechnology Research and Development
60.200.29.17	:	Assistance For Research and Development
60.200.29.17.35	:	Grant for creation of capital assets 2019-20

Recurring expenditure involved is debitable to:

Demand No.85	:	Department of Biotechnology
3425	:	Other Scientific Research (Major Head)
60	:	Others (Sub Major Head)
60.200	:	Assistance to other scientific bodies
60.200.29	:	Biotechnology Research and Development
60.200.29.17	:	Assistance For Research and Development
60.200.29.17.31	:	Grant in aid General 2019-20

Ramfawls

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Submission of formal agreement with DBT:

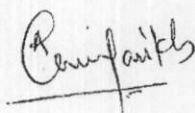
4. A Memorandum of Agreement (MoA) will be signed between the Department of Biotechnology and the grantee organization(s) on Non-Judicial stamp paper Rs. 100/- in the enclosed format and the second release/ installment will be made only after signing of MoA by the grantee organization(s) and its acceptance by DBT. In case of NGO or Private organization(s), signed MoA is mandatory before the first release. Format of the MoA alongwith annexures (as mentioned below) to be submitted with MoA is enclosed here with:
- Detailed project activities to be placed at **Annexure I**
 - Details of funds to be placed at **Annexure-II**
 - The other terms and conditions governing this sanction to be placed at **Annexure- III**

Conditions for submission of UC/SE and Progress Report:


5. (a) The grantee organization(s) will maintain separate bank account for the project and the entire amount of grant will be kept in an interest bearing account. The interest so earned should be reported to DBT in the Utilization Certificate and Statement of Expenditure. The Interest so earned will be treated as created to the organization(s) and shall be adjusted towards further installment of the grant and or at the time of Final Settlement of Accounts.
- (b) The Registrar, KLE Academy of Higher Education and Research, Belagavi would be responsible for submission of financial year wise Statements of Expenditure (SoE), Utilization Certificate (UC), Assets Acquired Certificate, Manpower Due Drawn Statement in prescribed DBT formats to DBT in respect of grants released in this project from time to time.
- (c) While submitting Utilization Certificate and Statement of Expenditure, the organization has to ensure submission of supporting documentary evidences with regard to purchase of equipment/capital assets and manpower certificate with qualification (including details of national level qualifying exam) details. Subsequent release of grants under the project shall be considered only on receipt of the said documents.
- (d) The grantee organization(s) shall submit up to date progress report at the end of each financial year in the proforma prescribed by DBT, and as and when required by DBT.

Conditions for acquiring Assets (Non-recurring grant):

6. (a) A transparent procurement procedure in line with the provisions of General Financial Rules 2017 will be followed by the organization(s) under the appropriate rules of the grantee organization(s) while procuring capital assets sanctioned for the above mentioned project and a certificate to this effect will be submitted by the Grantee organization(s) immediately on receipt of the grant.
- (b) DBT reserves sole rights on the assets created out of grants, Assets acquired wholly or substantially out of government grants (except those declared as obsolete and unserviceable or condemned in accordance with the procedure laid down in GFR 2017), shall not be disposed of without obtaining the prior approval of DBT.
- (c) The equipment/instrument shall have to be purchased within **nine (9) months** from the date of release of the capital grant. Fresh permission shall have to be sought from DBT in the event the organization fails to purchase the equipment/instrument within the prescribed period of **nine (9) months** from the date of release of sanctioned amount.



ATTESTED


Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Conditions of Domestic/International Travel:

7. (a) No International Travel will be undertaken from the sanctioned project grant for the purpose other than the specified in the project.
- (b) As per MoF instructions, it has been decided that in all cases of air travel both domestic and international, where the Government of India bears the cost of air passage, the investigator/research staff concerned may travel only by Air India. For travel to stations not connected by Air India, the investigator/research staff may travel by Air India to the Hub/Point closest to their eventual destination, beyond which they may utilize the services of another airline which should also preferably be an alliance partner of Air India. The tickets are to be booked in terms of guidelines issued under DoE OM. No. 19024/22/2017-EIV dated 19th July, 2017.

Other conditions:

8. PI's of DBT sponsored projects can consider appointment of manpower as per the Department of Science and Technology's O.M. No. SR/S9/Z-08/2018 dated 30.01.2019. In case investigator(s) inclined to explore provisions other than the stipulated herewith (i.e. institutional norms, ICMR norms, ICAR norms etc), prior approval from DBT shall be obtained in writing before appointment of manpower.
9. The data sharing among the partnering and any other organization needs to be accomplished without compromising on the national integrity, security business opportunities and IPR norm.
10. It is mandatory to acknowledge financial support provided by DBT via inclusion of Reference/Grant number, Name of the Department (i.e. DBT) and the duration of the financial support including the dates in acknowledgement section of publications/patents/technology transfer documents vide notification no. DBT/PCAH/Gen/01 dated 7th June 2012.
11. It is obligatory to assess/observe the biosafety compliance for rDNA activities to be performed by institutions and investigators for the proposals submitted to DBT for financial support as per the notification vide no. BT/BS/17/459/2011-PID dated 26th September 2012.
12. As per Rule 236(1) of GFR 2017, Audit of accounts- The account of Grantee Institutions or Organizations shall be open to inspection by the sanctioning authority and audit, both by the Comptroller and Auditor General of India under the provision of CAG(DPC) Act 1971 and internal audit by the Principal Account Office of the Ministry or Department, whenever the institution or Organization is called upon to do so.
13. In case the whole or a part of the amount of the grant-in-aid is being refunded, as an interest at the rate of ten per cent per annum thereon shall be recovered.
14. UC/SE must show all the heads as per the sanction order.
15. As per Ministry of Finance OM. No. C-13015(34)/MF CGA/PFMS/Misc/2014-15/2095-2127 dated 03.03.2015 all transaction involving cash component has to be made through Public Financial Management System (PFMS) w.e. 01.04.2015 to each beneficiaries.
16. Failure to comply with the terms and conditions of this sanction order will entail full refund with interest in terms of Rule 231 (2) of GFR 2017.

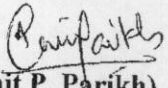
Sanjay

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

17. This issues under the powers delegated to this Department and with the concurrence of IFD vide their Dy. No. 102/IFD/SAN/338/2019-2020 dated 07.05.2019.
18. This sanction order has been noted at Serial No. 04 in the Register of Grants maintained in division.

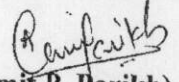

(Amit P. Parikh)
Scientist 'E'

To,

The Pay & Accounts Officer,
Department of Biotechnology,
New Delhi – 110 003

Copy to:

1. The Principal Director of Audit (Scientific Departments), IP Estate, AGCR Building, New Delhi-110002
2. Cash Section, DBT (2 copies)
3. IFD, DBT
4. The Registrar, KLE Academy of Higher Education and Research, Belagavi, Karnataka
5. Dr. Shivaprasad S Goudar, KLE Academy of Higher Education and Research, JN Medical College, Belgaum-590 010, Karnataka
6. Dr. Mrutyunjaya Bellad, JN Medical College, KLE Academy of Higher Education and Research, Belgaum-590 010, Karnataka
7. Dr. Mrityunjay Metgud, JN Medical College, KLE Academy of Higher Education and Research, Belgaum-590 010, Karnataka
8. Dr. Sangappa Dhaded, JN Medical College, KLE Academy of Higher Education and Research, Belgaum-590 010, Karnataka
9. Dr. Manjunath Somannavar, JN Medical College, KLE Academy of Higher Education and Research, Belgaum-590 010, Karnataka
10. Dr. Umesh Charantimath, JN Medical College, KLE Academy of Higher Education and Research, Belgaum-590 010, Karnataka
11. Sanction Folder


(Amit P. Parikh)
Scientist 'E'

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

BT/IN/DBT-MRC/DFID/SSG/16/2018-19

Government of India
Ministry of Science & Technology
Department of Biotechnology

Block 2, 7th Floor
CGO Complex, Lodhi Road
New Delhi 110 003
Dated: 09.05.2019

Admin Order

Sanction of the President is hereby accorded under Rule 18 of the Delegation of Financial Power Rules, 1978 for the implementation of the UK-India Global Research Partnership (GRP) joint research project titled "**CRADLE-4: Can Reduction of Adverse pregnancy outcomes occur with planned DeDelivery vs. Expectant management in pre-eclampsia?**" by **Dr. Shivaprasad S Goudar**, KLE Academy of Higher Education and Research, JN Medical College, Belgaum-590 010, Karnataka for a period of **3 years** at a total cost of **Rs.168.80 Lakhs (Rupees One Crore Sixty Eight Lakhs Eighty Thousand Only)** for the Indian component of the project on the terms and conditions as detailed hereunder:

2.0 PROJECT TITLE :

"CRADLE-4: Can Reduction of Adverse pregnancy outcomes occur with planned DeDelivery vs. Expectant management in pre-eclampsia?"

2.1 Investigators :

Indian Investigators:

Principal Investigator	Dr. Shivaprasad S Goudar , KLE Academy of Higher Education and Research, JN Medical College, Belgaum-590 010, Karnataka
Co-Principal Investigators	Dr. Mrutyunjaya Bellad , JN Medical College, KLE Academy of Higher Education and Research, Belgaum-590 010, Karnataka
	Dr. Mrityunjay Metgud , JN Medical College, KLE Academy of Higher Education and Research, Belgaum-590 010, Karnataka
	Dr. Sangappa Dhaded , JN Medical College, KLE Academy of Higher Education and Research, Belgaum-590 010, Karnataka
	Dr. Manjunath Somannavar , JN Medical College, KLE Academy of Higher Education and Research, Belgaum-590 010, Karnataka
	Dr. Umesh Charantimath , JN Medical College, KLE Academy of Higher Education and Research, Belgaum-590 010, Karnataka

UK Investigator:

Principal Investigator	Professor Andrew Shennan , Women's Health, King's College London
Co-Principal Investigators	Prof. Lucy Chappell , Women's Health, King's College London
	Prof. Jane Sandall , Women's Health, King's College London
	Mr. Paul Seed , Women's Health, King's College London
LIC PI:	Prof. Bellington Vwalika , MRC/UVRI Unit, Uganda

Rawfauks

ATTESTED

[Signature]
Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

2.2 Project Aims & Objectives:

- i) To determine whether in low and middle income country populations (LMIC) planned early delivery for women with pre-eclampsia after 34 weeks of gestation will reduce a composite outcome of maternal morbidity and mortality without increasing adverse neonatal outcomes compared to current practice.
- ii) To determine the impact to the intervention on short-term perinatal outcomes including adverse events related to planned delivery (e.g. increased NNU admission from RDS) and expectant management (e.g. stillbirths and NNU admissions related to growth restriction/asphyxia).
- iii) The impact of the intervention on other secondary short-term outcomes for the mother will also be determined such as the number of women that are referred to hospital for delivery, the length of hospital stay and the mode of delivery.
- iv) To determine how the intervention is influenced by context including political and cultural environment in each setting and explore the experiences of women and their families. The development work in Phase 1 will identify potential barriers to the intervention in each context and potential solutions.

2.3 Project Duration:

The duration of the project is **three years** from the date of this Admin order.

2.4 Project Cost:

The estimated cost for the Indian component of the project for three years is as under:

		(Rs. in Lakhs)			
S. No.	Head	Year I	Year II	Year III	Total
A.	Non-recurring				
1.	Equipment Desktop (Nos. 2)	1.50	0.00	0.00	1.50
	Total (A)	1.50	0.00	0.00	1.50
B.	Recurring				
1.	Consumables	1.15	0.35	0.35	1.85
2.	Manpower				
a.	Project Administrator (Sr. RS) - Consultant (Administration) and Consultant (Finance & Accounts) @ Rs. 60,000/- fixed per month	5.40	7.20	5.40	18.00
b.	Data Coordinator (RO)- Consultant (Scientific Technical/Medical/Non Medical) @ Rs. 1,00,000/- fixed per month (will work only 15% in the month)	1.35	1.80	1.35	4.50
c.	Data Manager & Network Manager- Consultant (Scientific technical/Medical/Non Medical) @ Rs. 1,00,000/- fixed per month (will work only 20% in the month)	1.80	2.40	1.80	6.00

Camfakh

ATTESTED

k
Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

d.	Data Entry Operator – Grade C @ Rs. 31000/- fixed per month	2.79	3.72	2.79	9.30
e.	Field Monitoring (LHV) – Junior Medical Officer (2 Nos.) @ Rs. 60000/- in the 1 st and 2 nd year and Rs. 75000/- in the 3 rd year (will work only 50% in the month)	5.40	7.20	6.75	19.35
f.	Training Coordinator (Sr. SN) - Consultant (Administration) and Consultant (Finance & Accounts) @ Rs. 1,00,000/- fixed per month (will work only 20% in the month)	1.80	2.40	1.80	6.00
g.	Officer Secretary (LDC) – Data Entry Operator – Grade C @ Rs. 31000/- fixed per month	2.79	3.72	2.79	9.30
h.	Budget Manager - Consultant (Administration) and Consultant (Finance & Accounts) @ Rs. 60000/- fixed per month (will work only 15% in the month)	0.81	1.08	0.81	2.70
i.	Field Assistant - Data Entry Operator – Grade C (4 Nos.) @ Rs. 31000/- fixed per month	11.16	14.88	11.16	37.20
Total Manpower		33.30	44.40	34.65	112.35
3.	Travel				
	Domestic	3.35	3.10	1.80	8.25
	International	2.50	4.00	3.50	10.00
	Local Hospitality for visiting Scientist	1.00	1.00	1.00	3.00
	Total	6.85	8.10	6.30	21.25
4.	Contingency	0.25	0.25	0.25	0.75
5.	Overhead	2.00	2.00	2.00	6.00
6.	Other Expenses	3.10	5.90	3.10	12.10
7.	Training & FGD & Expenditure	9.00	2.00	2.00	13.00
Total (B) (1+2+3+4+5+6+7)		55.65	63.00	48.65	167.30
Total (A+B)		57.15	63.00	48.65	168.80

3. HEAD OF ACCOUNT:

Non-Recurring expenditure involved is debit to:

Demand No.85	:	Department of Biotechnology
3425	:	Other Scientific Research (Major Head)
60	:	Others (Sub Major Head)
60.200	:	Assistance to other scientific bodies
60.200.29	:	Biotechnology Research and Development
60.200.29.17	:	Assistance For Research and Development
60.200.29.17.35	:	Grant for creation of capital assets 2019-20

Recurring expenditure involved is debit to:

Demand No.85	:	Department of Biotechnology
3425	:	Other Scientific Research (Major Head)
60	:	Others (Sub Major Head)
60.200	:	Assistance to other scientific bodies
60.200.29	:	Biotechnology Research and Development
60.200.29.17	:	Assistance For Research and Development
60.200.29.17.31	:	Grant in aid General 2019-20

Ramfath

ATTESTED

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

Submission of formal agreement with DBT:

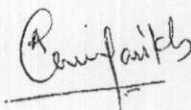
4. A Memorandum of Agreement (MoA) will be signed between the Department of Biotechnology and the grantee organization(s) on Non-Judicial stamp paper Rs. 100/- in the enclosed format and the second release/ installment will be made only after signing of MoA by the grantee organization(s) and its acceptance by DBT. In case of NGO or Private organization(s), signed MoA is mandatory before the first release. Format of the MoA alongwith annexures (as mentioned below) to be submitted with MoA is enclosed here with:
- Detailed project activities to be placed at **Annexure I**
 - Details of funds to be placed at **Annexure-II**
 - The other terms and conditions governing this sanction to be placed at **Annexure- III**

Conditions for submission of UC/SE and Progress Report:


5. (a) The grantee organization(s) will maintain separate bank account for the project and the entire amount of grant will be kept in an interest bearing account. The interest so earned should be reported to DBT in the Utilization Certificate and Statement of Expenditure. The Interest so earned will be treated as created to the organization(s) and shall be adjusted towards further installment of the grant and or at the time of Final Settlement of Accounts.
- (b) The Registrar, KLE Academy of Higher Education and Research, Belagavi would be responsible for submission of financial year wise Statements of Expenditure (SoE), Utilization Certificate (UC), Assets Acquired Certificate, Manpower Due Drawn Statement in prescribed DBT formats to DBT in respect of grants released in this project from time to time.
- (c) While submitting Utilization Certificate and Statement of Expenditure, the organization has to ensure submission of supporting documentary evidences with regard to purchase of equipment/capital assets and manpower certificate with qualification (including details of national level qualifying exam) details. Subsequent release of grants under the project shall be considered only on receipt of the said documents.
- (d) The grantee organization(s) shall submit up to date progress report at the end of each financial year in the proforma prescribed by DBT, and as and when required by DBT.

Conditions for acquiring Assets (Non-recurring grant):

6. (a) A transparent procurement procedure in line with the provisions of General Financial Rules 2017 will be followed by the organization(s) under the appropriate rules of the grantee organization(s) while procuring capital assets sanctioned for the above mentioned project and a certificate to this effect will be submitted by the Grantee organization(s) immediately on receipt of the grant.
- (b) DBT reserves sole rights on the assets created out of grants, Assets acquired wholly or substantially out of government grants (except those declared as obsolete and unserviceable or condemned in accordance with the procedure laid down in GFR 2017), shall not be disposed of without obtaining the prior approval of DBT.
- (c) The equipment/instrument shall have to be purchased within **nine (9) months** from the date of release of the capital grant. Fresh permission shall have to be sought from DBT in the event the organization fails to purchase the equipment/instrument within the prescribed period of **nine (9) months** from the date of release of sanctioned amount.



ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Conditions of Domestic/International Travel:

7. (a) No International Travel will be undertaken from the sanctioned project grant for the purpose other than the specified in the project.
- (b) As per MoF instructions, it has been decided that in all cases of air travel both domestic and international, where the Government of India bears the cost of air passage, the investigator/research staff concerned may travel only by Air India. For travel to stations not connected by Air India, the investigator/research staff may travel by Air India to the Hub/Point closest to their eventual destination, beyond which they may utilize the services of another airline which should also preferably be an alliance partner of Air India. The tickets are to be booked in terms of guidelines issued under DoE OM. No. 19024/22/2017-EIV dated 19th July, 2017.

Other conditions:

8. PI's of DBT sponsored projects can consider appointment of manpower as per the Department of Science and Technology's O.M. No. SR/S9/Z-08/2018 dated 30.01.2019. In case investigator(s) inclined to explore provisions other than the stipulated herewith (i.e. institutional norms, ICMR norms, ICAR norms etc), prior approval from DBT shall be obtained in writing before appointment of manpower.
9. The data sharing among the partnering and any other organization needs to be accomplished without compromising on the national integrity, security business opportunities and IPR norm.
10. It is mandatory to acknowledge financial support provided by DBT via inclusion of Reference/Grant number, Name of the Department (i.e. DBT) and the duration of the financial support including the dates in acknowledgement section of publications/patents/technology transfer documents vide notification no. DBT/PCAH/Gen/01 dated 7th June 2012.
11. It is obligatory to assess/observe the biosafety compliance for rDNA activities to be performed by institutions and investigators for the proposals submitted to DBT for financial support as per the notification vide no. BT/BS/17/459/2011-PID dated 26th September 2012.
12. As per Rule 236(1) of GFR 2017, Audit of accounts- The account of Grantee Institutions or Organizations shall be open to inspection by the sanctioning authority and audit, both by the Comptroller and Auditor General of India under the provision of CAG(DPC) Act 1971 and internal audit by the Principal Account Office of the Ministry or Department, whenever the institution or Organization is called upon to do so.
13. In case the whole or a part of the amount of the grant-in-aid is being refunded, as an interest at the rate of ten per cent per annum thereon shall be recovered.
14. UC/SE must show all the heads as per the sanction order.
15. As per Ministry of Finance OM. No. C-13015(34)/MF CGA/PFMS/Misc/2014-15/2095-2127 dated 03.03.2015 all transaction involving cash component has to be made through Public Financial Management System (PFMS) w.e. 01.04.2015 to each beneficiaries.
16. Failure to comply with the terms and conditions of this sanction order will entail full refund with interest in terms of Rule 231 (2) of GFR 2017.

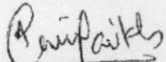
Ramfaith

ATTESTED

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

17. This issues under the powers delegated to this Department and with the concurrence of IFD vide their Dy. No. 102/IFD/SAN/338/2019-2020 dated 07.05.2019.
18. This sanction order has been noted at Serial No. 04 in the Register of Grants maintained in division.

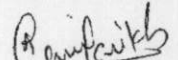

(Amit P. Parikh)
Scientist 'E'

To,


The Pay & Accounts Officer,
Department of Biotechnology,
New Delhi – 110 003

Copy to:

1. The Principal Director of Audit (Scientific Departments), IP Estate, AGCR Building, New Delhi-110002
2. Cash Section, DBT (2 copies)
3. IFD, DBT
4. The Registrar, KLE Academy of Higher Education and Research, Belagavi, Karnataka
5. Dr. Shivaprasad S Goudar, KLE Academy of Higher Education and Research, JN Medical College, Belgaum-590 010, Karnataka
6. Dr. Mrutyunjaya Bellad, JN Medical College, KLE Academy of Higher Education and Research, Belgaum-590 010, Karnataka
7. Dr. Mrityunjay Metgud, JN Medical College, KLE Academy of Higher Education and Research, Belgaum-590 010, Karnataka
8. Dr. Sangappa Dhaded, JN Medical College, KLE Academy of Higher Education and Research, Belgaum-590 010, Karnataka
9. Dr. Manjunath Somannavar, JN Medical College, KLE Academy of Higher Education and Research, Belgaum-590 010, Karnataka
10. Dr. Umesh Charantimath, JN Medical College, KLE Academy of Higher Education and Research, Belgaum-590 010, Karnataka
11. Sanction Folder


(Amit P. Parikh)
Scientist 'E'

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

**FDP Research Subaward Agreement
Amendment (Number 1)**

Pass-Through Entity (PTE)

Subrecipient

Thomas Jefferson University	Entity Name	Jawaharlal Nehru Medical College, KLE
125 S 9th St, 2nd Floor Sheridan, Philadelphia, PA 19107	Email Address	sgoudar@jnmc.edu, sgoudar@jnmc.edu
Richard Derman	Principal Investigator	Shivaprasad Goudar

Project Title: Breastfeeding Education Support Tool for Baby (BEST4Baby)

PTE Federal Award No: 5R21TW010609-2	Federal Awarding Agency: National Institutes of Health (NIH)
---	---

Subaward Period of Performance:		Amount Funded This Action:	Subaward No:
Start Date: Dec 9, 2017	End Date: Nov 30, 2019	\$ 46,910.00	080-70000-S28101
Effective Date of Amendment: Dec 1, 2018	Total Amount of Federal Funds Obligated to Date: \$ 102,098.00	Subject to FFATA: <input checked="" type="radio"/> Yes <input type="radio"/> No	Automatic Carryover: <input checked="" type="radio"/> Yes <input type="radio"/> No

Amendment(s) to Original Terms and Conditions
This Amendment revises the above-referenced Research Subaward Agreement as follows:

ACTION:

To increase the funding by \$46,910. Total authorized amount is \$102,098.

To extend the end date of the period of performance from November 30, 2018 to November 30, 2019.

For clarity all amounts stated in this amendment are in United States Dollars.

All other terms and conditions of this Subaward Agreement remain in full force and effect.

By an Authorized Official of PTE: Name: Timothy Schailey Title: Director, Office of Research Administration Date: 2/13/19	By an Authorized Official of Subrecipient: Name: Dr N.S Mahantashetti Title: Principal, J N Medical College, Belagavi, India Date: Feb 9, 2019
--	---

ATTESTED
Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Attachment 1

Notice of Award

Federal Award Date: 11/21/2018



EXPLORATORY/DEVELOPMENT GRANT
Department of Health and Human Services
National Institutes of Health



FOGARTY INTERNATIONAL CENTER

Grant Number: 5R21TW010609-02
FAIN: R21TW010609

Principal Investigator(s):
RICHARD J DERMAN, MD

Project Title: Breastfeeding Education Support Tool for Baby (BEST4Baby)

Ms. Johnston, Jeanmarie
Thomas Jefferson University
Office Of Research Admin
125 South 9th Street
Sheridan Bldg., 2nd Floor
Philadelphia, PA 191075125

Award e-mailed to: resadmin@jefferson.edu

Period Of Performance:
Budget Period: 12/01/2018 – 11/30/2019
Project Period: 12/09/2017 – 11/30/2019

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$170,503 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to THOMAS JEFFERSON UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Fogarty International Center of the National Institutes of Health under Award Number R21TW010609. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website <http://grants.nih.gov/grants/policy/coi/> for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

ATTESTED

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

FDP Cost Reimbursement Research Subaward Agreement

Pass-through Entity (PTE): Thomas Jefferson University Subrecipient: Jawaharlal Nehru Medical College, KLE

PTE Principal Investigator (PI): Richard Derman, M.D. Subrecipient Principal Investigator (PI): Dr. Shivaprasad S. Goudar

PTE Federal Award No: 1R21TW010609-01 FAIN: R21TW010609 Federal Awarding Agency: NIH

Federal Award Issue Date: Dec 11, 2017 Total Amount of Federal Award to PTE: \$ 199,846.00 CFDA No: 93.989 CFDA Title: International Research and Research Training

Project Title: Breastfeeding Education Support Tool for Baby (BEST4Baby)


Subaward Period of Performance: Start: Dec 9, 2017 End: Nov 30, 2018 Amount Funded This Action: \$ ~~246,910.00~~ \$ 55,188.12 Subaward No. 080-70000-528101


Estimated Project Period (if incrementally funded): Start: Dec 9, 2017 End: Nov 30, 2019 Incrementally Estimated Total: \$ 102,098.00 Is this Award R & D Yes or No


Check all that apply Reporting Requirements (Attachment 4) Subject to FFATA (Attachment 3B) Cost Sharing (Attachment 5)

Terms and Conditions

- 1) PTE hereby awards a cost reimbursable subaward, as described above, to Subrecipient. The statement of work and budget for this subaward are (check one) as specified in Subrecipient's proposal dated _____ or as shown in Attachment 5. In its performance of subaward work, Subrecipient shall be an independent entity and not an employee or agent of PTE.
- 2) PTE shall reimburse Subrecipient not more often than monthly for allowable costs. All invoices shall be submitted using Subrecipient's standard invoice, but at a minimum shall include current and cumulative costs (including cost sharing), subaward number, and certification, as required in 2 CFR 200.415 (a). Invoices that do not reference PTE Subaward number shall be returned to Subrecipient. Invoices and questions concerning invoice receipt or payments should be directed to the appropriate party's Financial Contact, as shown in Attachments 3A. (Invoices should be submitted electronically)
- 3) A final statement of cumulative costs incurred, including cost sharing, marked "FINAL" must be submitted to PTE's Financial Contact, as shown in Attachments 3A, NOT LATER THAN 60 days after subaward end date. The final statement of costs shall constitute Subrecipient's final financial report.
- 4) All payments shall be considered provisional and subject to adjustment within the total estimated cost in the event such adjustment is necessary as a result of an adverse audit finding against the Subrecipient. PTE reserves the right to reject an invoice, in accordance with 2 CFR 200.305.
- 5) Matters concerning the technical performance of this subaward should be directed to the appropriate party's Principal Investigator as shown in Attachments 3A and 3B. Technical reports are required as shown above, "Reporting Requirements."
- 6) Matters concerning the request or negotiation of any changes in the terms, conditions, or amounts cited in this subaward agreement, and any changes requiring prior approval, should be directed to the appropriate party's Administrative Contact, as shown in Attachments 3A and 3B. Any such changes made to this subaward agreement require the written approval of each party's Authorized Official, as shown in Attachments 3A and 3B.
- 7) Substantive changes made to this subaward agreement require the written approval of each party's Authorized Official as shown in Attachments 3A and 3B. The PTE may issue non-substantive changes to the Period of Performance (check one) Bilaterally, or Unilaterally. Unilateral modifications shall be considered valid 14 days after receipt unless otherwise indicated by Subrecipient.
- 8) Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, or directors, to the extent allowed by law.
- 9) Either party may terminate this subaward with thirty days written notice to the appropriate party's Administrative Contact, as shown in Attachments 3A and 3B. PTE shall pay Subrecipient for termination costs as allowable under Uniform Guidance, 2 CFR 200, or 45 CFR Part 75 Appendix IX, "Principles for Determining Costs Applicable to Research & Development under Grants and Contracts with Hospitals, as applicable.
- 10) No-cost extensions require the approval of the PTE. Any requests for a no-cost extension should be addressed to and received by the Administrative Contact, as shown in Attachments 3A, not less than 30 days prior to the desired effective date of the requested change.
- 11) The Subaward is subject to the terms and conditions of the PTE Award and other special terms and conditions, as identified in Attachment 2.
- 12) By signing this Research Subaward Agreement Subrecipient makes the certifications and assurances shown in Attachments 1 and 2.
- 13) Research Terms & Conditions – RESERVED

By an Authorized Official of Pass-through Entity:

 Name: Timothy Schailey Date: 1/19/18
 Title: Director, Office of Research Administration

By an Authorized Official of Subrecipient:

 Name: Dr N S Mahantashetti Date: Jan 13, 2018
 Title: Principal, J N Medical College, Belagavi

ATTESTED

 Dr. V.A. Kothiwale
 Registrar
 KLE Academy of Higher Education and Research,
 (Deemed-to-be-University u/s 3 of the UGC Act, 1956)
 Belagavi-590 010, Karnataka

Notice of Award



EXPLORATORY/DEVELOPMENT GRANT
Department of Health and Human Services
National Institutes of Health

Federal Award Date: 12/11/2017



FOGARTY INTERNATIONAL CENTER

Grant Number: 1R21TW010609-01
FAIN: R21TW010609

Principal Investigator(s):
RICHARD J DERMAN, MD

Project Title: Breastfeeding Education Support Tool for Baby (BEST4Baby)

Ms. Johnston, Jeanmarie
Thomas Jefferson University
Office Of Research Admin
125 South 9th Street
Sheridan Bldg., 2nd Floor
Philadelphia, PA 191075125

Award e-mailed to: resadmin@jefferson.edu

Period Of Performance:

Budget Period: 12/09/2017 – 11/30/2018

Project Period: 12/09/2017 – 11/30/2019

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$199,846 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to THOMAS JEFFERSON UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Fogarty International Center of the National Institutes of Health under Award Number R21TW010609. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website <http://grants.nih.gov/grants/policy/coi/> for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Page-1

ATTESTED

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka



Chandrashekhar Kajagar <ckajagar@gmail.com>

Fwd: Regarding HMSC Decision

dr.umesh charanthimath <drumesh.charantimath@gmail.com>

8 November 2017 at 15:19

To: Chandrashekhar Kajagar <ckajagar@gmail.com>, Roopa M Bellad <belladroopa5@gmail.com>

----- Forwarded message -----

From: <icmr@cdac.in>

Date: 08-Nov-2017 3:10 pm

Subject: Regarding HMSC Decision

To: <drumesh.charantimath@gmail.com>

Cc:

Dear DR. NIRANJANA S MAHANTASHETTI,

The proposal with proposal id **2017-3816** entitled **BREASTFEEDING EDUCATION SUPPORT TOOL FOR BABY (BEST4BABY)**, was considered during the HMSC meeting held on 27-10-2017 and the decision of the HMSC is as follows:

Approved .

You may now take necessary action at your end to initiate the project and let us know the date of initiation of the project. You are requested to kindly ensure submission of progress report of the project to ICMR.

You are also requested to upload the duly filled in and signed DST project summary sheet and DST check list by logging into your account at <http://icmrextramural.in/ICMR/> for onward transmission to DST by ICMR. For any further queries please contact the coordinator, ICMR at 011-26589492

With Regards
ICMR Team.

This is a system generated mail. Please do not reply to it. For Any Further Correspondence please contact only at "onlineicmrteam@gmail.com / 011-26588590 "

[C-DAC is on Social-Media too. Kindly follow us at:

Facebook: <https://www.facebook.com/CDACINDIA> & Twitter: @cdacindia]

This e-mail is for the sole use of the intended recipient(s) and may contain confidential and privileged information. If you are not the intended recipient, please contact the sender by reply e-mail and destroy all copies and the original message. Any unauthorized review, use, disclosure, dissemination, forwarding, printing or copying of this email is strictly prohibited and appropriate legal action will be taken.

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

डॉ के. सत्यनारायण
Dr K. SATYANARAYANA
Head, Division of Publication & Information
and RHN



भारतीय आयुर्विज्ञान अनुसंधान परिषद
भारतीय आयुर्विज्ञान परिषद
भारतीय आयुर्विज्ञान अनुसंधान परिषद
भारतीय आयुर्विज्ञान अनुसंधान परिषद
Indian Council of Medical Research
Department of Health Research
Ministry of Health & Family Welfare
V Ramalingaiah M. Bhawan Area, New Delhi
New Delhi - 110 054, INDIA

No. 5/7/273/08-RHN
Dated: March 13, 2009

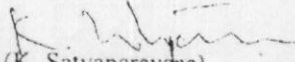
Subject: Indo-Foreign project entitled "Maternal and Newborn Registry & Evaluation of an Emergency Obstetric and Newborn care (EmONC) intervention package to reduce adverse pregnancy outcome in low resource settings – the EmONC trial" under Dr BS Kodkany, Belgaum.

Dear Dr Kodkany,

This is to inform you that the above mentioned proposal was placed in the meeting of Health Ministry's Screening Committee (HMSC) and has been APPROVED.

With warm regards,

Yours sincerely


(K. Satyanarayana)

Dr BS Kodkany
Professor of OBGYN & Senior Foreign Investigator
JNMC-UMKC Women's and Children's Health Research Unit,
Jawaharlal Nehru Medical College
Belgaum – 590010

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Tele.: (O) 26589258. PABX: 26589334, 26589335, 26589336 Extn. 286
(R): 25082707. Fax: 26589497. E-mail: kanikaram_s@yahoo.com, kanikaram@icmr.org.in

पौ.सं.बैंक/PAIX : 26588980, 26588707, 26589336, 26589745,
26589873, 26589414
फैक्स/TAX : 011-26588662, 011-26589791, 011-26589258

नगर / GRAM : विज्ञान / SCIENTIST-B
Web-site : www.icmr.gov.in
E-mail : icmr@icmr.gov.in



भारतीय आयुर्विज्ञान अनुसंधान परिषद्
INDIAN COUNCIL OF MEDICAL RESEARCH

वी.रामलिंगस्वामी भवन, अन्सारी नगर, पोस्ट बॉक्स 4911, नई दिल्ली -110 029
V.RAMALINGASWAMI BHAWAN, ANSARI NAGAR, POST BOX 4911, NEW DELHI - 110 029

Dr Shalini Singh
Scientist D, Div of RHN
Email: shalinisingh_icmr@yahoo.co.in
Ph : 011-26589493

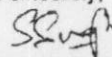
No. 57/624/11-RHN
Dated: Oct 7th, 2011

Subject : Project titled "Antenatal corticosteroids trial in preterm births to increase neonatal survival in developing countries in Belgaum district, Kamataka".

Dear Dr Kodkany,

This is to inform you that the above mentioned proposal has been approved by Chair, Health Ministry's Screening Committee (HMSC) at Indian Council of Medical Research, New Delhi. However, the Committee suggested that the PI should ascertain that the ANMs/birth attendants involved in the study are adequately trained to identify the eligible women at high risk for preterm birth and to estimate gestational age in enrolled pregnant women

With warm regards,


Yours sincerely,

(SHALINI SINGH)
for Director General

Dr BS Kodkany
Professor of OBGYN & Senior Foreign Investigator
JNMC-UMKC Women's and Children's Health Research Unit,
Jawaharlal Nehru Medical College
Belgaum - 590010

File
BSK

22

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

फोन/टेलीफोन/फैक्स : 26589780, 26589707, 26589336, 26589745,
26589873, 26589414
टेलीफैक्स : 011-26589662, 011-26589791, 011-26589258

फैक्स / ग्राम - फोन / साइंटिफिक
वेबसाइट : www.icmr.nic.in
ई-मेल : icmrhqdt@airtel.nic.in



भारतीय आयुर्विज्ञान अनुसंधान परिषद
INDIAN COUNCIL OF MEDICAL RESEARCH

बी. रामलिंगस्वामी भवन, अन्सारी नगर, पोस्ट बॉक्स 4911, नई दिल्ली - 110 029
V. RAMALINGASWAMI BHAWAN, ANSARI NAGAR, POST BOX 4911, NEW DELHI - 110 029

Dr. Vasantha Thavara;
DDG(SG)
Division of RHN
Telefax : 011 - 26589356

No No. 5/7/705/2011-RHN
Date : 23.03.2012

Fax (work): +91 831 247 2891

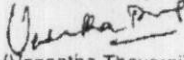
Sub: "Evaluation of HELPING BABIES BREATHE in Belgaum, Kenya and Nagpur"

Dear Dr. Goudar,

This is to inform you that the letter No. INDO/FRC/442/2012-IHD received from the IHD, ICMR Dated 12th March, 2012 has approved the above project. The Minutes are attached. Kindly acknowledge the receipt of this letter.


With kind regards,

Yours sincerely,


(Vasantha Thavara)

Dr. Shivaprasad S. Goudar, MD, MHPE
Professor and Head, Department of Physiology &
Research Coordinator, Women's and Children's Health Research Unit,
J N Medical College, Belgaum 590 010 Karnataka INDIA

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

16. Visceral Leishmaniasis in Bihar State, India under Prof. Shyam Sunder, Banaras Hindu University, Varanasi.

Approved. State Health Department, Government of Bihar should be apprised of the study and should be included as a partner.

17. Share: South Asian Hub for Advocacy, Research and Education in Mental Health under Dr. Vikram Patel, SANGATH, Goa.

Approved for Phase I part of study only. There should be a mid term appraisal of the study.

18. Evaluation of helping babies breathe in Belgaum, Kenya and Nagpur: Does implementation of helping babies breathe save lives? under Dr. Shivaprasad S. Goudar, J.N. Medical College, Belgaum.

Approved.

19. Evaluation/ of helping babies breathe in Belgaum, Kenya and Nagpur: Does implementation of helping babies breathe save lives? under Dr. Archana Patel, Indira Gandhi Government Medical College, Nagpur.

Approved.

II.3. Proposal for assistance / collaboration under Indo-US Joint Statement on Environmental and Occupational Health

20. Identification and validation of early biomarkers for predicting toxicity including precarcinogenic lesions in individuals occupationally exposed to polycyclic aromatic hydrocarbons (PAHs) and through tobacco use under Dr. Devendra Pamar, Indian Institute of Toxicology Research, Lucknow.

Approved.

II.4. Proposals for assistance / collaboration from Centers for Disease Control and Prevention, DHHS, USA

21. Influenza immunization of children in India under Dr. Shobha Broor, All India Institute of Medical Sciences, New Delhi.

Approved. The title should mention "a rural community in Ballabgarh, North India" since it is the area being covered in the study.

22. Epidemiological study of respiratory pathogens in acute respiratory tract infection among children and elderly in India under Dr. Anand Krishna, All India Institute of Medical Sciences, New Delhi.

Approved.

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

**FDP Research Subaward Agreement
Amendment (Number 1)**

Pass-Through Entity (PTE)

Subrecipient

Thomas Jefferson University	Entity Name: Jawaharlal Nehru Medical College, KLE
125 S 9th St, 2nd Floor Sheridan, Philadelphia, PA 19107	Email Address: sgoudar@jnmc.edu, bkilledar@jnmc.edu,
Richard Derman	Principal Investigator: Shivaprasad Goudar

Project Title: TJU-JNMC Global Network for Women's & Children's Health Research Unit

PTE Federal Award No: 2UG1HD076457-07	Federal Awarding Agency: National Institutes of Health (NIH)
--	---

Subaward Period of Performance:		Amount Funded This Action:	Subaward No:
Start Date: Jun 1, 2019	End Date: May 31, 2020	\$ 478,086.00	080-70000-S22902
Effective Date of Amendment: Jun 1, 2019	Total Amount of Federal Funds Obligated to Date: \$ 478,086.00	Subject to FFATA: <input checked="" type="radio"/> Yes <input type="radio"/> No	Automatic Carryover: <input type="radio"/> Yes <input checked="" type="radio"/> No

Amendment(s) to Original Terms and Conditions
This Amendment revises the above-referenced Research Subaward Agreement as follows:

ACTION:

To authorize funding of \$478,086 for the current budget period from June 1, 2019 to May 31, 2020.

If there are funds remaining from the prior budget period, a request for carryover may be submitted, along with the final invoice, within 60 days of end of the period of performance.

For clarity, all amounts stated in this amendment are in United States Dollars.

All other terms and conditions of this Subaward Agreement remain in full force and effect.

By an Authorized Official of PTE: 10/16/19 Name: Timothy Schailey Date Title: Director, Office of Research Administration	By an Authorized Official of Subrecipient: Jul 16, 2019 Name: Dr. (Mrs.) Niranjana S. Mahantashetti Date Title: Principal
--	--

FDP Bilateral Mod Sept.2017

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

Attachment 1

RESEARCH & RELATED BUDGET - Budget Period 1

OMB Number: 4040-0001
Expiration Date: 10/31/2019

ORGANIZATIONAL DUNS:

Enter name of Organization:

Budget Type: Project Subaward/Consortium

Budget Period: 1 Start Date: End Date:

A. Senior/Key Person

Prefix	First	Middle	Last	Suffix	Base Salary (\$)	Months			Requested Salary (\$)	Fringe Benefits (\$)	Funds Requested (\$)
						Cal.	Acad.	Sum.			
Dr.	Shivaprasad	S.	Goudar		49,011.00	3.00			12,253.00	0.00	12,253.00
Project Role: <input type="text" value="Sr. Foreign Investigator"/>											
Dr.	Bhalachandra		Kodkany		66,470.00	0.40			2,216.00	0.00	2,216.00
Project Role: <input type="text" value="Senior Research Adviser"/>											
Dr.	Niranjana		Mahantashetti		36,886.00	0.50			1,536.00	0.00	1,536.00
Project Role: <input type="text" value="Senior Research Adviser"/>											
Dr.	Manjunath		Somannavar		23,460.00	4.20			8,211.00	0.00	8,211.00
Project Role: <input type="text" value="Research Coordinator"/>											
Dr.	Sangappa		Dhaded		36,163.00	2.20			6,630.00	0.00	6,630.00
Project Role: <input type="text" value="Pediatric Research Coordinator"/>											
Dr.	Mrutyunjaya		Bellad		36,886.00	1.30			3,994.00	0.00	3,994.00
Project Role: <input type="text" value="Obstetric Research Coordinator"/>											

Additional Senior Key Persons:

Total Funds requested for all Senior Key Persons in the attached file

Total Senior/Key Person

ATTESTED

Dr. V.A. Kothiwale

Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University as 3 of the UGC Act 1956)
Belagavi-590 010, Karnataka

B. Other Personnel

Number of Personnel	Project Role	Months			Requested Salary (\$)	Fringe Benefits (\$)	Funds Requested (\$)
		Cal.	Acad.	Sum.			
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Data Mgr/IT Coord.	2.50			3,371.00	0.00	3,371.00
1	Asst Res Coord/Data Entry Spec.	5.00			4,636.00	0.00	4,636.00
1	Ex. Adm/Finance	5.50			6,506.00	0.00	6,506.00
6	Field Research Officer	25.80			38,700.00	0.00	38,700.00
8	Data Management/Log Support/County Coordination	15.10			14,397.00	0.00	14,397.00
1	Senior Field Research Officer/Data Coordinator	8.30			12,450.00	0.00	12,450.00

18	Total Number Other Personnel						Total Other Personnel	80,060.00
							Total Salary, Wages and Fringe Benefits (A+B)	114,900.00

C. Equipment Description

List items and dollar amount for each item exceeding \$5,000

Equipment item	Funds Requested (\$)

Additional Equipment:

Total funds requested for all equipment listed in the attached file	
Total Equipment	

D. Travel

	Funds Requested (\$)
1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)	13,020.00
2. Foreign Travel Costs	16,156.00
Total Travel Cost	29,176.00

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

F. Other Direct Costs		Funds Requested (\$)
1. Materials and Supplies		8,483.00
2. Publication Costs		
3. Consultant Services		179,626.00
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		9,125.00
7. Alterations and Renovations		
8. Other		101,362.00
9.		
10.		
Total Other Direct Costs		298,596.00

G. Direct Costs	Funds Requested (\$)
Total Direct Costs (A thru F)	442,672.00

H. Indirect Costs			
Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)
Foreign	8.00	442,672.00	35,413.00
Total Indirect Costs			35,413.00

Cognizant Federal Agency
 (Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested (\$)
Total Direct and Indirect Institutional Costs (G + H)	478,085.00

J. Fee	Funds Requested (\$)

K. Total Costs and Fee	Funds Requested (\$)
Total Costs and Fee (I + J)	478,085.00

L. Budget Justification

(Only attach one file.)

ATTESTED



Dr. V.A. Kothiwale
 Registrar

KLE Academy of Higher Education and Research,
 (Deemed-to-be-University u/s 3 of the UGC Act, 1956)
 Belagavi-590 010, Karnataka



Cooperative Agreement
Department of Health and Human Services
National Institutes of Health



EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Grant Number: 5UG1HD076457-07

FAIN: UG1HD076457

Principal Investigator(s):
RICHARD J DERMAN, MD

Project Title: TJU-JNMC Global Network for Women's & Children's Health Research Unit

Margaret Burwell
Assistant to the Director
125 S. 9th Street
Philadelphia, PA 191075125

Award e-mailed to: resadmin@jefferson.edu

Period Of Performance:

Budget Period: 06/01/2019 – 05/31/2020

Project Period: 07/01/2013 – 05/31/2023

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$607,360 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to THOMAS JEFFERSON UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number UG1HD076457. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to Issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website <http://grants.nih.gov/grants/policy/coi/> for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Page-1

NIH NGA R | Version: 55 - 10/26/2016 2:22:09 PM | Generated on: 06/13/2019 12:42:13 AM

ATTESTED

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

Dr. V.A.Kothiwale

Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

Kimberly Durkin
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN
DEVELOPMENT

Additional information follows

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Page-2

SECTION I – AWARD DATA – 5UG1HD076457-07

Award Calculation (U.S. Dollars)

Salaries and Wages	\$36,764
Fringe Benefits	\$8,750
Personnel Costs (Subtotal)	\$45,514
Consultant Services	\$27,524
Travel	\$9,830
Other	\$403,030
Subawards/Consortium/Contractual Costs	\$75,056

Federal Direct Costs	\$560,954
Federal F&A Costs	\$46,406
Approved Budget	\$607,360
Total Amount of Federal Funds Obligated (Federal Share)	\$607,360
TOTAL FEDERAL AWARD AMOUNT	\$607,360

AMOUNT OF THIS ACTION (FEDERAL SHARE) \$607,360

SUMMARY TOTALS FOR ALL YEARS		
YR	THIS AWARD	CUMULATIVE TOTALS
7	\$607,360	\$607,360
8	\$607,360	\$607,360
9	\$607,360	\$607,360
10	\$607,360	\$607,360

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

CFDA Name: Child Health and Human Development Extramural Research
CFDA Number: 93.865
EIN: 1231352651A1
Document Number: UHD076457C
PMS Account Type: P (Subaccount)
Fiscal Year: 2019

IC	CAN	2019	2020	2021	2022
HD	8014707	\$607,360	\$607,360	\$607,360	\$607,360

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:

PCC: PPB -PS / OC: 414P / Released: SHAWK00 06/12/2019
Award Processed: 06/13/2019 12:12:13 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5UG1HD076457-07

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm>

SECTION III – TERMS AND CONDITIONS – 5UG1HD076457-07

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- The grant program legislation and program regulation cited in this Notice of Award.
- Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- 45 CFR Part 75.

ATTESTED

ke
Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

- d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm> for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part § 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See <http://grants.nih.gov/grants/policy/awardconditions.htm> for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) UG1HD076457. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see <http://grants.nih.gov/grants/policy/awardconditions.htm> for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: <http://publicaccess.nih.gov/>.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration System Information Website. NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/

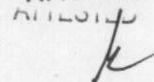
This award provides support for one or more NIH defined Phase III Clinical Trials. The NIH Policy for research supported as an NIH Phase III Clinical Trial has been amended in Section II.B. of the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research – Amended October 2001 (see http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm).

A description of plans to conduct analyses, as appropriate, by sex/gender and racial/ethnic groups must be included in clinical trial protocols. Cumulative subject accrual and progress in conducting subset analyses must be reported to NIH in the annual Progress Reports. Final analyses of sex/gender and racial/ethnic differences must be reported in the required Final

Page-4

NIH NGA R | Version 54 - 12/20/2014 2:22:03 PM | Generated on: 6/13/2019 12:12:13 AM

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Progress Report or Competitive Renewal Applications (or Contract Renewals/Extensions) as stated in Section II.B. of the Guidelines.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – HD Special Terms and Conditions – 5UG1HD076457-07

Clinical Trial Indicator: Yes

This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

NIH staff has determined that the submitted Continuation Progress Report is within the approved scope of work.

TOTAL COSTS

This award is funded at a total cost ceiling of \$607,360. Funds may be rebudgeted as necessary between direct and facilities and administrative costs consistent with policy and institutional requirements for prior approval; however, no additional funds will be provided.

CLINICAL TRIALS

The clinical trial(s) supported by this award are subject to the plan dated 11/24/2017 submitted to NICHHD and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. The policy states that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and that primary summary results will be reported in ClinicalTrials.gov not later than one year after the completion date. The reporting of summary results is required even if the primary completion date occurs after the period of performance.

This award is subject to additional certification requirements with submission of the Annual, Interim and Final Research Performance Progress Reports (RPPR). The recipient must agree to the following annual certification when submitting each RPPR. By submitting the RPPR, the AOR signifies compliance, as follows:

In submitting this RPPR, the SO (or PD/PI with delegated authority), certifies to the best of his/her knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials are in compliance with the recipient's plan addressing compliance with the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded in whole or in part under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the completion date, even if the completion date occurs after the period of performance.

Page-5

NIH NGA-R | Vision: 56x1528x2815 2:32:00 PM | Generated on: 6/13/2019 12:12:13 AM

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

CONSORTIA

This award includes funds awarded for consortium activity with KLE Society's Jawaharlal Nehru Medical College in Karnataka, India .

Consortia are to be established and administered as described in the NIH Grants Policy Statement (rev. 10/17) (<http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>).

FOREIGN COMPONENT

This award includes funding for the following sites: KLE Society's Jawaharlal Nehru Medical College in Karnataka, India .

COOPERATIVE AGREEMENTS

This award is issued as a cooperative agreement, a financial assistance mechanism in which substantial NIH scientific and/or programmatic involvement is anticipated in the performance of the activity. This award is subject to the terms and conditions of award as set forth in the SPECIAL REQUIREMENTS section of RFA-HD-HD18-009, "Re-Competition of Global Network for Women's and Children's Health Research (UG1)," posted date July 18, 2017, which are hereby incorporated by reference as special terms and conditions of award.

Copies of this RFA are available at <http://www.nih.gov/grants/guide/index.html>

These special terms and conditions of award are in addition to, and not in lieu of, otherwise applicable OMB administrative guidelines; Federal Regulations, including HHS Grant Administration Regulations at 45 CFR Part 75; other HHS regulations; and the NIH Grants Policy Statement (rev. 10/17).

Project Scientist Contact Information:

Project Scientist: Marion Koso-Thomas, MD
Email: kosomari@mail.nih.gov **Phone:** 301.435.6873

FUNDING OPPORTUNITY

This award is subject to the requirements indicated in RFA-HD18-009, which are hereby incorporated by reference. Copies of this Funding Opportunity Announcement are available at <http://grants.nih.gov/grants/guide/index.html>.


STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Kimberly Durkin
Email: kimberly.durkin@nih.gov **Phone:** 301-451-0820

Program Official: Caroline Signore
Email: signorec@mail.nih.gov **Phone:** (301) 496-5577 **Fax:** (301) 496-3790

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka


SPREADSHEET SUMMARY
GRANT NUMBER: 5UG1HD076457-07

INSTITUTION: THOMAS JEFFERSON UNIVERSITY

Budget	Year 7	Year 8	Year 9	Year 10
Salaries and Wages	\$36,764	\$36,764	\$36,764	\$36,764
Fringe Benefits	\$8,750	\$8,750	\$8,750	\$8,750
Personnel Costs (Subtotal)	\$45,514	\$45,514	\$45,514	\$45,514
Consultant Services	\$27,524	\$27,524	\$27,524	\$27,524
Travel	\$9,830	\$9,830	\$9,830	\$9,830
Other	\$403,030	\$403,030	\$403,030	\$403,030
Subawards/Consortium/Contractual Costs	\$75,056	\$75,056	\$75,056	\$75,056
TOTAL FEDERAL DC	\$560,954	\$560,954	\$560,954	\$560,954
TOTAL FEDERAL F&A	\$46,406	\$46,406	\$46,406	\$46,406
TOTAL COST	\$607,360	\$607,360	\$607,360	\$607,360

Facilities and Administrative Costs	Year 7	Year 8	Year 9	Year 10
F&A Cost Rate 1	56%	56%	56%	56%
F&A Cost Base 1	\$82,868	\$82,868	\$82,868	\$82,868
F&A Costs 1	\$46,406	\$46,406	\$46,406	\$46,406

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



**World Health
Organization**

**COVERING LETTER
LETTRE D'ACCOMPAGNEMENT**

**GLOBAL
PROCUREMENT AND
LOGISTICS**
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS

WHO Registration 2019/933680-0
Purchase Order 202328665
Unit Reference

Shivaprasad Goudar
(sgoudar@jnmc.edu)/gshivaprasad@hotmail.com
KLE UNIVERSITY
BELGAUM
KLE UNIVERSITY BELAGAVI
BELGAUM
KARNATAKA
590010
India

AGREEMENT FOR PERFORMANCE OF WORK (APW)

Re: The aim of this APW is to conduct an evaluation of the WHO Labour Care Guide in two facilities in India.

We are enclosing the Agreement for Performance of Work between the World Health Organization and KLE UNIVERSITY, BELGAUM, in the amount of INR 1,393,418.18 (One Million Three Hundred Ninety-Three Thousand Four Hundred Eighteen And 18/100), for conducting the above-mentioned work. We also enclosed two attachment(s) referenced in the Agreement.

Kindly acknowledge your acceptance of this contract by returning the email with a copy of duly signed Purchase Order (all pages).

For any technical questions relating to this Agreement, please contact the responsible technical officer, Mercedes BONET SEMENAS, bonetm@who.int.

Invoicing Instructions for Contractors who are legal entities (Company Contractors):

Invoices must be sent via email to accountspayable@who.int. Other than invoices, please do not send any enquiry to this email address. You may contact the above responsible technical officer for enquiries.

In order to ensure timely and accurate payment, invoices must include:

- Invoice number
- Purchase Order number against each invoice line;
- Invoice descriptions matching with PO descriptions
- Invoice currency same as the Purchase Order Currency also corresponding with the currency of the bank account provided to WHO;
- Supplier name as in the PO

Invoices shall be clearly readable and stamps or any other additional markings should not obscure the original invoice content. Invoices shall not be handwritten.

On behalf of the World Health Organization, we would like to thank you for your collaboration.

cc: WHO India

WHO Global Service Centre

Concerne: The aim of this APW is to conduct an evaluation of the WHO Labour Care Guide in two facilities in India.

Veuillez trouver ci-joint l' Accord pour Exécution de Travaux entre l'Organisation Mondiale de la Santé et KLE UNIVERSITY, BELGAUM, pour un montant de INR 1,393,418.18, vous permettant de mener à bien le travail susmentionné. Veuillez également trouver 2 pièce(s) jointe(s) mentionnée(s) dans l'Accord.

Merci de confirmer votre acceptation de ce contrat en nous retournant le courriel et une copie dûment signée du Bon de Commande (

8/9/8/2019

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



**World Health
Organization**

**AGREEMENT FOR
PERFORMANCE OF WORK
ACCORD POUR
EXECUTION DE TRAVAUX**

complet)

**GLOBAL
PROCUREMENT AND
LOGISTICS**

Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS

WHO Registration 2019/933680-0
Purchase Order 202328665
Unit Reference

Pour toutes questions à caractère technique ayant trait à cet Accord, veuillez contacter le responsable Mercedes BONET SEMENAS, bonetm@who.int.

Instructions concernant la facturation pour les contractants qui sont des personnes morales. (Personne Morale):
Les factures doivent être envoyées par courriel à accountspayable@who.int. Outre les factures, n'envoyez aucune enquête à cette adresse de courrier électronique. Vous pouvez contacter le responsable technique responsable ci-dessus pour toute demande de renseignements.

De manière à garantir un paiement exact et ponctuel, les factures doivent impérativement comporter:

- Le Numéro de facture
- Le Numéro du bon de commande, répété à chaque ligne de facturation
- Des descriptifs des produits identiques à ceux du Bon de commande
- Une devise de facturation identique à celle du Bon de commande et à celle du compte en banque fourni à l'OMS
- Un intitulé de facture (nom de fournisseur) identique à celui du Bon de commande.

Les factures doivent être parfaitement lisibles. Le contenu de la facture ne doit en aucun cas être masqué par un tampon ou tout autre marquage. La facture ne doit pas être manuscrite.

Au nom de l'Organisation mondiale de la Santé, nous vous remercions de votre collaboration.

Centre mondial de services de l'OMS

cc: OMS India

gp
19/8/2019

AGREEMENT FOR PERFORMANCE OF WORK

Page 1 of 7

Sensitivity: Internal & Restricted

ATTESTED

k

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



World Health Organization

**AGREEMENT FOR
PERFORMANCE OF WORK
ACCORD POUR
EXECUTION DE TRAVAUX**

**GLOBAL
PROCUREMENT AND
LOGISTICS**

Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS

WHO Registration 2019/933680-0
Purchase Order 202328665
Unit Reference

The WORLD HEALTH ORGANIZATION hereby agrees to provide to
L'ORGANISATION MONDIALE DE LA SANTÉ s'engage par la présente à fournir à
KLE UNIVERSITY
BELGAUM
BELGAUM
INDIA

The Fixed amount of/Un montant Fixe de: INR 1,393,418.18 (One Million Three Hundred Ninety-Three Thousand Four Hundred Eighteen And 18/100) in respect of/en vue de: The aim of this APW is to conduct an evaluation of the WHO Labour Care Guide in two facilities in India.

For the period financed by this Agreement From/De: 20-JUL-2019
Période du projet financée par le présent Accord To/A: 15-NOV-2019

Summary of work/ Description sommaire des travaux:

Description of work under this Agreement/ Description des travaux faisant l'objet du présent Accord:

1. Co-ordinate training workshops (1 per facility) for participating providers (around 10 per facility) using standardized training materials (Providers to complete questionnaires after initial training)
2. Support participating providers to pilot-test the LCG in two facilities (target of 100 women per facility) and complete postpartum questionnaires after each case.
3. Co-ordinate focus group discussions (1 per facility), including transcription and translation (if required) and collect endline questionnaires from participating providers
4. Enter questionnaire data into online database
5. Attend multi-country project team calls and respond to requests for technical input as required

Financial arrangements/ Dispositions financières:

Payments will be made as follows/Les versements seront effectués comme suit:

	Deliverable/ Résultat	Due date/ Date remise	%	Currency amount/ Montant en devise
1	On receipt of counter-signed contract	26-JUL-2019	0.00	0.00
2	On submission of deliverable 1 (local approvals)	30-AUG-2019	50.00	696,709.09
3	On submission of interim report on training workshops (deliverable 2)	30-SEP-2019	30.00	418,025.45
4	On submission of final report, including deliverables 2 to 5	15-NOV-2019	20.00	278,683.64

Annexes

The following annexes form an integral part of this Agreement/ Les annexes listées ci-dessous font partie intégrante de l'Accord:

Annex/Annexes	File Name/ Nom du fichier
1	2019/933680 Contractual - Budget Breakdown
2	2019/933680 Contractual - Terms of Reference

AGREEMENT FOR PERFORMANCE OF WORK

Page 2 of 7

Sensitivity: Internal & Restricted

ATTESTED

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

9/8/2019



**World Health
Organization**

**AGREEMENT FOR
PERFORMANCE OF WORK
ACCORD POUR
EXECUTION DE TRAVAUX**

**GLOBAL
PROCUREMENT AND
LOGISTICS**

Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS

WHO Registration 2019/933680-0
Purchase Order 202328665
Unit Reference

In the event that the annexes contain any provisions which are contrary to the terms of this Agreement, the terms of this Agreement shall take precedence/ En cas de contradiction entre les dispositions des annexes et celles de l'Accord, les dispositions de l'Accord prévaudront dans tous les cas.

The undersigned parties, having read the terms and General Conditions, hereby conclude the present Agreement and confirm their agreement and acceptance thereof.

ON BEHALF OF WHO/ POUR L'OMS

Responsible WHO Technical Officer:
Fonctionnaire technique responsable de l'OMS:

Mercedes Bonet Semenas
Medical Officer
HQ/RHR - Reproductive Health and Research

Approved by:
Approuvé par:

Olufemi Taiwo OLADAPO
Medical Officer
HQ/RHR - Reproductive Health and Research

Authorized Signatory:
Signataire autorisé:

Mr Richard Preston
Director (ai)
Global Service Centre
(WHO/GMG/GSC)

Processed by:
Traité par:

Katerina Gnanapragasam
Senior Procurement Assistant
HQ/GSC Global Service Centre
19-JUL-2019

Les parties soussignées, ayant lu les modalités et les Conditions Générales, ratifient l'Accord et confirment leur acceptation.

CONTRACTOR/ CONTRACTANT

Signature :

Date: 09/08/2019

Name & Title/ Nom & Fonction : **Dr. N. S. Mahantashetti**

Principal
JNMC, BELAGAVI

9/8/2019
Principal Investigator
JNMC Women's and Children's
Health Research Unit,
KAHER, J.N. Medical College,
BELAGAVI - 590 010.



ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



World Health Organization

**AGREEMENT FOR PERFORMANCE OF WORK
ACCORD POUR EXECUTION DE TRAVAUX**

GLOBAL PROCUREMENT AND LOGISTICS
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS

WHO Registration 2019/933680-0
Purchase Order 202328665
Unit Reference

GENERAL CONDITIONS

1. **Relationship of the Parties.** It is understood that the execution of the work does not create any employer/employee relationship. In this respect, the contractor shall be solely responsible for the manner in which the work is carried out. Thus, WHO shall not be responsible for any loss, accident, damage or injury suffered by any person whatsoever arising in or out of the execution of this work, including travel. Insurance coverage for any such loss, accident, damage or injury will be the contractor's responsibility, including where appropriate, insurance coverage for persons used by the contractor to carry out the work.

Without prejudice to the foregoing, WHO may in certain cases provide insurance coverage for the contractor for travel in WHO vehicles. WHO declines all responsibility for non-payment by the insurance company of all or part of a claim submitted by or for the contractor for any accident. In case of such non-payment, the contractor shall be obliged to immediately reimburse all or part of any advance which WHO may have paid to the contractor.

2. **Rights.** All rights in the work, including ownership of the original work and copyright thereof, shall be vested in WHO, which reserves the right (a) to revise the work, (b) to use the work in a different way from that originally envisaged, or (c) not to publish or use the work.

3. **Payment and use of funds.** If the option, on the face of this agreement, for payment of a fixed sum applies, that sum is payable in the manner provided, subject to proper performance of the work.

If the option for payment of a maximum amount applies:

(i) the funds shall be used exclusively for the work specified in this agreement and any unspent balance shall be refunded to WHO. In this latter case, any financial statement required shall reflect expenditures according to the relevant main categories of expenditure; and

(ii) to the extent the contractor is required to purchase any goods and/or services in connection with its performance of this agreement, the contractor shall ensure that such goods and/or services shall be procured in accordance with the principle of best value for money. "Best value for money" means the responsive offer that is the best combination of technical specifications, quality and price.

Contractors who are legal entities (hereinafter referred to as "Company Contractors") must submit an invoice to the contracting WHO department or the WHO Global Service Center in order to receive payment. Invoices are not required from contractors who are individuals (hereinafter referred to as "Individual Contractors"), who can be paid upon receipt by the contracting WHO department of the required deliverables (including any required technical reports and financial statements) in a satisfactory manner.

The invoice from Company Contractors shall reflect any tax exemption to which WHO may be entitled by reason of the immunity it enjoys. WHO is, as a general rule, exempt from all direct taxes, custom duties and the like, and the Company Contractor will consult with WHO so as to avoid the imposition of such charges with respect to this agreement and the work performed hereunder. As regards excise duties and other taxes imposed on the provision of goods and services (e.g. value added tax), the Company Contractor agrees to verify in consultation with WHO whether in the country where the tax would be payable, WHO is exempt from such tax at the source, or entitled to claim reimbursement thereof. If WHO is exempt from value added tax, this shall be indicated on the invoice, whereas if WHO can claim reimbursement thereof, the Company Contractor agrees to list such charges on its invoices as a separate item and, to the extent required, cooperate with WHO to enable reimbursement thereof.

WHO shall have no responsibility whatsoever for any taxes, duties or other contributions payable by contractors. Payment of any taxes, duties and other contributions which a contractor may be required to pay shall be the sole responsibility of that contractor who shall not be entitled to any reimbursement thereof by WHO.

4. **Satisfactory performance.** If the work is not satisfactorily completed (and, where applicable, delivered) by the date fixed in this agreement and/or if any financial statement required is not satisfactorily submitted to WHO in accordance with general condition 5 below, WHO may specify an additional period within which this agreement must be satisfactorily performed. Normally such additional period should be of at least one week's

CONDITIONS GENERALES

1. **Relation entre les Parties.** Il n'est pas institué de relations d'employeur à employé aux fins de l'exécution des travaux. À cet égard, le contractant est seul responsable de la manière dont les travaux sont exécutés. Ainsi, l'OMS ne saurait assumer, à l'égard de quelque personne que ce soit, aucune responsabilité pour toute perte, tout accident, tout dommage ou toute blessure subis au cours ou en raison de l'exécution des travaux ou d'un déplacement les concernant. La mise en place d'une couverture d'assurance pour toute perte, tout accident, tout dommage ou toute blessure subis au cours ou en raison de l'exécution des travaux sera de la responsabilité du contractant y compris le cas échéant, toute couverture d'assurance pour les personnes auxquelles le contractant recourt pour l'exécution des travaux.

Sans préjudice de ce qui précède, l'OMS peut, dans certains cas, fournir une couverture d'assurance au contractant en cas de déplacement dans un véhicule de l'OMS. L'OMS décline toute responsabilité pour le non-paiement par la compagnie d'assurance de la totalité ou d'une partie d'une demande d'indemnisation soumise par ou pour le contractant suite à un accident. En cas de non-paiement, le contractant sera obligé d'immédiatement rembourser la totalité ou une partie des avances que l'OMS pourrait lui avoir versées.

2. **Droits.** Tous les droits attachés aux travaux, y compris la propriété des travaux originaux et le droit d'auteur y afférent, seront dévolus à l'OMS qui se réserve le droit a) de réviser les travaux, b) d'utiliser les travaux d'une autre manière que celle initialement envisagée, ou c) de ne pas publier ni utiliser les travaux.

3. **Paiement et utilisation des fonds.** Si l'option applicable - prévue au recto du présent accord - est celle du paiement d'une somme fixe, celle somme est payable dans les conditions prévues, sous réserve de l'exécution satisfaisante des travaux.

Si l'option applicable est celle du paiement d'un montant maximum :

(i) les fonds seront utilisés exclusivement aux fins des travaux précisés dans l'accord et tout solde non utilisé sera remboursé à l'OMS. Dans ce dernier cas, les états financiers requis devront indiquer les montants engagés pour les principaux postes de dépense ; et
(ii) dans la mesure où le contractant doit acheter des biens et/ou des services quelconques dans le cadre de l'exécution du présent accord, il devra veiller à ce que l'achat de ces biens et/ou services soit effectué sur la base du principe du meilleur rapport qualité-prix. On entend par « meilleur rapport qualité-prix » l'offre qui présente la meilleure combinaison du point de vue des spécifications techniques, de la qualité et du prix.

Afin d'être payé, les contractants qui sont des personnes morales (ci-après dénommées « Personnes Morales ») doivent présenter une facture au département contractant de l'OMS ou au centre mondial de services de l'OMS. Les contractants qui sont des personnes physiques (ci-après dénommées « Personnes Physiques ») ne sont pas tenus de présenter de facture et peuvent être payés au moment de la réception, sous une forme satisfaisante, des livrables requis (y compris tout rapport technique et état financier requis) par le département contractant de l'OMS.

La facture des Personnes Morales devra refléter toute exonération d'impôt à laquelle l'OMS pourrait avoir droit en vertu de l'immunité dont elle jouit. De manière générale, l'OMS est exonérée de tout impôt direct, de tout droit de douane et de tous droits et taxes similaires, et la Personne Morale devra se mettre en rapport avec l'OMS afin d'éviter l'application des dites charges en rapport avec le présent accord et les travaux qui en résultent. En ce qui concerne les impôts et autres charges indirectes imposés sur la fourniture de biens et de services, (par ex: taxe à la valeur ajoutée), la Personne Morale accepte de vérifier en consultation avec l'OMS si, dans le pays où la charge serait exigible, l'OMS est exonérée de ladite charge à la source ou est en droit d'en réclamer le remboursement. Si l'OMS est exonérée de la taxe à la valeur ajoutée, celle devra être indiquée sur la facture, tandis que si l'OMS est en droit d'en réclamer le remboursement, la Personne Morale accepte de mentionner cette charge de façon séparée sur ses factures et, si nécessaire, de coopérer avec l'OMS afin d'en obtenir le remboursement.

L'OMS n'encourra aucune responsabilité pour quelque taxe, droit ou autre contribution dû par les contractants. Le paiement de quelque taxe, droit ou autre contribution qu'un contractant pourrait être tenu de payer sera de l'entière responsabilité de celui-ci et il n'aura droit à aucun remboursement de la part de l'OMS à ce titre.

4. **Exécution satisfaisante.** Si les travaux ne sont pas accomplis correctement (et, le cas échéant, fournis) à la date prévue par l'accord ou si tout état financier requis n'est pas soumis de façon satisfaisante à l'OMS conformément à la condition générale 5 ci-dessous, l'OMS peut accorder un délai supplémentaire à l'expiration duquel l'accord doit être exécuté de façon satisfaisante. En règle générale, ce délai supplémentaire est d'une semaine au moins, à moins

AGREEMENT FOR PERFORMANCE OF WORK

Sensitivity: Internal & Restricted

Page 4 of 7

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

JP
9/18/2019



World Health Organization

**AGREEMENT FOR PERFORMANCE OF WORK
ACCORD POUR EXECUTION DE TRAVAUX**

GLOBAL PROCUREMENT AND LOGISTICS
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS

WHO Registration 2019/933680-0
Purchase Order 202328665
Unit Reference

duration, unless it is clear from the agreement that it was particularly important that the performance be completed on the date specified, in which case WHO may specify a shorter period or refuse to grant any additional period at all. In the event that the work is not satisfactorily completed and delivered on the date fixed, or any additional period granted by WHO and/or if any financial statement required is not satisfactorily submitted to WHO in accordance with general condition 5 below, WHO may immediately terminate this agreement (in addition to the other remedies), in accordance with general condition 13 below (without being held to grant the contractor an additional period of thirty (30) days to perform, complete and deliver the work).

qu'il ne ressorte clairement de l'accord qu'il était particulièrement important d'achever les travaux à la date initialement prévue, auquel cas l'OMS peut accorder un délai plus court ou refuser la moindre prorogation. Si les travaux ne sont pas achevés et livrés de façon satisfaisante à la date prévue ou à l'expiration de tout délai supplémentaire accordé par l'OMS, et/ou si tout état financier requis n'est pas soumis de façon satisfaisante à l'OMS conformément à la condition générale 5 ci-dessous, l'Organisation peut immédiatement résilier le présent accord (sans préjudice d'autres recours dont elle peut disposer), conformément à la condition générale 13 ci-dessous (sans être tenue d'accorder au contractant une période supplémentaire de trente (30) jours pour exécuter, achever et livrer les travaux).

5. Completion and delivery. The contractor shall complete and deliver the work to WHO (including any technical report that may be required) by the date fixed in this agreement or any additional period that may be granted by WHO under general condition 4 above. Any financial statement required shall be submitted within thirty (30) days thereafter at the latest. If the payment schedule on the face of this agreement provides for a final payment upon completion of the work, this final payment shall be made only after satisfactory receipt of all deliverables called for under this agreement, including any technical report and financial statement.

5. Achèvement et livraison. Le contractant achève et livre les travaux à l'OMS (y compris tout rapport technique qui pourrait être requis) à la date prévue par l'accord ou à l'expiration de tout délai supplémentaire accordé par l'OMS en application de la condition générale 4 ci-dessus. Tout état financier requis est soumis au plus tard dans les trente (30) jours qui suivent. Si le calendrier de paiement prévu au recto de l'accord prévoit le paiement à la fin des travaux, celui-ci n'est effectué qu'après réception, sous une forme satisfaisante, de tous les livrables exigés aux termes de l'accord, y compris les rapports techniques et les états financiers.

6. Certification of status of individual contractors. Each Individual Contractor certifies that he/she does not presently, and will not during the term of this agreement, hold any form of contractual relationship with WHO (including any WHO regional, country or project office, as well as any programme, center or other entity where staff is subject to WHO Staff Regulations and Rules) that confers upon the Individual Contractor the status of a WHO staff member. The Individual Contractor understands that a false statement may result in the cancellation of any or all contracts, and/or the withdrawal of any offer of a contract with WHO.

6. Certification du statut des personnes physiques. Toute Personne Physique certifie qu'elle n'a pas actuellement et n'aura pas pour la durée du présent accord, de relation contractuelle avec l'OMS (y compris les bureaux régionaux de l'OMS, les bureaux de pays ou de projet, les programmes, centres ou entités où le personnel est soumis au Statut et au Règlement du Personnel de l'OMS) lui conférant le statut de membre du personnel de l'OMS. Toute Personne Physique comprend qu'une fausse déclaration de sa part peut entraîner l'annulation de tous les contrats, et/ou le retrait de toute offre de contrat, avec l'OMS.

7. Research involving human participants. If and to the extent the work to be performed under this agreement includes surveys or interviews involving human participants (hereinafter referred to as "research"), the following shall apply:

7.1 Ethical Aspects

It is the responsibility of the contractor to safeguard the rights and welfare of human subjects involved in research performed under this agreement, in accordance with the appropriate national code of ethics or legislation, if any, and in the absence thereof, the Helsinki Declaration and any subsequent amendments. Prior to commencing any such research, the contractor shall ensure that (a) the rights and welfare of the subjects involved in the research are adequately protected, (b) freely given informed consent has been obtained for all participants, (c) the balance between risk and potential benefits involved has been assessed and deemed acceptable by a panel of independent experts appointed by the contractor, and (d) any special national requirements have been met.

7.2 Regulatory Requirements

It is the responsibility of the contractor to comply with the relevant national regulations pertaining to research involving human subjects.

7.3 Protection of Subjects

Without prejudice to obligations under applicable laws, the contractor shall make appropriate arrangements to eliminate or mitigate any negative consequences to subjects or their families resulting from the conduct of the research under this agreement. Such arrangements shall to the extent feasible include appropriate counseling, medical treatment and financial relief. The contractor furthermore undertakes to protect the confidentiality of the information relating to the possible identification of subjects involved in the research.

7. Recherches impliquant des êtres humains. Si et dans la mesure où les travaux à effectuer dans le cadre du présent accord incluent des études ou interviews impliquant des êtres humains (ci-après dénommés "recherches" ou "étude de sujets humains"), les points suivants sont applicables:

7.1 Aspects éthiques

Il incombe au contractant de s'assurer qu'au cours des travaux effectués dans le cadre de cet accord et impliquant l'étude de sujets humains, les droits et la santé de ces derniers soient protégés conformément au code d'éthique ou à la législation du pays, ou, à défaut, à la Déclaration d'Helsinki et aux amendements qui pourraient lui être ultérieurement apportés. Avant de commencer toute recherche, le contractant doit s'assurer que: a. les droits et le bien-être des sujets impliqués sont suffisamment protégés; b. le consentement libre et éclairé a été obtenu pour tous les participants; c. des experts indépendants désignés par le contractant ont évalué les risques et les avantages potentiels et ont jugé qu'ils s'équilibrent de manière acceptable et; d. toute exigence particulière de la réglementation nationale a été satisfaite.

7.2 Exigences réglementaires

Il incombe au contractant de respecter la réglementation nationale relative aux recherches impliquant l'étude de sujets humains.

7.3 Protection des sujets humains

Sans préjudice des obligations lui incombant aux termes des lois en vigueur, le contractant prendra des mesures appropriées en vue d'éliminer ou d'atténuer toute conséquence négative pour les sujets ou leur famille résultant de la conduite des recherches dans le cadre de cet accord. Ces mesures comprendront, dans la mesure du possible, des conseils appropriés, un traitement médical et un dédommagement financier. Le contractant s'engage en outre à protéger le caractère confidentiel des informations qui pourraient permettre d'identifier les sujets impliqués dans les études.

8. Compliance with WHO Policies. By entering into this agreement, the contractor acknowledges that it has read, and hereby accepts and agrees to comply with, the WHO Policies (as defined below). In connection with the foregoing:

- Company Contractors shall take appropriate measures to prevent and respond to any violations of the standards of conduct, as described in the WHO Policies, by their employees and any other persons engaged by them to perform the work under the agreement; and

- Individual Contractors shall not engage in any conduct that would constitute a violation of the standards of conduct, as described in the WHO Policies;

Without limiting the foregoing, the contractor shall promptly report to WHO, in accordance with the terms of the applicable WHO Policies, any actual or suspected violations of any WHO Policies of which the contractor becomes aware. For purposes of this agreement, the term "WHO Policies" means collectively: (i) the WHO Code of Ethics and Professional Conduct; (ii) the WHO Policy on Sexual Exploitation and Abuse Prevention and Response; (iii) the WHO Code of Conduct for responsible Research; (iv) the WHO Policy on Whistleblowing and Protection Against Retaliation; and (v) the UN Supplier Code of Conduct; in each case, as amended from time to time and which are publicly available on the WHO website at the following links:

8 Respect des politiques de l'OMS. En concluant cet accord, le contractant reconnaît qu'il a lu les Politiques de l'OMS (telles que définies ci-dessous), et qu'il les accepte et convient de s'y conformer. En lien avec ce qui précède :

- les Personnes Morales doivent prendre des mesures appropriées afin de prévenir et répondre à toute violation des normes de conduite, telles que décrites dans les Politiques de l'OMS, par leurs employés et par toute autre personne qu'elles ont engagées pour exécuter les travaux en vertu de cet accord; et

- les Personnes Physiques ne doivent pas adopter un comportement pouvant constituer une violation des normes de conduites, telles que décrites dans les Politiques de l'OMS.

Sans limiter la portée de ce qui précède, le contractant doit immédiatement signaler à l'OMS, conformément aux dispositions des Politiques de l'OMS applicables, toute violation réelle ou présumée dont il a connaissance concernant toute Politique de l'OMS. Aux fins du présent accord, l'expression « Politiques de l'OMS » signifie collectivement : (i) le Code d'éthique et de déontologie de l'OMS, (ii) la Politique de l'OMS relative à la prévention et à la lutte contre l'exploitation et les abus sexuels, (iii) le Code de conduite pour une recherche responsable, (iv) la Politique de l'OMS sur le signalement des actes répréhensibles et la protection contre les représailles, et (v) le Code de conduite des fournisseurs des Nations Unies, y compris leurs modifications éventuelles et qui sont publiquement accessibles sur le site internet de l'OMS aux liens suivants : <http://www.who.int/about/finances-accountability/procurement/en/> pour ce

Handwritten signature and date: 9/18/2019

ATTESTED

Handwritten signature
Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka



World Health Organization

**AGREEMENT FOR PERFORMANCE OF WORK
ACCORD POUR EXECUTION DE TRAVAUX**

GLOBAL PROCUREMENT AND LOGISTICS
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS	
WHO Registration	2019/933680-0
Purchase Order	202328665
Unit Reference	

<http://www.who.int/about/finances-accountability/procurement/en/> for the UN Supplier Code of Conduct and at <http://www.who.int/about/ethics/en/> for the other WHO Policies.

qui est du Code de conduite des fournisseurs des Nations Unies, et <http://www.who.int/about/ethics/en/> pour ce qui est des autres Politiques de l'OMS.

9. Zero tolerance for sexual exploitation and abuse. WHO has zero tolerance towards sexual exploitation and abuse. In this regard, and without limiting any other provisions contained herein:

- each Company Contractor warrants that it will: (i) take all reasonable and appropriate measures to prevent sexual exploitation or abuse as described in the WHO Policy on Sexual Exploitation and Abuse Prevention and Response by any of its employees and any other persons engaged by it to perform the work under the agreement; and (ii) promptly report to WHO and respond to, in accordance with the terms of the Policy, any actual or suspected violations of the Policy of which the Company Contractor becomes aware; and
- each Individual Contractor warrants that he/she will: (i) not engage in any conduct that would constitute sexual exploitation or abuse as described in the WHO Policy on Sexual Exploitation and Abuse Prevention and Response; and (ii) promptly report to WHO, in accordance with the terms of the Policy, any actual or suspected violations of the Policy of which the Individual Contractor becomes aware.

9. Tolérance zéro pour l'exploitation et les abus sexuels. L'OMS applique la tolérance zéro en matière d'exploitation et d'abus sexuels. À cet égard, et sans limiter la portée de toute autre disposition du présent accord :

- chaque Personne Morale garantit: i) qu'elle prendra toutes les mesures raisonnables et appropriées pour prévenir tout acte d'exploitation ou d'abus sexuels tels que décrits dans la Politique de l'OMS relative à la prévention et à la lutte contre l'exploitation et les abus sexuels, par l'un quelconque de ses employés et toute autre personne engagée par elle pour exécuter les travaux prévus au titre du présent accord; et (ii) qu'elle signalera immédiatement à l'OMS et donnera suite à toute violation réelle ou présumée de cette Politique dont elle a connaissance, conformément aux dispositions de la Politique; et
- chaque Personne Physique garantit: i) qu'elle n'adoptera aucun comportement qui relèverait de l'exploitation ou l'abus sexuels tels que décrits dans la Politique de l'OMS relative à la prévention et à la lutte contre l'exploitation et les abus sexuels; et ii) qu'elle signalera immédiatement à l'OMS toute violation réelle ou présumée de la Politique dont elle a connaissance, conformément aux dispositions de la Politique.

10. Tobacco/Arms Related Disclosure Statement. Company Contractors may be required to disclose relationships they may have with the tobacco and/or arms industry through completion of the WHO Tobacco/Arms Disclosure Statement. In the event WHO requires completion of this Statement, the Company Contractor undertakes not to permit work on the agreement to commence, until WHO has assessed the disclosed information and confirmed to the Company Contractor in writing that the work can commence.

10. Déclaration relative à l'industrie du tabac/de armement. Il peut être demandé aux Personnes Morales de déclarer leurs éventuelles relations avec l'industrie du tabac et/ou de l'armement en remplissant la déclaration requise par l'OMS relative à l'industrie du tabac/de l'armement. Dans les cas où l'OMS demande une telle déclaration, la Personne Morale s'engage à ne pas autoriser le commencement des travaux au titre de l'accord tant que l'OMS n'a pas évalué les informations communiquées et confirmé par écrit à la Personne Morale que ces travaux peuvent commencer.

11. Anti-terrorism and UN sanctions: Fraud and Corruption. The contractor warrants for the entire duration of the agreement that:

- (i) it is not and will not be involved in, or associated with, any person or entity associated with terrorism, as designated by any UN Security Council sanctions regime, that it will not make any payment or provide any other support to any such person or entity and that it will not enter into any employment or subcontracting relationship with any such person or entity;
- (ii) it shall not engage in any illegal, corrupt, fraudulent, collusive or coercive practices (including bribery, theft and other misuse of funds) in connection with the execution of the agreement; and
- (iii) the contractor shall take all necessary precautions to prevent the financing of terrorism and/or any illegal corrupt, fraudulent, collusive or coercive practices (including bribery, theft and other misuse of funds) in connection with the execution of the agreement.

Any payments used by the contractor for the promotion of any terrorist activity or any illegal, corrupt, fraudulent, collusive or coercive practice shall be repaid to WHO without delay.

11. Anti-terrorisme et sanctions de l'ONU: fraude et corruption. Le contractant garantit, pour toute la durée de l'accord

- (i) qu'il n'est ni ne sera impliqué à l'égard de, ni associé à, aucune personne ou entité que le régime de sanctions du Conseil de sécurité de l'ONU a désignée comme étant associée au terrorisme, qu'il ne fera aucun paiement à, ou ne soutiendra d'aucune autre manière, une telle personne ou entité, et qu'il ne conclura aucune relation d'emploi ni de sous-traitance avec une telle personne ou entité ;
- (ii) qu'il ne prendra part à aucune pratique illégale, de corruption, de fraude, de collusion ou de coercition (y compris, pots de vin, vol ou autre utilisation abusive de fonds) en lien avec l'exécution de l'accord ; et
- (iii) le contractant prendra toutes les précautions nécessaires pour empêcher le financement du terrorisme et/ou toute pratique illégale, de corruption, de fraude, de collusion ou de coercition (y compris, pots de vin, vol ou autre utilisation abusive de fonds) en lien avec l'exécution de l'accord.

Tout paiement utilisé par le contractant pour la promotion de toute activité terroriste ou de toute pratique illégale, de corruption, de fraude, de collusion ou de coercition doit être immédiatement remboursé à l'OMS.

12. Breach of essential terms. The contractor acknowledges and agrees that each of the provisions of general conditions 8, 9, 10 and 11 above constitutes an essential term of this agreement, and that in case of breach of any of these provisions, WHO may, in its sole discretion, decide to:

- (i) terminate this agreement, and/or any other contract concluded by WHO with the contractor, immediately upon written notice to the contractor, without any liability for termination charges or any other liability of any kind; and/or
- (ii) exclude the contractor from participating in any ongoing or future tenders and/or entering into any future contractual or collaborative relationships with WHO.

WHO shall be entitled to report any violation of such provisions to WHO's governing bodies, other UN agencies, and/or donors.

12. Violation de clauses essentielles. Le contractant reconnaît et accepte que chacune des dispositions des conditions générales 8, 9, 10 et 11 ci-dessus constitue une clause essentielle du présent accord, et qu'en cas de manquement à l'une quelconque de ces dispositions, l'OMS peut, à sa seule discrétion, décider :

- (i) de résilier immédiatement cet accord, et/ou tout autre contrat conclu par l'OMS avec le contractant, moyennant une notification écrite adressée au contractant, sans être redevable d'aucune pénalité au titre d'une telle résiliation et sans que sa responsabilité ne soit engagée d'une quelconque manière que ce soit, et/ou
- (ii) d'exclure le contractant de toute participation à des appels d'offres en cours ou à venir et/ou de toute relation contractuelle ou de collaboration future avec l'OMS.

L'OMS sera en droit de rapporter toute violation de ces dispositions aux organes directeurs de l'OMS, aux autres organismes des Nations Unies et/ou aux donateurs.

13. Termination. WHO may terminate this agreement or any part thereof with immediate effect (in addition to any other rights or remedies to which WHO may be entitled, including the right to claim damages), on written notice to the contractor if the contractor is:

- (i) in breach of any material obligation(s) under this agreement and, to the extent such breach is capable of being remedied, fails to correct such breach within a period of thirty (30) days after having received a written notification to that effect from WHO; or
- (ii) adjudicated bankrupt or formally seeks relief of its financial obligations.

13. Résiliation. L'OMS peut résilier avec effet immédiat le présent accord ou toute partie de celui-ci (en plus de tous les autres droits ou recours dont l'OMS peut se prévaloir, y compris celui de réclamer des dommages-intérêts), moyennant une notification écrite adressée au contractant, si ce dernier :

- (i) est en violation d'une (ou plusieurs) obligation(s) importante(s) du présent accord et, dans le cas d'une violation susceptible d'être réparée, manque de remédier à une telle violation dans les trente (30) jours suivant la réception d'une notification écrite de l'OMS envoyée à cet effet ; ou
- (ii) s'est déclaré en faillite ou a demandé officiellement à être exonéré de ses obligations financières.

14. Use of WHO name and emblem. Without WHO's prior written approval, the contractor shall not, in any statement or material of an advertising or promotional nature,

SP
9/8/2019

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



**World Health
Organization**

**AGREEMENT FOR
PERFORMANCE OF WORK
ACCORD POUR
EXECUTION DE TRAVAUX**

**GLOBAL
PROCUREMENT AND
LOGISTICS**
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS

WHO Registration 2019/933680-0
Purchase Order 202328665
Unit Reference

refer to this agreement or the contractor's relationship with WHO, or otherwise use the name (or any abbreviation thereof) and/or emblem of the World Health Organization.

15. **Publication of agreement.** Subject to considerations of confidentiality, WHO may acknowledge the existence of this agreement to the public and publish and/or otherwise publicly disclose the contractor's name and for Company Contractors, the country of incorporation, general information with respect to the work described herein and the agreement's value. Such disclosure will be made in accordance with WHO's Information Disclosure Policy and shall be consistent with the terms of this agreement.

16. **Audit.** WHO may request a financial and operational review or audit of the work performed by Company Contractors under this agreement, to be conducted by WHO and/or parties authorized by WHO, and the Company Contractor undertakes to facilitate such review or audit. This review or audit may be carried out at any time during the implementation of the work performed under this agreement, or within five years of completion of the work. In order to facilitate such financial and operational review or audit, the Company Contractor shall keep accurate and systematic accounts and records in respect of the work performed under this agreement. The Company Contractor shall make available, without restriction, to WHO and/or parties authorized by WHO:

- (i) the Company Contractor's books, records and systems (including all relevant financial and operational information) relating to this agreement; and
- (ii) reasonable access to the Company Contractor's premises and personnel.

The Company Contractor shall provide satisfactory explanations to all queries arising in connection with the aforementioned audit and access rights.

WHO may request the Company Contractor to provide complementary information about the work performed under this agreement that is reasonably available, including the findings and results of an audit (internal or external) conducted by the Company Contractor and related to the work performed under this agreement.

17. **Surviving provisions.** Those provisions of this agreement that are intended by their nature to survive its expiration or earlier termination shall continue to apply.

18. **Settlement of disputes.** Any matter relating to the interpretation or application of this agreement which is not covered by its terms shall be resolved by reference to Swiss law. Any dispute relating to the interpretation or application of this agreement shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or, in the absence of agreement, with the Rules of Arbitration of the International Chamber of Commerce. The parties shall accept the arbitral award as final.

19. **Privileges and immunities.** Nothing contained in or relating to this agreement shall be deemed to constitute a waiver of any of the privileges and immunities enjoyed by WHO and/or as submitting WHO to any national court jurisdiction.

14. **Utilisation du nom et de l'emblème de l'OMS.** Le contractant n'a pas le droit, dans aucune déclaration ni aucun support à caractère publicitaire ou promotionnel, de faire référence au présent accord ou à sa relation avec l'OMS, ni d'utiliser d'une autre manière le nom (ou toute abréviation de celui-ci) et/ou l'emblème de l'Organisation mondiale de la Santé, sans l'autorisation écrite préalable de l'OMS.

15. **Publication de l'accord.** Sous réserve de considérations relatives à la confidentialité, l'OMS a le droit de divulguer l'existence de cet accord et de publier, et/ou rendre public d'une autre manière, le nom du contractant ainsi que, le pays d'enregistrement si le contractant est une Personne Morale, des informations générales concernant les travaux décrits dans le présent accord et la valeur de l'accord. Cette divulgation se fera conformément à la politique de l'OMS sur la divulgation des informations et aux dispositions du présent accord.

16. **Vérification.** L'OMS peut demander qu'un examen ou une vérification de type financier et opérationnel des travaux effectués par les Personnes Morales en vertu du présent accord soit effectué(e) par l'OMS et/ou par des parties autorisées par l'OMS, et la Personne Morale s'engage à faciliter cet examen ou cette vérification. Cet examen ou cette vérification peut être effectué(e) à tout moment pendant l'exécution des travaux effectués au titre du présent accord, ou dans les cinq ans suivant l'achèvement des travaux. Afin de faciliter cet examen ou cette vérification de type financier et opérationnel, la Personne Morale doit tenir des comptes et des registres précis et systématiques sur les travaux effectués en vertu du présent accord. La Personne Morale doit mettre à la disposition de l'OMS et/ou des parties autorisées par l'OMS, sans restriction:

- (i) les livres, les archives et les systèmes de la Personne Morale concernant le présent accord (y compris l'ensemble des informations financières et opérationnelles pertinentes); et
- (ii) un accès raisonnable aux locaux et au personnel de la Personne Morale.

La Personne Morale doit fournir des explications satisfaisantes en réponse à toutes les questions découlant de la vérification et des droits d'accès susmentionnés.

L'OMS peut demander à la Personne Morale de lui communiquer des informations complémentaires concernant les travaux exécutés au titre du présent accord qui sont raisonnablement à sa disposition, y compris les conclusions et les résultats d'une vérification (interne ou externe) effectuée par la Personne Morale au sujet des travaux exécutés au titre du présent accord.

17. **Dispositions restant en vigueur après la fin du contrat.** Les dispositions du présent accord qui sont, de par leur nature, destinées à survivre à l'expiration ou à la résiliation anticipée dudit accord continueront de s'appliquer.

18. **Règlement des différends.** Toute question concernant l'interprétation ou l'application du présent accord que les dispositions de ce dernier ne permettent pas de résoudre doit être résolue par référence au droit suisse. Tout différend relatif à l'application ou à l'interprétation du présent accord qui n'aurait pu être résolu à l'amiable fera l'objet d'une conciliation. En cas d'échec de celle-ci, le différend sera réglé par arbitrage. Les modalités de l'arbitrage seront convenues entre les parties ou, en l'absence d'accord, déterminées selon le Règlement d'arbitrage de la Chambre de Commerce internationale. Les parties reconnaissent que la sentence arbitrale sera finale.

19. **Privilèges et immunités.** Aucun des termes du présent accord ne sera considéré comme constituant une renonciation à quelque privilège ou immunité que ce soit dont jouit l'OMS en vertu du droit national ou international et/ou interprété comme une soumission de l'OMS à la compétence d'une quelconque juridiction nationale.

SP
9/8/2019

ATTESTED

[Signature]
Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

UNIVERSITY OF ILLINOIS
URBANA-CHAMPAIGN • CHICAGO • SPRINGFIELD

CONTRACT BETWEEN
THE BOARD OF TRUSTEES OF THE UNIVERSITY OF ILLINOIS
AND
KLE JAWAHARLAL NEHRU MEDICAL COLLEGE

Version 06/29/16 OBFS - UIC Purchasing

CN-00046428

ATTESTED




Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Table of Contents

Article 1.	Identification of Parties	3
Article 2.	Scope of Services	3
Article 3.	Term and Termination	4
Article 4.	Compensation	4
Article 5.	Notices	5
Article 6.	Insurance	6
Article 7.	Indemnification	8
Article 8.	Subcontracts	9
Article 9.	Confidentiality	9
Article 10.	Rights in Work Product	9
Article 11.	Record Retention and Audits	10
Article 12.	General Terms	10
Exhibits.	Exhibit A - State Clauses and Certifications	14

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

UNIVERSITY OF ILLINOIS

URBANA-CHAMPAIGN • CHICAGO • SPRINGFIELD

Contract for Procurement of Services

ARTICLE 1. Identification of Parties

The parties to this contract are:

(a) The Board of Trustees of the University of Illinois, a body corporate and politic of the State of Illinois ("University"), on behalf of Pediatrics and (b) KLE Jawaharlal Nehru Medical College, a(n) Not-For-Profit Corporation with its principal office at Faculty of Medicine, KLE University, Kptcl Colony, Nehru Nagar, Belagavi Belagavi, Karnataka, India 590010 ("Vendor" or "Contractor").

ARTICLE 2. Scope of Services

2.1 Services. Vendor will perform the following "Services" and will obtain at Vendor's expense all necessary licenses and permissions necessary for Vendor's performance:


Support the participants and data-related activities for the project including, but not limited to: assisting with recruitment, administering the intervention, organizing supplies and intervention materials, daily management of study data, conducting in-clinic assessments, scoring data entry of assessments, and working with the University of Illinois at Chicago and Jawaharlal Nehru Medical College data managers to compile, clean, and recode data and other project-related activities as requested.

2.2. Work Product. As part of Vendor's performance of Services, Vendor will furnish to University the following work product ("Work Product"):

Data set

2.3. Discrepancies/Questions. If any discrepancies or questions arise during Vendor's performance of the contract, Vendor is responsible for obtaining written clarification from University's Technical Representative before providing the Services at issue. Vendor waives all claims for adjustment arising from Vendor's performance outside the scope of Services without a written contract amendment.

2.4. Warranty. Vendor warrants that the Services (i) will be performed in a timely, competent, workmanlike and professional manner and (ii) will conform to the contract specifications, documentation and requirements and to applicable industry standards for quality.


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

ARTICLE 3. Term and Termination

- 3.1. **Term.** This contract shall not be binding until it is signed by both parties. The Effective Date of the contract shall be the last signature date appearing below. The term of this contract shall commence on the "Effective Date". Unless renewed by University in accordance with Section 3.2, this contract shall expire on 12/31/2020.
- 3.2. **Right to Renew.** This contract is not renewable.
- 3.3. **Termination for Cause.** A party that defaults in performance or commits a material breach of this contract ("defaulting party") shall have 10 days to cure the default or breach after receiving notice from the other party. The non-defaulting party may terminate this contract without further notice and pursue other available legal remedies if the defaulting party fails to cure the breach within the prescribed period, or within such other period of time that is agreed by the parties in writing.
- 3.4. **Termination for Convenience.** University may terminate this contract for convenience and without any cause by providing at least 30 calendar days' prior written notice to Vendor.
- 3.5. **Termination for Non-Appropriation.** This contract is subject to termination by University in any year for which the General Assembly fails to make an appropriation to make payments under the contract.
- 3.6. **Effect of Termination.** In the event of early termination for any cause, Vendor shall stop performance in accordance with the notice of termination and shall submit to University a final bill for Services performed to the date of termination. University is not obligated to pay Vendor for Services until Vendor provides all Work Product that is in progress or completed as of the date of termination. Vendor must comply with University's instructions to either destroy or return to University all information previously furnished to Vendor.

ARTICLE 4. Compensation

- 4.1. **Compensation.** University shall pay Vendor compensation at the rate of \$7110 for Services performed to University's reasonable satisfaction in accordance with the Scope of Services set forth in Section 2.1 above and with the specifications and requirements set forth in Section 2.2 above, if any. University shall reimburse Vendor in accordance with University policy for expenses not included in the compensation rate only if preauthorized in writing by University's representative. Expenses shall be reimbursable only if submitted with all supporting documentation reasonably required by University. University's obligation for total

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka


compensation, including authorized expenses, shall not exceed \$7,110.00 unless approved by written amendment to this contract in accordance with University policies and applicable law.

- 4.2. **Billing and Payment.** In order to be paid, Vendor must submit a proper invoice to University of Illinois, Invoice Processing Center, P.O. Box 820, Rantoul IL 61866 no more frequently than monthly. A proper bill must include: itemized detail, invoice number, invoice date, invoice amount, remittance address and the University purchase order number. University will either approve the bill for payment, or deny a bill with defects, in accordance with the State Prompt Payment Act (30 ILCS 540) (the "Act"). University will assign a new date of receipt to a bill resubmitted in proper form. University will pay interest on approved bills that are not paid within the time period prescribed by the Act. The rate of interest shall be the rate established in the Act on the date that payment becomes late within the meaning of the Act. University will not pay interest of \$5 or less and may subtract any applicable discounts before payment.
- 4.3. **Withholdings.** University may withhold or may void any invoice to the extent University deems necessary to protect University from loss due to Vendor's: (a) unsatisfactory performance; (b) failure to pay subcontractors; (c) damage to University property; or (d) incomplete, inaccurate or unauthorized billing. University may withhold final payment until Vendor has performed all Services to University's reasonable satisfaction in accordance with the specification and requirements for the Work Product.
- 4.4. **Price Adjustments upon Renewal.** If renewals are permitted, Vendor must notify University at least 90 calendar days prior to the contract expiration date of any changes to rates and price schedules. Any rate changes shall be in accordance with Vendor's original quotation or response to solicitation. The parties will reflect any rate/price changes in a written contract amendment.

ARTICLE 5. Notices

- 5.1 **Delivery.** To be enforceable, all notices must be in writing and delivered to the party's representative(s) named below, appropriate to the nature of the notice, by either certified mail, return receipt requested, or commercial carrier with delivery receipt. Notices are effective upon receipt by the designated representative. A party may change its representative at any time by written notice to the other party.
- 5.2 **Directing Notices.** Vendor shall direct all general notices or matters of contract interpretation to University Contract Representative and notices involving technical or scheduling issues to University's Technical Representative. Vendor must include University's contract number or

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

relevant purchase order number in any notice. Vendor shall direct all formal legal notices to the Board of Trustees.

University Contract Representative	Vendor Contract Representative
Nester Komolafe Purchasing Division 809 S. Marshfield, M/C 560 Chicago, IL 60612 Telephone: (312) 217-1682 Facsimile: (312) 996-3135 Email: nester@uic.edu	Shivaprasad Goudar KLE Jawaharlal Nehru Medical College Faculty of Medicine, KLE University Kptcl Colony, Nehru Nagar, Belagavi Belagavi, Karnataka, India 590010 Telephone: +91-831-2474200 Facsimile: +91-831-2472891 Email: sgoudar@jnmc.edu
University Technical Representative	University Legal Notices
Helene Gussin Pediatrics hgussin@uic.edu	The Board of Trustees of the University of Illinois Attn: Secretary of the Board 352 Henry Administration Building, MC-350 506 South Wright Street Urbana, Illinois 61801

ARTICLE 6. INSURANCE

Unless exempt by law, Vendor shall maintain the insurance coverages set forth below and shall provide evidence of such coverage to University's Contract Representative upon request. Vendor shall ensure that all subcontractors comply with the same insurance requirements. Subcontractors shall submit the required Certificate of Insurance through Vendor. Failure to comply with the insurance requirements constitutes a material breach of this contract.

With respect to the Commercial General Liability Insurance, Vendor shall name the Board of Trustees of the University of Illinois as an additional insured. In order to meet this requirement, wording substantially similar to the following must appear on the Certificate of Insurance: *The Board of Trustees of the University of Illinois is an additional insured for liability incurred by the University arising out of the activities of Vendor/Contractor and any of its subcontractors.* Vendor shall ensure that the relevant P.O. or Contract Number is indicated on the Certificate of Insurance.

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

<p>Worker's Compensation, including Occupational Diseases</p>	
<ul style="list-style-type: none"> • Coverage A • Coverage B <p>Check if "sole proprietor" and Workers' Compensation (Coverage A&B) are not applicable. NOTE: If company is in the construction business, trucking business operating at a construction site, or other hazardous occupation, 820 ILCS 185 of the Illinois Combined Statutes requires that even "sole proprietors" MUST obtain insurance.</p>	<p>minimum Illinois Statutory limits</p> <p>minimum \$500,000 E.L. each disease minimum \$500,000 E.L. each employee minimum \$500,000 E.L. policy limit</p>
<p>Commercial General Liability, including contractual liability</p> <ul style="list-style-type: none"> • Each Occurrence • General Aggregate • Products-Completed Operations Aggregate • Personal & Advertising Injury • Fire Damage Legal Liability 	<p>minimum \$1,000,000</p> <p>minimum \$2,000,000 aggregate</p> <p>minimum \$2,000,000 aggregate</p> <p>minimum \$1,000,000</p> <p>minimum \$100,000</p>
<p>Auto Liability (either personal or commercial as applicable)</p> <ul style="list-style-type: none"> • Combined Single Limit <p>OR</p> <ul style="list-style-type: none"> • Bodily Injury • Property Damage 	<p>minimum \$1,000,000 per occurrence</p> <p>minimum \$1,000,000</p> <p>minimum \$1,000,000</p>

Umbrella liability insurance may be used to meet the minimum coverage requirements shown above.

Additional insurance requirements for this contract are checked below:

ATTESTED


Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

<input type="checkbox"/> Professional Liability – Specialty Errors and Omissions	\$1,000,000 per claim \$3,000,000 annual aggregate
<input type="checkbox"/> Professional Liability – Medical Malpractice	\$1,000,000 per claim \$3,000,000 annual aggregate

When the services include any professional services, Vendor shall maintain professional liability insurance coverage for Vendor and its employees and agents to include coverage for errors, omissions, and negligent acts related to the rendering of such professional services with limits not less than \$1,000,000 per claim and \$3,000,000 annual aggregate. Coverage extensions shall include contractual liability. When policies are renewed or replaced, any retroactive date must coincide with, or precede commencement of services by Vendor or subcontractor under this contract. A claims-made policy that is replaced or not renewed must have an extended reporting period not less than two years.

<input type="checkbox"/> Employee Dishonesty	\$150,000 each occurrence
--	---------------------------

Vendor shall furnish any original Certificate(s) of Insurance evidencing the required coverage to be in force on the date of this contract, and any renewal Certificate(s) of Insurance if coverage has an expiration or renewal date occurring during the term of this contract to the University of Illinois, Purchasing Division, 809 S. Marshfield, m/c 560, Chicago, IL 60612. University's receipt of a Certificate of Insurance does not constitute University's acknowledgment or agreement that insurance requirements have been met. Failure of University to obtain Certificate(s) or other insurance evidence from the Vendor shall not be deemed a waiver of these insurance requirements by University. Vendor's failure to comply with insurance requirements constitutes a material breach of contract terms.

ARTICLE 7. Indemnification

Vendor shall fully indemnify University, its officers, employees, trustees, students, and agents against all demands, claims, damages, liabilities, expenses and reasonable attorney fees and cost arising out of the performance of this Contract by Vendor, its employees, and agents. This indemnification obligation shall survive the termination or the cancellation of the Contract and any order made under it.

ATTESTED
ATTESTED

[Signature]
Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

ARTICLE 8. Subcontracts

Vendor shall provide an attachment listing all known or anticipated subcontracts with an annual value of \$50,000 or more. The attachment shall include the proposed value of each subcontract and the name and address of the subcontractor. Vendor shall not subcontract any portion of the Services without University's prior written permission and shall promptly notify University of any proposed change in subcontractors, together with all relevant information requested by University.

ARTICLE 9. Confidentiality

- 9.1. **General.** Vendor must treat all information relating to this contract as confidential ("University Information"). Unless required by law, Vendor shall not disclose University Information to third parties or use University Information for any purpose other than in performing the Services except as authorized in advance in writing by University.
- 9.2. **Family Educational Rights and Privacy Act, 20 U.S.C. §1232g (FERPA).** Unless authorized by law or by written permission of the student, Vendor shall not disclose to any third party information concerning University students. Vendor shall protect all records containing student information in accordance with FERPA and University policy. In addition to other remedies, University may terminate this contract immediately upon information that Vendor may have violated this provision.
- 9.3. **Illinois Personal Information Protection Act, 815 Ill. Comp. Stat. 530 (PIPA).** If applicable, Vendor will cooperate in good faith with University to maintain security and integrity of *personal information* in compliance with PIPA.
- 9.4. **Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, 45 C.F.R. parts 160 and 164.** If Vendor is University's *Business Associate*, as that term is defined by the HIPAA Privacy Rule at 45 C.F.R. §160.103, then Vendor agrees to the terms of the HIPAA Business Associate Agreement attached as Exhibit C.

ARTICLE 10. Rights in Work Product

- 10.1. **Title to Work Product.** Title to all Work Product made under this contract vests in University upon delivery by Vendor. University shall have the exclusive right to use Work Product for any purpose without further obligation to Vendor. Vendor represents that Work Product is original and does not infringe on third party rights. Vendor will not place any restrictive markings upon Work Product.

ATTESTED
k

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- 10.2. **Pre-Existing Rights.** University shall not claim any interest in Vendor's materials, products, inventions or know-how existing prior to formation of this contract. Vendor grants to University a royalty-free, nonexclusive, irrevocable, worldwide license to make, use, sell, and to reproduce, distribute, prepare derivative works and perform, as the case may be, any pre-existing materials, products, inventions or know-how that are included by Vendor in the Work Product provided to University under this contract.
- 10.3. **Third Party Property.** Vendor shall not incorporate into the Work Product any third party property without University's prior written authorization. If University permits Vendor's use of third party property in the Work Product, Vendor must obtain for University a license at no cost to University that will enable University to use the Work Product without restriction. Vendor shall defend and indemnify University against all third party claims for infringements related to the Work Product unless otherwise expressly agreed by University in writing.

ARTICLE 11. Records Retention and Audits

- 11.1. **Maintenance of Books and Records.** Vendor shall maintain books and records that relate to performance of this contract and that support amounts charged for three years from the date of final payment or for such longer period of time as is necessary to complete ongoing or announced audits or to comply with any applicable federal requirements.
- 11.2. **Right of Inspection.** University may reasonably inspect Vendor's premises, facilities, equipment, and investigate the business reputation and other qualifications of Vendor and any of Vendor's subcontractors throughout the term of this contract.
- 11.3. **Litigation Hold Order Compliance.** Vendor shall, and shall cause Vendor's employees and subcontractors to, fully comply with any litigation hold order issued by University in anticipation of third party litigation relating to this contract. Vendor shall promptly retrieve, recover, preserve, and retain and, subject to legal privileges, deliver any information and documents, in any format, covered by a litigation hold order.

ARTICLE 12. General Terms

- 12.1. **Ambiguities.** Any rule of construction that would resolve ambiguities against the drafting party shall not apply in interpreting this contract.
- 12.2. **Amendments.** No modification of this contract shall be effective unless made by a written amendment signed by each party's authorized signatory.
- 12.3. **Assignment.** Neither party may assign its obligations under this contract without the prior

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

written consent of the other party.

- 12.4. **Authorized Signatories.** The individuals signing this contract on a party's behalf represent that they have the requisite authority and intent to bind that party to this contract.
- 12.5. **Choice of Law.** This contract shall be interpreted by application of Illinois law without regard to its conflicts provisions.
- 12.6. **Compliance with Laws.** Vendor shall perform all obligations under this contract in compliance with all applicable laws governing the performance. Breach of this provision constitutes a material breach of this contract.
- 12.7. **Counterparts/Facsimile Signatures.** This contract may be signed in counterparts. Facsimile signatures constitute original signatures for all purposes.
- 12.8. **Excluded Parties.** Vendor certifies that neither Vendor nor any of Vendor's directors, officers, employees, agents and subcontractors who may provide services pursuant to this contract (individually an "Agent") is presently debarred, suspended, proposed for debarment, declared ineligible or otherwise excluded from transactions with the U.S. Government or by any federal government agency. Vendor shall provide University immediate written notice if Vendor learns that this certification was erroneous when made or if Vendor or any of Agents hereafter becomes debarred, suspended, proposed for debarment, declared ineligible or otherwise excluded from transactions with the U.S. Government or by any Federal agency. Vendor further certifies that neither Vendor nor any Agents is presently subject to an investigation or proceeding to exclude either as a provider under Medicare or Medicaid or under any other federal or state health care program or under any third party insurance program, nor is currently excluded or debarred from submitting claims to Medicare or Medicaid or to any other federal or state health care program or to any third party insurer. University may terminate this contract immediately without any penalty to University if either of these certifications was erroneous when made or becomes no longer valid during the term of this contract.
- 12.9. **Force Majeure.** A party is excused from performing its obligations under this contract when conditions beyond its control and unforeseen by the parties make its performance commercially impractical, illegal, or impossible. Conditions of excuse include, but are not limited to: natural disasters, strikes, fires, war, terrorism and threats of terrorism, government actions, and acts or omissions of third parties. So long as the conditions continue, the party whose performance is affected shall keep the other party fully informed about the conditions and the prospects of their ending.
- 12.10. **Headings.** Headings in this contract are intended only to assist with readability and are not

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

substantive.

12.11. Independent Contractor. The parties are independent contractors with respect to each other. Nothing in this contract is intended to create any association, partnership, joint venture, or agency relationship between them.

12.12. Integration. This contract with its attachments, amendments and incorporated references constitutes the parties' entire agreement regarding the subject matter.

Attachments include:

Exhibit A - State Clauses and Certifications (Included below)

Optional Attachments:

- Exhibit B - Financial Disclosures & Conflicts of Interest
- Exhibit C - Business Associate Agreement
- Exhibit D - (federal clauses)
- Exhibit E - Joint Commission CMS Clauses
- Other:

12.13. Jurisdiction. Any claims against University must be filed in accordance with the Illinois Court of Claims Act.

12.14. Severability. If any provision of this contract is held by a court of competent jurisdiction to be unenforceable, the provision shall be severed from this contract so long as severance does not affect the enforceability or essential purpose of the remainder of the contract.

12.15. Sovereign Immunity. By entering into this contract, University does not waive the sovereign immunity or any other defenses and immunities afforded to it by Illinois and federal law.

12.16. Use of Name. Vendor shall not use University's name or protected marks for any commercial purpose without University's advance written consent.

12.17. Waiver. The failure of either party to enforce any provision of this contract shall not waive the party's right to later enforce the provision or the contract.

ATTESTED

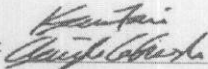


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

THE BOARD OF TRUSTEES OF THE
UNIVERSITY OF ILLINOIS

KLE JAWAHARLAL NEHRU MEDICAL
COLLEGE

By:  _____

Kevin Fair, Associate Director of Purchasing
2019.12.17 13:21:21 -06'00'

By:  _____

Printed: Dr. N.S. Mahantashetti

Title: Principal, J.N. Medical College, Belagavi

Date: 26/12/2019

Approved as to legal form by Office of University Counsel on 1/16/15

Text

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Exhibit A

Certifications

Vendor acknowledges and agrees that compliance with this subsection in its entirety for the term of any resulting contract and any renewals is a material requirement and condition of the contract. By executing the contract Vendor certifies compliance with this subsection in its entirety, and is under a continuing obligation to remain in compliance and report any non-compliance.

This subsection, in its entirety, applies to subcontractors used on this contract. Vendor shall include these Standard Certifications in any subcontract used in the performance of the contract using the Standard Subcontractor Certification form provided by the State.

If the contract extends over multiple fiscal years, including the initial term and all renewals, Vendor and its subcontractors shall confirm compliance with this section in the manner and format determined by the State by the date specified by the State and in no event later than July 1 of each year that the contract remains in effect.

If the Parties determine that any certification in this section is not applicable to the contract it may be stricken without affecting the remaining subsections.

1. As part of each certification, Vendor acknowledges and agrees that should Vendor or its subcontractors provide false information, or fail to be or remain in compliance with the Standard Certification requirements, one or more of the following sanctions will apply:

- the contract may be void by operation of law,
- the State may void the contract, and
- the Vendor and its subcontractors may be subject to one or more of the following: suspension, debarment, denial of payment, civil fine, or criminal penalty.

Identifying a sanction or failing to identify a sanction in relation to any of the specific certifications does not waive imposition of other sanctions or preclude application of sanctions not specifically identified.

2. Vendor certifies it and its employees will comply with applicable provisions of the United States Civil Rights Act, Section 504 of the Federal Rehabilitation Act, the Americans with Disabilities Act, and applicable rules in performance of this contract.
3. **This applies to individuals, sole proprietorships, partnerships and LLCs, but is otherwise not applicable.** Vendor, if an individual, sole proprietor, partner or an individual as member of a LLC, certifies he/she is not in default on an educational loan. 5 ILCS 385/3
4. Vendor certifies that it has reviewed and will comply with the Department of Employment Security Law (20 ILCS 1005/1005-47) as applicable.
5. **This applies only to certain service contracts and does NOT include contracts for professional or artistic services.** To the extent there was a current Vendor providing the services covered by this contract and the employees of that Vendor who provided those services are covered by a collective bargaining agreement, Vendor certifies (i) that it will offer to assume the collective bargaining obligations of the prior employer, including any existing collective bargaining agreement with the bargaining representative of any existing collective bargaining unit or units performing substantially similar work to the services covered by the contract subject to its bid or offer; and (ii) that it shall offer employment to all employees currently employed in any existing bargaining unit who perform substantially similar work to the work that will be performed pursuant to this contract. This does not apply to heating, air conditioning, plumbing and electrical service contracts. 30 ILCS 500/25-80

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

6. Vendor certifies it has neither been convicted of bribing or attempting to bribe an officer or employee of the State of Illinois or any other State, nor made an admission of guilt of such conduct that is a matter of record. 30 ILCS 500/50-5
7. If Vendor has been convicted of a felony, Vendor certifies at least five years have passed after the date of completion of the sentence for such felony, unless no person held responsible by a prosecutor's office for the facts upon which the conviction was based continues to have any involvement with the business. 30 ILCS 500/50-10
8. If Vendor or any officer, director, partner, or other managerial agent of Vendor has been convicted of a felony under the Sarbanes-Oxley Act of 2002, or a Class 3 or Class 2 felony under the Illinois Securities Law of 1953, Vendor certifies at least five years have passed since the date of the conviction. Vendor further certifies that it is not barred from being awarded a contract. 30 ILCS 500/50-10.5
9. Vendor certifies it is not barred from having a contract with the State based upon violating the prohibitions related to either submitting/writing specifications or providing assistance to an employee of the State of Illinois by reviewing, drafting, directing, or preparing any invitation for bids, a request for proposal, or request of information, or similar assistance (except as part of a public request for such information). 30 ILCS 500/50-10.5(e)
10. Vendor certifies that it and its affiliates are not delinquent in the payment of any debt to the State (or if delinquent have entered into a deferred payment plan to pay the debt. 30 ILCS 500/50-11, 50-60
11. Vendor certifies that it and all affiliates shall collect and remit Illinois Use Tax on all sales of tangible personal property into the State of Illinois in accordance with provisions of the Illinois Use Tax Act. 30 ILCS 500/50-12
12. Vendor certifies that it has not been found by a court or the Pollution Control Board to have committed a willful or knowing violation of the Environmental Protection Act within the last five years, and is therefore not barred from being awarded a contract. 30 ILCS 500/50-14
13. Vendor certifies it has neither paid any money or valuable thing to induce any person to refrain from bidding on a State contract, nor accepted any money or other valuable thing, or acted upon the promise of same, for not bidding on a State contract. 30 ILCS 500/50-25
14. Vendor certifies it has read, understands and is not knowingly in violation of the "Revolving Door" provisions of the Illinois Procurement Code. 30 ILCS 500/50-30
15. Vendor certifies that if it hires a person required to register under the Lobbyist Registration Act to assist in obtaining any State contract, that none of the lobbyist's costs, fees, compensation, reimbursements or other remuneration will be billed to the State. 30 ILCS 500/50-38
16. Vendor certifies that it will not retain a person or entity to attempt to influence the outcome of a procurement decision for compensation contingent in whole or in part upon the decision or procurement. 30 ILCS 500/50-38
17. Vendor certifies it will report to the Illinois Attorney General and the Chief Procurement Officer any suspected collusion or other anti-competitive practice among any bidders, offerors, contractors, proposers, or employees of the State. 30 ILCS 500/50-40, 50-45, 50-50

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

18. Vendor certifies that if it is awarded a contract through the use of the preference required by the Procurement of Domestic Products Act, then it shall provide products pursuant to the contract or subcontract that are manufactured in the United States. 30 ILCS 517
19. Vendor certifies steel products used or supplied in the performance of a contract for public works shall be manufactured or produced in the United States, unless the executive head of the procuring Agency/University grants an exception. 30 ILCS 565
20. Drug Free Workplace
 - 20.1 If Vendor employs 25 or more employees and this contract is worth more than \$5,000, Vendor certifies it will provide a drug free workplace pursuant to the Drug Free Workplace Act
 - 20.2 If Vendor is an individual and this contract is worth more than \$5000, Vendor certifies it shall not engage in the unlawful manufacture, distribution, dispensation, possession, or use of a controlled substance during the performance of the contract. 30 ILCS 580
21. Vendor certifies that neither Vendor nor any substantially owned affiliate is participating or shall participate in an international boycott in violation of the U.S. Export Administration Act of 1979 or the applicable regulations of the United States Department of Commerce. 30 ILCS 582
22. Vendor certifies that no foreign-made equipment, materials, or supplies furnished to the State under the contract have been or will be produced in whole or in part by forced labor or indentured labor under penal sanction. 30 ILCS 583
23. Vendor certifies that no foreign-made equipment, materials, or supplies furnished to the State under the contract have been produced in whole or in part by the labor of any child under the age of 12. 30 ILCS 584
24. This applies to information technology contracts and is otherwise not applicable. Vendor certifies that information technology, including electronic information, software, systems and equipment, developed or provided under this contract comply with the applicable requirements of the Illinois Information Technology Accessibility Act Standards as published at (www.dhs.state.il.us/iitaa). 30 ILCS 587
25. **This only applies to vendors who own residential buildings but is otherwise not applicable** . Vendor certifies, if it owns residential buildings, that any violation of the Lead Poisoning Prevention Act has been mitigated. 410 ILCS 45
26. Vendor certifies it has not been convicted of the offense of bid rigging or bid rotating or any similar offense of any state or of the United States. 720 ILCS 5/33 E-3, E-4
27. Vendor certifies it complies with the Illinois Department of Human Rights Act and rules applicable to public contracts, which include providing equal employment opportunity, refraining from unlawful discrimination, and having written sexual harassment policies. 775 ILCS 5/2-105
28. Vendor certifies it does not pay dues to or reimburse or subsidize payments by its employees for any dues or fees to any "discriminatory club." 775 ILCS 25/2
29. Vendor warrants and certifies that it and, to the best of its knowledge, its subcontractors have and will comply with Executive Order No. 1 (2007). The Order generally prohibits Vendors and subcontractors from hiring the then-serving Governor's family members to lobby procurement activities of the State, or any other unit of government in Illinois including local governments if that

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

procurement may result in a contract valued at over \$25,000. This prohibition also applies to hiring for that same purpose any former State employee who had procurement authority at any time during the one-year period preceding the procurement lobbying activity.

30. Vendor certifies that if an individual, sole proprietor, partner or an individual as a member of a LLC, he/she has not received an early retirement incentive prior to 1993 under Section 14-108.3 or 16-133.3 of the Illinois Pension Code or an early retirement incentive on or after 2002 under Section 14-108.3 or 16-133.3 of the Illinois Pension Code. 30 ILCS 105/15a; 40 ILCS 5/14-108.3; 40 ILCS 5/16-133

31. Vendor certifies that it has read, understands, and is in compliance with the registration requirements of the Elections Code (10 ILCS 5/9-35) and the restrictions on making political contributions and related requirements of the Illinois Procurement Code. Vendor will not make a political contribution that will violate these requirements. 30 ILCS 500/20-160 and 50-37

In accordance with section 20-160 of the Illinois Procurement Code, Vendor certifies as applicable:

Vendor is not required to register as a business entity with the State Board of Elections.

or

Vendor has registered with the State Board of Elections. As a registered business entity, Vendor acknowledges a continuing duty to update the registration as required by the Act.

32. A person (other than an individual acting as a sole proprietor) must be a duly constituted legal entity and authorized to do business in Illinois prior to submitting a bid or offer. If you do not meet these criteria, then your bid or offer will be disqualified. 30 ILCS 500/20-43

Vendor must make one of the following four certifications by checking the appropriate box. If C or D is checked, then Vendor must attach to this form the requested documentation.

- A. Vendor certifies it is an individual acting as a sole proprietor and is therefore not subject to the requirements of section 20-43 of the Procurement Code.
- B. Vendor certifies that it is a legal entity, and was authorized to do business in Illinois as of the date for submitting this bid or offer. The State may require Vendor to provide evidence of compliance before award.
- C. Vendor certifies it is a legal entity, and is a foreign corporation performing activities that do not constitute transacting business in Illinois as defined by Illinois Business Corporations Act (805 ILCS 5/13.75). A vendor claiming exemption under the Act must include a detailed explanation of the legal basis for the claim with its bid or offer and must provide additional detail upon request. If Vendor fails to provide the mandatory documentation with the bid or offer, or does not provide additional detail upon request within the timeframe specified in said request, then the State may deem the Vendor as being non-responsive or not responsible and may disqualify the Vendor.
- D. Vendor certifies it is a legal entity, and is an entity otherwise recognized under Illinois law as eligible for a specific form of exemption similar to those found in the Illinois Business Corporation Act (805 ILCS 5/13.75). A vendor claiming exemption under a specific law must provide a detailed explanation of the legal basis for the claim with its bid or offer and must provide additional detail upon request. If Vendor fails to provide the mandatory documentation with the bid or offer, or does not provide additional detail upon request within the timeframe specified in said request, then the State may deem the Vendor as being non-responsive or not responsible and may disqualify the Vendor.

v.14.2

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



World Health
Organization

**COVERING LETTER
LETTRE D'ACCOMPAGNEMENT**

Global Procurement
and Logistics
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS

WHO Reference 2018/791908-0
Purchase Order 201940772
Unit Reference

DR. Shivaprasad Goudar
PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM (JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM)
KARNATAKA
Nehru Nagar
Belgaum
Karnataka
India

TECHNICAL SERVICES AGREEMENT (TSA)

Re: Original TSA: PO 201737246

This additional amount is required to complete the tasks under the original TSA.

To conduct preparatory activities for WHO ACTION-1 and ACTION-2 Trials. To initiate participant recruitment for WHO ACTION-1 Trial

We are enclosing the Technical Services Agreement between the World Health Organization and PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM (JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM), KARNATAKA, in the amount of INR 2,803,640.00 (Two Million Eight Hundred Three Thousand Six Hundred Forty), for conducting the above-mentioned work. We also enclosed five attachment(s) referenced in the Agreement.

Kindly acknowledge your acceptance of this contract by returning the email with a copy of duly signed Purchase Order (all pages).

For any technical or scientific questions related to this Agreement, please contact the responsible technical officer, Joshua VOGEL, vogeljo@who.int.

On behalf of the World Health Organization, we thank you for your collaboration.

Cc: WHO Representative, India

WHO Global Service Centre

Concerne: Original TSA: PO 201737246

This additional amount is required to complete the tasks under the original TSA.

To conduct preparatory activities for WHO ACTION-1 and ACTION-2 Trials. To initiate participant recruitment for WHO ACTION-1 Trial

Veillez trouver ci-joint l'Accord de Services Techniques entre l'Organisation Mondiale de la Santé et PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM (JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM), KARNATAKA, pour un montant de INR 2,803,640.00 (Two Million Eight Hundred Three Thousand Six Hundred Forty), vous permettant de mener à bien le travail susmentionné. Veuillez également trouver five pièces jointes mentionnées dans l'Accord.

Merci de confirmer votre acceptation de ce contrat en nous retournant le courriel et une copie dûment signée du Bon de Commande (complet)

Pour toutes questions à caractère scientifique ou technique ayant trait à cet Accord, veuillez contacter le responsable technique Joshua VOGEL, vogeljo@who.int.

Au nom de l'Organisation Mondiale de la Santé, nous vous remercions de votre collaboration.

Centre de Soutien Administratif Mondial de l'OMS

Cc: Représentant de l'OMS, India

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



**TECHNICAL SERVICES
AGREEMENT
ACCORD DE SERVICES
TECHNIQUES**

The WORLD HEALTH ORGANIZATION hereby agrees to provide to
L'ORGANISATION MONDIALE DE LA SANTÉ s'engage par la présente à fournir à
INSTITUTION:

PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM
(JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM)
KARNATAKA
PRINCIPAL INVESTIGATOR
Karnataka
India

Principal Investigator: DR.Shivaprasad Goudar
Telephone:
Fax:
Email/Courriel:

The Amount of/Un Montant de: INR 2,803,640.00 (Two Million Eight Hundred Three Thousand Six Hundred Forty)
in respect of/en vue de: Original TSA: PO 201737246

This additional amount is required to complete the tasks under the original TSA.
To conduct preparatory activities for WHO ACTION-1 and ACTION-2 Trials. To initiate participant recruitment for WHO ACTION-1 Trial

For the period financed by this Agreement From/De : 16-FEB-2018
Période du projet financée par le présent accord To/A : 30-JUN-2018

Summary of work/ Description sommaire des travaux:

1. Description of work under this Agreement/ Description des travaux faisant l'objet du présent accord:

Please see PO 201737246.

This additional amount (44'075 USD) is required to complete the tasks under the original TSA.

A65913 (ACTION 1)
A65916 (ACTION 2)

See attached protocol

2. Contribution of the Institution and/or other sources for the project (Staff, equipment, supplies, etc. excluding general facilities).
The Institute will provide all facilities, equipment and personnel not covered by this Agreement.
Contribution de l'Institution ou de tout autre organisme à l'exécution du projet (personnel, matériel, fournitures, etc. à l'exclusion des services d'ordre général). L'Institution s'engage à fournir les locaux, équipement et personnels non couverts par cet accord.

Financial Arrangements/ Dispositions financiers:

1. Payments will be made as follows/Les versements seront effectués comme suit:

	Deliverable/ Résultat	Due Date/ Date Remise	%	Currency Amount/ Montant en Devise
1	Upon signature	22-FEB-2018	100.00	2,803,640.00
2	Financial Report	30-JUN-2018	0.00	0.00
3	Technical report	30-JUN-2018	0.00	0.00

2. INR 0.00 will be used by WHO for the purchase of equipment and supplies to be ordered by the Institution as soon as practicable, but not beyond 31 December of the year following the end of the Agreement period as indicated above at which time any uncommitted balance will revert to WHO.

INR 0.00 seront affectés par l'OMS à l'achat de matériels et de fournitures à commander par l'Institution dès que possible, mais au plus tard avant le 31 décembre de l'année suivant la fin de la période susmentionnée d'exécution de l'accord, étant entendu qu'à ce moment tout solde non engagé fera retour à l'OMS.

Annexes

The following annexes form an integral part of this Agreement/ Les annexes listées ci-dessous font partie intégrante de cet accord:

Annex	File Description/Description de fichier
1	2018/791908 Contractual - Budget Breakdown
2	2018/791908 Contractual - Statement of Work
3	2018/791908 Contractual - Statement of Work
4	2018/791908 Contractual - Statement of Work
5	2018/791908 Contractual - Terms of Reference

In the event that the terms of the annexes contain any provisions which are contrary to the terms of this Agreement, the terms of this Agreement shall take precedence/ En cas de contradiction entre les termes apparaissant sur les



World Health Organization

Global Procurement and Logistics
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS	
WHO Reference	2018/791908-0
Purchase Order	201940772
Unit Reference	

**TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES**

annexes et ceux de l'Accord, les dispositions de l'Accord prévaudront dans tous les cas.

General

The parties accept the "General Conditions" overleaf, which constitute an integral part of this Agreement. The Institution certifies the correctness of the banking instructions provided on Page 1.
All necessary arrangements to comply with national regulations relating to this project and relevant to the Institution's responsibilities shall have been under-taken by the Institution; failure to do so will nullify this Agreement. The responsibility of the World Health Organization is limited only to the financial support as specified in this Agreement.

Généralités

Les parties acceptent les "Conditions générales" reproduites au verso, lesquelles font partie intégrante du présent accord. L'Institution certifie l'exactitude des instructions bancaires indiquées à la page 1.
Toutes les dispositions relevant des responsabilités de l'Institution et nécessaires à la mise en conformité de ce Projet avec la réglementation nationale, devront avoir été prises par l'Institution, faute de quoi l'accord sera nul. La responsabilité de l'Organisation Mondiale de la Santé se limite au soutien financier spécifié dans le présent accord.

ON BEHALF OF WHO/ POUR L'OMS

Responsible WHO Technical Officer:
Fonctionnaire technique responsable de l'OMS:

Joshua Vogel
Technical Officer
HQ/RHR - Reproductive Health and Research

Responsible Divisional Director
Directeur de division responsable

Ian ASKEW
Director
HQ/RHR - Reproductive Health and Research

Authorized Signatory:
Signataire autorisé:

Mr. Motohiro Ogita
Coordinator
Global Procurement and Logistics
(WHO/GMG/GSC/GPL)

Fauziah Binti Ahmad
National Professional Officer (Procurement)
HQ/GSC Global Service Centre
02-MAR-2018

* An official of the Institution - other than the Principal Investigator - fully empowered to enter into contracting arrangements on behalf of the Institution. *Un responsable de l'institution autre que le Chercheur principal - ayant pleins pouvoirs pour passer un contrat au nom de l'institution.*

PRINCIPAL INVESTIGATOR/ CHERCHEUR PRINCIPAL

Principal Investigator or Technical Officer responsible for the project.
Chercheur Principal ou membre du personnel technique responsable de l'exécution du projet.

Signature :

Dr Shivaprasad Goudar
20/03/2018

ON BEHALF OF THE INSTITUTION/ POUR L'INSTITUTION

Responsible Administrative Authority*
*Autonté administrative responsable**

Signature :
Name/nom : (Dr. (ms)) N.S. Mahantshetti
Division : Principal
Date : 20/03/2018

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



TECHNICAL SERVICES AGREEMENT ACCORD DE SERVICES TECHNIQUES

Global Procurement and Logistics Block 3510 Jalan Teknokrat 6 63000 Cyberjaya MALAYSIA gsc-procurement@who.int

Table with WHO Reference, Purchase Order, and Unit Reference details.

GENERAL CONDITIONS

The following are the general conditions relating to this Agreement concerning WHO support for research or other technical services.

1 INSTITUTION AND PRINCIPAL INVESTIGATOR

1.1 The Institution and the Principal Investigator (or Responsible Technical Officer), who must be an employee of the Institution, shall be jointly responsible for all the technical and administrative aspects of the work referred to in this Agreement.

2. FINANCIAL ARRANGEMENTS

2.1 Payments shall be made to the bank account(s) of the Institution as specified in this Agreement and in accordance with the schedule of payments contained therein.

3. EQUIPMENT AND SUPPLIES

3.1 Unless otherwise agreed, and subject to subparagraph 3.2 below, any equipment acquired under this Agreement shall become the property of the Institution.

4. REPORTS

The Institution shall submit technical and financial reports to WHO on the work as required, or at least annually, in accordance with the following provisions:

5. RELATIONSHIP AND RESPONSIBILITY OF PARTIES

The relationship of the Institution to WHO shall be that of an independent contractor. The employees of the Institution are not entitled to describe themselves as staff members of WHO.

6. USE OF RESULTS, EXPLOITATION OF RIGHTS, AND PUBLICATION

6.1 The results of the project funded under this Agreement may be freely used or disclosed by either party provided that, without the consent of the other party, no use may be made for commercial purposes and confidentiality shall be maintained with respect to results that may be eligible for protection by proprietary rights.

including the ownership of know-how, arising from the project shall be designed to achieve, in so far as circumstances permit, the following objectives in the following order of priority:

- a. the general availability of the products of creative activity;
b. the availability of those products to the public health sector on preferential terms, particularly in developing countries;
c. the grant to each party of additional benefits, including royalties, account being taken of the relative value of each party's financial, intellectual and other contribution to the research.

7. RESEARCH INVOLVING HUMAN SUBJECTS

7.1 Ethical Aspects
It is the responsibility of the Institution and the Principal Investigator to safeguard the rights and welfare of human subjects involved in research supported in whole or in part by funds from WHO, in accordance with the appropriate national code of ethics or legislation, if any, and in the absence thereof, the Helsinki Declaration and any subsequent amendments.

8. RESEARCH INVOLVING THE USE OF LABORATORY ANIMALS

The Institution undertakes that living vertebrate animals, required for use as laboratory animals for the research to be carried out under this Agreement, shall be handled in accordance with generally accepted principles for the humane treatment of such animals and the avoidance of unnecessary suffering.

9. RESEARCH SAFETY

It is the responsibility of the Institution to establish and implement policies and practices to assure and provide for the safety of its employees, the public, and the environment during the conduct of the supported research.

10. PUBLICITY

The Institution and the Principal Investigator shall not refer to the relationship of WHO to the project, or to products or processes connected with the project, in any statement or material of a publicity or promotional nature issued for commercial purposes, or with a view to financial benefit.

11. SETTLEMENT OF DISPUTES

Any matter relating to the interpretation or application of this Agreement which is not covered by its terms shall be resolved by reference to Swiss law. Any dispute relating to the interpretation or application of this Agreement shall, unless amicably settled, be subject to conciliation.

12. PRIVILEGES AND IMMUNITIES

Nothing contained in or relating to this Agreement shall be deemed to constitute a waiver of any of the privileges and immunities enjoyed by WHO and/or as submitting WHO to any national court jurisdiction.

ATTESTED

Signature of Dr. V.A. Kothiwale, Registrar

KLE Academy of Higher Education and Research, (Deemed-to-be-University u/s 3 of the UGC Act, 1956) Belagavi-590 010, Karnataka



**TECHNICAL SERVICES
AGREEMENT
ACCORD DE SERVICES
TECHNIQUES**

**Global Procurement
and Logistics**
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS

WHO Reference 2018/791908-0
Purchase Order 201940772
Unit Reference

CONDITIONS GENERALES

Les conditions générales énoncées ci-après s'appliquent au présent Accord sur l'appui de l'OMS aux recherches ou autres services techniques. Cet appui vise à aider une institution à entreprendre pour le compte de l'OMS, des investigations portant sur un problème particulier ou des travaux convenus entre l'institution et l'OMS.

1. INSTITUTION ET CHERCHEUR PRINCIPAL

1.1 L'Institution et le Chercheur principal (ou l'Administrateur technique responsable), lequel doit être employé par l'Institution, sont conjointement responsables de l'ensemble des aspects techniques et administratifs des travaux visés par le présent Accord.

1.2 L'Institution est tenue d'aviser immédiatement l'OMS lorsqu'elle apprend que le Chercheur principal va cesser, ou a cessé, d'être employé par elle, ou bien qu'il ne continue pas à exercer les fonctions visées par le présent Accord. En pareil cas, l'OMS peut:

- a. soit annuler le présent Accord;
- b. soit accepter de poursuivre le projet sous la conduite d'un nouveau Chercheur principal proposé par l'Institution et approuvé par l'OMS.

2. DISPOSITIONS FINANCIERES

2.1 Des versements seront faits au(x) compte(s) bancaire(s) de l'Institution comme il est stipulé dans le présent Accord et conformément au calendrier qui y figure. Si, après communication du rapport financier final mentionné plus loin au paragraphe 4.3, il apparaît que l'Institution délient un solde non utilisé, ce solde reste payable à l'OMS. En cas d'annulation du présent Accord, quelles qu'en soient les circonstances, l'Institution restituera à l'OMS les sommes non encore engagées. Les sommes fournies en vertu du présent Accord ne pourront être dépensées que conformément aux dispositions dudit Accord.

2.2 Les fonds versés à l'Institution en vertu du présent Accord ne peuvent être utilisés pour verser des émoluments quelconques à un fonctionnaire de l'OMS, couvrir ses frais de voyage ou lui rembourser toute autre dépense.

2.3 Sauf dispositions contraires du présent Accord, ces fonds ne peuvent être utilisés pour couvrir:

- a. les dépenses administratives et les frais généraux normaux de l'Institution;
- b. le coût de l'entretien, de la réparation, de l'exploitation ou de l'assurance de matériels ou d'appareils existants qui appartiennent à l'Institution;
- c. le coût de la construction de nouveaux bâtiments, ou de la transformation ou de la modification de bâtiments et locaux existants;
- d. le versement d'un complément de traitement au Chercheur principal.

3. MATERIEL ET FOURNITURES

3.1 Sauf convention contraire, et sous réserve des dispositions de l'alinéa 3.2 ci-après, tout matériel obtenu en vertu du présent Accord sera la propriété de l'Institution. L'Institution et le Chercheur principal seront conjointement responsables du bon état de conservation et d'entretien de tout matériel acquis en application du présent Accord.

3.2 Nonobstant les dispositions de l'alinéa 3.1 ci-dessus et si l'OMS en fait la demande, l'Institution transférera à celle-ci, lors de la résiliation ou de l'expiration du présent Accord les droits de propriété afférents à tout matériel acquis au titre dudit Accord. L'Institution expédiera alors ce matériel vers toute destination que lui aura indiquée l'OMS, les frais d'expédition étant à la charge de cette dernière.

4. RAPPORTS

L'Institution soumettra à l'OMS des rapports techniques et financiers concernant ses travaux, chaque fois qu'il y a lieu et au moins une fois par an, selon les modalités suivantes.

4.1 Les rapports techniques seront établis par le Chercheur principal, envoyés sous couvert du responsable de l'Institution ou de son représentant l'un et l'autre dûment autorisés, et contresignés par eux. Chaque rapport annuel résumera les résultats du projet et en exposera les conclusions positives ou négatives de façon assez détaillée pour permettre d'apprécier la valeur des travaux.

4.2 Les rapports financiers devront être envoyés, après avoir été visés conjointement par le Chef des Services financiers de l'Institution et par le Chercheur principal qui utilisera à cette fin la formule WHO 782. Les rapports devront indiquer l'utilisation des fonds provenant de l'OMS au regard des prévisions de dépenses initiales dont étaient convenues l'Institution et l'OMS.

4.3 Tous les rapports financiers et techniques sont soumis par l'OMS à une vérification comprenant l'examen de toutes pièces justificatives ainsi que des écritures comptables correspondantes dans les livres de l'Institution. En vue de faciliter l'établissement et la vérification de ces rapports, l'Institution veillera à la tenue de comptes et de registres exacts et systématiques pour tout ce qui concerne le projet. Les rapports techniques et financiers finaux devront être présentés dans les 90 jours suivant l'expiration du présent Accord.

5. RELATIONS ENTRE LES PARTIES ET LEURS RESPONSABILITES

L'Institution agira à l'égard de l'OMS en tant qu'entrepreneur indépendant; ses employés ne pourront se prévaloir de la qualité de membres du personnel de l'OMS. L'Institution sera seule responsable de la façon dont s'exécute le projet et, partant, assumera l'entière responsabilité de tout dommage résultant de recherches ou d'autres services techniques visés par le présent Accord. Aucune responsabilité ne pourra incomber à l'OMS, ses conseillers, agents ou employés.

6. UTILISATION DES RESULTATS, EXPLOITATION DES DROITS, ET PUBLICATION

6.1 Les résultats du projet financé en vertu du présent Accord pourront être librement utilisés ou divulgués par l'une ou l'autre partie. Toutefois, à défaut de l'assentiment de l'autre partie, les résultats ne pourront être utilisés à des fins commerciales et, s'ils sont susceptibles d'être protégés par des droits de propriété, ils conserveront leur caractère strictement confidentiel. L'Institution communiquera à l'OMS les résultats des recherches, sous forme de savoir-faire et autres

intellectuelle, y compris les droits qui s'attachent au savoir-faire, découlant du projet, devra permettre, dans toute la mesure du possible, d'atteindre les objectifs suivants énoncés par ordre de priorité:

- a. mise à la disposition de tous les produits de l'activité créatrice;
- b. leur mise à la disposition du secteur de la santé publique, notamment dans les pays en développement à des conditions préférentielles;
- c. octroi à chaque partie d'avantages additionnels, y compris sous formes de redevances, compte tenu de la valeur relative de ses contributions financières, intellectuelles et autres.

6.3 Les droits mentionnés plus haut au paragraphe 6.2 seront la propriété de l'Institution, ou du Chercheur principal si l'Institution et l'OMS en conviennent ainsi. Dans la mesure où l'Institution n'entend pas les exercer, les droits seront promptement transmis à l'OMS, si celle-ci le demande. Chaque partie coopérera pleinement avec l'autre pour lui permettre d'exercer effectivement ses droits. La partie détentrice des droits pourra déposer des demandes de propriété industrielle et devra alors remettre à l'autre partie copie de ces dépôts et des autres documents relatifs au brevet. Tous les droits autres que celui de déposer des demandes s'exercent aux termes d'un accord qui sera négocié de bonne foi entre l'Institution et l'OMS.

6.4 Dans aucune de ses publications concernant les résultats du projet, l'Institution ou le Chercheur principal n'attribuera à l'OMS la responsabilité de la direction des travaux. Sauf instructions contraires de l'OMS, toutes les publications comporteront une note indiquant que les recherches qui sont à l'origine des résultats ont reçu un appui financier de l'OMS. A moins qu'un autre chiffre n'ait été stipulé, deux exemplaires ou tirés à part de ces publications seront envoyés à l'OMS et, sauf autorisation expresse, les fonds de l'OMS ne pourront être utilisés pour couvrir les coûts de publication.

7. RECHERCHES IMPLIQUANT L'ETUDE DE SUJETS HUMAINS.

7.1 Aspects déontologiques

Il incombe à l'Institution et au Chercheur principal de s'assurer qu'au cours des travaux financés totalement ou en partie par l'OMS et impliquant l'étude de sujets humains, les droits et la santé de ces derniers soient protégés conformément au code de déontologie ou à la législation du pays, ou, à défaut, à la Déclaration d'Helsinki et aux amendements qui pourraient lui être ultérieurement apportés. Les fonds ne peuvent être utilisés pour financer des recherches que si les conditions suivantes sont remplies:

- a. les droits et le bien-être des sujets impliqués sont suffisamment protégés;
- b. le consentement libre et éclairé des intéressés a été obtenu;
- c. des experts indépendants désignés par l'Institution ont pesé les risques et les avantages potentiels et ont jugé qu'ils s'équilibraient de manière acceptable; et
- d. il ait satisfait à toute exigence particulière de la réglementation nationale.

7.2 Dispositions réglementaires

Il incombe à l'Institution et au Chercheur principal de respecter la réglementation nationale relative aux recherches impliquant l'étude de sujets humains.

7.3 Protection des sujets d'expérience

Sans préjudice des obligations qui lui incombent aux termes des lois en vigueur, l'Institution prendra des mesures appropriées en vue d'éliminer ou d'atténuer les conséquences des expériences pour les sujets ou leur famille en cas de décès, de traumatisme ou de maladie résultant de la conduite des recherches mentionnées au paragraphe 7.1. Ces mesures comprendront, dans la mesure du possible, un traitement médical et un dédommagement financier. L'Institution et le Chercheur principal s'engagent à protéger le caractère confidentiel des informations qui pourraient permettre d'identifier les sujets impliqués dans les études effectuées en vertu du présent Accord.

8. RECHERCHES IMPLIQUANT L'UTILISATION D'ANIMAUX DE LABORATOIRE

L'Institution s'engage à veiller à ce que les animaux vertébrés vivants qu'il sera nécessaire d'utiliser comme animaux de laboratoire pour des recherches entreprises en vertu du présent Accord soient traités conformément aux principes universellement reconnus qui veulent que l'on épargne à ces animaux toute souffrance inutile.

9. SECURITE DES RECHERCHES

Il incombe à l'Institution d'arrêter et d'appliquer des politiques et pratiques préservant et garantissant la sécurité de ses employés et du public ainsi que celle de l'environnement pendant les recherches soutenues par l'OMS. Si les travaux impliquent l'utilisation de substances biologiques dangereuses, l'Institution établira et appliquera un plan de sécurité approprié.

10. PUBLICITE

L'Institution et le Chercheur principal ne pourront faire mention, dans un quelconque écrit ou déclaration à caractère publicitaire ou promotionnel diffusé à des fins commerciales, ou en vue d'un avantage financier, du lien existant entre l'OMS et le projet ou les produits ou procédés en découlant.

11. REGLEMENT DES LITIGES

Toute question concernant l'application ou l'interprétation du présent Accord que les dispositions de ce dernier ne permettent pas de résoudre doit être résolue par référence au droit suisse. Tout différend relatif à l'application ou à l'interprétation du présent Accord qui n'aurait pu être résolu à l'amiable, fera l'objet d'une conciliation. En cas d'échec de celle-ci, le différend sera réglé par arbitrage. Les modalités de l'arbitrage seront convenues entre les parties ou, en absence d'accord, seront déterminées selon le règlement d'arbitrage de la Chambre de Commerce Internationale. Les parties reconnaissent que la sentence arbitrale sera finale.

12. PRIVILEGES ET IMMUNITES

Aucun des termes du présent Accord ne sera considéré comme constituant une

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



World Health
Organization

**TECHNICAL SERVICES
AGREEMENT
ACCORD DE SERVICES
TECHNIQUES**

informations pertinentes et, dans la mesure du possible, lui fournira des produits concrets.
6.2 L'exploitation industrielle ou commerciale de tout droit de propriété

Global Procurement
and Logistics
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS

WHO Reference 2018/791908-0
Purchase Order 201940772
Unit Reference

renonciation à quelque privilège ou immunité que ce soit dont jouit l'OMS et/ou comme constituant une soumission de l'OMS à la compétence d'un quelconque tribunal national.

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



World Health
Organization

**COVERING LETTER
LETTRE D'ACCOMPAGNEMENT**

Global Procurement
and Logistics
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS

WHO Reference	2019/928926-0
Purchase Order	202319732
Unit Reference	A65913

DR. Shivaprasad Goudar
PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM (JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM)
KARNATAKA
Nehru Nagar
Belgaum
Karnataka
India

TECHNICAL SERVICES AGREEMENT (TSA)

Re: To conduct activities for WHO ACTION-1 and ACTION-2 Trials.

We are enclosing the Technical Services Agreement between the World Health Organization and PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM (JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM), KARNATAKA, in the amount of INR 11,773,153.21 (Eleven Million Seven Hundred Seventy-Three Thousand One Hundred Fifty-Three), for conducting the above-mentioned work. We also enclosed three attachment(s) referenced in the Agreement.

Kindly acknowledge your acceptance of this contract by returning the email with a copy of duly signed Purchase Order (all pages).

For any technical or scientific questions related to this Agreement, please contact the responsible technical officer, Olufemi Taiwo OLADAPO, 234 0 37 783403, oladapoo@who.int.

On behalf of the World Health Organization, we thank you for your collaboration.

WHO Global Service Centre

Cc: WHO Representative, India

Concerne: To conduct activities for WHO ACTION-1 and ACTION-2 Trials.

Veillez trouver ci-joint l'Accord de Services Techniques entre l'Organisation Mondiale de la Santé et PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM (JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM), KARNATAKA, pour un montant de INR 11,773,153.21 (Eleven Million Seven Hundred Seventy-Three Thousand One Hundred Fifty-Three), vous permettant de mener à bien le travail susmentionné. Veillez également trouver three pièces jointes mentionnées dans l'Accord.

Merci de confirmer votre acceptation de ce contrat en nous retournant le courriel et une copie dûment signée du Bon de Commande (complet)

Pour toutes questions à caractère scientifique ou technique ayant trait à cet Accord, veuillez contacter le responsable technique Olufemi Taiwo OLADAPO, 234 0 37 783403, oladapoo@who.int.

Au nom de l'Organisation Mondiale de la Santé, nous vous remercions de votre collaboration.

Centre de Soutien Administratif Mondial de l'OMS

Cc: Représentant de l'OMS, India

R. 9/7/2019

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



**World Health
Organization**

**Global Procurement
and Logistics**
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS

WHO Reference 2019/928926-0
Purchase Order 202319732
Unit Reference A65913

**TECHNICAL SERVICES
AGREEMENT
ACCORD DE SERVICES
TECHNIQUES**

The WORLD HEALTH ORGANIZATION hereby agrees to provide to
L'ORGANISATION MONDIALE DE LA SANTÉ s'engage par la présente à fournir à
INSTITUTION:

PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM
(JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM)
KARNATAKA

Principal Investigator: DR.Shivaprasad Goudar

Telephone:

Fax:

Email/Courriel:

PRINCIPAL INVESTIGATOR

Karnataka

India

The Amount of/Un Montant de: INR 11,773,153.00 (Eleven Million Seven Hundred Seventy-Three Thousand One Hundred Fifty-Three)

In respect of/en vue de: To conduct activities for WHO ACTION-1 and ACTION-2 Trials.

For the period financed by this Agreement **From/De :** 10-JUL-2019
Période du projet financée par le présent accord **To/A :** 31-OCT-2019

Summary of work/ Description sommaire des travaux:

1. Description of work under this Agreement/ Description des travaux faisant l'objet du présent accord:

A65913 (ACTION 1)
A65916 (ACTION 2)

See attached protocol

2. Contribution of the Institution and/or other sources for the project (Staff, equipment, supplies, etc. excluding general facilities). The Institute will provide all facilities, equipment and personnel not covered by this Agreement.

Contribution de l'Institution ou de tout autre organisme à l'exécution du projet (personnel, matériel, fournitures, etc. à l'exclusion des services d'ordre général). L'Institution s'engage à fournir les locaux, équipement et personnels non couverts par cet accord.

Financial Arrangements/ Dispositions financiers:

1. Payments will be made as follows/Les versements seront effectués comme suit:

	Deliverable/ Résultat	Due Date/ Date Remise	%	Currency Amount/ Montant en Devise
1	Upon signature	12-JUL-2019	100.00	11,773,153.21
2	Financial Report	31-OCT-2019	0.00	0.00
3	Technical report	31-OCT-2019	0.00	0.00

2. INR 0.00 will be used by WHO for the purchase of equipment and supplies to be ordered by the Institution as soon as practicable, but not beyond 31 December of the year following the end of the Agreement period as indicated above at which time any uncommitted balance will revert to WHO.

INR 0.00 seront affectés par l'OMS à l'achat de matériels et de fournitures à commander par l'Institution dès que possible, mais au plus tard avant le 31 décembre de l'année suivant la fin de la période susmentionnée d'exécution de l'accord, étant entendu qu'à ce moment tout solde non engagé fera retour à l'OMS.

Annexes

The following annexes form an integral part of this Agreement/ Les annexes listées ci-dessous font partie intégrante de cet accord:

Annex	File Description/Description de fichier
1	2019/928926 Contractual - Budget Breakdown
2	2019/928926 Contractual - Terms of Reference
3	2019/928926 Contractual - Terms of Reference

In the event that the terms of the annexes contain any provisions which are contrary to the terms of this Agreement, the terms of this Agreement shall take precedence/ En cas de contradiction entre les termes apparaissant sur les annexes et ceux de l'Accord, les dispositions de l'Accord prévaudront dans tous les cas.

General

The parties accept the "General Conditions" overleaf, which constitute an integral part of this Agreement. The Institution certifies the correctness of the banking

Généralités

Les parties acceptent les "Conditions générales" reproduites au verso, lesquelles font partie intégrante du présent accord. L'Institution certifie l'exactitude des

Technical Services Agreement

Sensitivity: Internal & Restricted

ATTESTED

Page 1 of 6

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

9/7/2019



**World Health
Organization**

**Global Procurement
and Logistics**
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS	
WHO Reference	2019/928926-0
Purchase Order	202319732
Unit Reference	A65913

**TECHNICAL SERVICES
AGREEMENT
ACCORD DE SERVICES
TECHNIQUES**

Instructions provided on Page 1.

All necessary arrangements to comply with national regulations relating to this project and relevant to the Institution's responsibilities shall have been under-taken by the Institution; failure to do so will nullify this Agreement. The responsibility of the World Health Organization is limited only to the financial support as specified in this Agreement.

Instructions bancaires indiquées à la page 1.

Toutes les dispositions relevant des responsabilités de l'Institution et nécessaires à la mise en conformité de ce Projet avec la réglementation nationale, devront avoir été prises par l'Institution, faute de quoi l'accord sera nul. La responsabilité de l'Organisation Mondiale de la Santé se limite au soutien financier spécifié dans le présent accord.

ON BEHALF OF WHO/ POUR L'OMS

Responsible WHO Technical Officer:
Fonctionnaire technique responsable de l'OMS:

Olufemi Taiwo Oladapo
Medical Officer
HQ/RHR - Reproductive Health and Research

Responsible Divisional Director
Directeur de division responsable

Peter Joseph SALAMA
Executive Director
HQ/HIA ADGO Health Systems and Innovation

Authorized Signatory:
Signataire autorisé:

Mr Richard Preston
Director (ai)
Global Service Centre
(WHO/GMG/GSC)

Processed by:
Traité par:

Kiranjeet Kaur
Senior Procurement Assistant
HQ/GSC Global Service Centre
09-JUL-2019

PRINCIPAL INVESTIGATOR/ CHERCHEUR PRINCIPAL

Principal Investigator or Technical Officer responsible for the project.
Chercheur Principal ou membre du personnel technique responsable de l'exécution du projet.

Signature :
DR. Shivaprasad Goudar

ON BEHALF OF THE INSTITUTION/ POUR L'INSTITUTION

Responsible Administrative Authority*
*Autorité administrative responsable**

Signature :
Name/nom : **Dr. N. B. Mahantashetti**
PRINCIPAL
Division :
Date : **JANAHARAL NEHRU MEDICAL COLLEGE**
BELAGAVI-590010

09/07/2019



* An official of the Institution - other than the Principal Investigator - fully empowered to enter into contracting arrangements on behalf of the Institution./Un responsable de l'Institution autre que le Chercheur principal - ayant pleins pouvoirs pour passer un contrat au nom de l'Institution.

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act 1956)
Belagavi-590 010, Karnataka Page 2 of 6



**World Health
Organization**

**TECHNICAL SERVICES
AGREEMENT
ACCORD DE SERVICES
TECHNIQUES**

**Global Procurement
and Logistics**
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS

WHO Reference 2019/928926-0
Purchase Order 202319732
Unit Reference A65913

GENERAL CONDITIONS

The following are the general conditions relating to this Agreement concerning WHO support for research or other technical services. The purpose of such support is to assist an Institution to undertake, for WHO, investigations on a particular problem or other work which has been agreed upon by the Institution and WHO. If the support to be provided under this Agreement is a sub-grant under a principal grant to WHO, this Agreement shall be subject to WHO receiving the full amount of the principal grant. In the event WHO does not receive the full amount of the principal grant, WHO shall be entitled to either cancel this Agreement or adjust the amount to be provided hereunder (at WHO's sole discretion and without incurring any liability towards the Institution).

1. INSTITUTION AND PRINCIPAL INVESTIGATOR

1.1 The Institution and the Principal Investigator (or Responsible Technical Officer), who must be an employee of the Institution, shall be jointly responsible for all the technical and administrative aspects of the work referred to in this Agreement.
1.2 The Institution is required to notify WHO immediately of knowledge that the Principal Investigator will cease or ceases to be an employee of the Institution or is no longer continuing the responsibilities covered by this Agreement. Under such circumstances WHO has the right to:
(a) terminate this Agreement; or
(b) agree to continue the project under a new Principal Investigator proposed by the Institution and approved by WHO.

2. FINANCIAL ARRANGEMENTS

2.1 Payments shall be made into the bank account(s) of the Institution as specified in this Agreement and in accordance with the schedule of payments contained therein. If, after the submission of the final financial report referred to in paragraph 4.4 below, there remains an unused balance of funds with the Institution, this balance shall be due to WHO. In the event of this Agreement being terminated under any circumstances, the Institution shall refund to WHO the balance of uncommitted funds. The funds provided under this Agreement shall be expended only in accordance with its terms.
2.2 The funds transferred to the Institution under this Agreement may not be used to meet any form of emoluments, travel costs or any other reimbursements of expenditure to a staff member of WHO.
2.3 Unless otherwise provided in this Agreement, the funds transferred to the Institution hereunder may not be used to cover:
(a) normal administrative and overhead expenses of the Institution;
(b) cost of maintenance, repair, running or insurance of existing equipment and machinery belonging to the Institution;
(c) cost of construction of new buildings or alterations and modifications of existing buildings and premises; or
(d) salary support of the Principal Investigator.

3. EQUIPMENT AND SUPPLIES; PROCUREMENT

3.1 Unless otherwise agreed, and subject to subparagraph 3.2 below, any equipment and supplies acquired under this Agreement shall become the property of the Institution. The Institution and the Principal Investigator shall be jointly responsible for the proper safeguard, maintenance and care of all equipment and supplies acquired under this Agreement.
3.2 Notwithstanding subparagraph 3.1 above, the Institution shall transfer ownership of any equipment and supplies acquired under this Agreement to WHO, if so requested by WHO, upon termination or expiry of this Agreement. In such cases the Institution shall dispatch the equipment and supplies to any destination chosen by WHO, the cost of which will be borne by WHO.
3.3 To the extent the Institution needs to purchase any goods and/or services in connection with its performance of this Agreement, the Institution shall ensure that such goods and/or services shall be procured in accordance with the principle of best value for money. "Best value for money" means the responsive offer that is the best combination of technical specifications, quality and price.

4. REPORTS; AUDIT

The Institution shall submit technical and financial reports to WHO on the work as required, or at least annually, in accordance with the following provisions:
4.1 Technical reports shall be prepared by the Principal Investigator and forwarded through and countersigned by the authorized official of the Institution or his authorized representative. Each annual report shall summarize the results of the project and give in sufficient detail its positive and negative findings so that the value of the work can be assessed.
4.2 Financial reports shall be forwarded after being jointly certified by the Institution's chief financial officer and the Principal Investigator, using form WHO 782. The reports must show the use of the funds provided by WHO compared with the original budget expenditure pattern agreed between the Institution and WHO.
4.3 WHO may request a financial and/or operational review or audit of the project and related activities, to be conducted by WHO and/or parties authorized by WHO, and the Institution undertakes to facilitate such review or audit. This review or audit may be carried out at any time during the implementation of the work performed under this Agreement, or within five years of completion of the work hereunder. The Institution shall make available, without restriction, to WHO and/or parties authorized by WHO:
(a) the Institution's books, records and systems (including all relevant financial and operational information) relating to the project and related activities; and
(b) reasonable access to the Institution's premises and personnel.
In order to facilitate financial reporting and audit, the Institution shall ensure that accurate and systematic accounts and records are kept in respect of the project and related activities. The Institution shall provide satisfactory explanations to all queries arising in connection with the aforementioned audit and access rights. WHO may request the Institution to provide complementary information about the project and related activities that is reasonably available, including the findings and results of an audit (internal or external) conducted by the Institution and related to

Such funds may be used only to support investigations where
(a) the rights and welfare of the subjects involved in the research are adequately protected,
(b) freely given informed consent has been obtained,
(c) the balance between risk and potential benefits involved has been assessed and deemed acceptable by a panel of independent experts appointed by the Institution and
(d) any special national requirements have been met.

8.2 Regulatory Requirements

It is the responsibility of the Institution and the Principal Investigator to comply with the relevant national regulations pertaining to research involving human subjects.

8.3 Protection of Subjects

Without prejudice to obligations under applicable laws, the Institution shall make appropriate arrangements to eliminate or mitigate the consequences to subjects or their families in the case of death, injury or illness resulting from the conduct of research referred to in paragraph 8.1. Such arrangements shall, to the extent feasible, include medical treatment and financial relief. The Institution and Principal Investigator undertake to protect the confidentiality of the information relating to the possible identification of subjects involved in the research involving human subjects conducted under the auspices of this Agreement.

9. RESEARCH INVOLVING THE USE OF LABORATORY ANIMALS

The Institution undertakes that living vertebrate animals, required for use as laboratory animals for the research to be carried out under this Agreement, shall be handled in accordance with generally accepted principles for the humane treatment of such animals and the avoidance of unnecessary suffering.

10. RESEARCH SAFETY

It is the responsibility of the Institution to establish and implement policies and practices to assure and provide for the safety of its employees, the public, and the environment during the conduct of the research to be carried out under this Agreement. If the supported research involves the use of dangerous biological agents, the Institution shall establish and implement an appropriate safety plan.

11. COMPLIANCE WITH WHO POLICIES

By entering into this Agreement, the Institution and Principal Investigator acknowledge that they have read, and hereby accept and agree to comply with, the WHO Policies (as defined below). In connection with the foregoing, the Institution and Principal Investigator shall take appropriate measures to prevent any violations of the standards of conduct (as described in the WHO Policies) by employees of the Institution and any other persons engaged by the Institution and/or Principal Investigator to perform any services under this Agreement. Without limiting the foregoing, the Institution and Principal Investigator shall each promptly report to WHO, in accordance with the terms of the applicable WHO Policies, any actual or suspected violations of any WHO Policies of which the Institution and/or Principal Investigator become aware. For purposes of this Agreement, the term "WHO Policies" means collectively:
(a) the WHO Code of Ethics and Professional Conduct;
(b) the WHO Policy on Sexual Exploitation and Abuse Prevention and Response;
(c) the WHO Code of Conduct for Responsible Research;
(d) the WHO Policy on Whistleblowing and Protection Against Retaliation; and
(e) the UN Supplier Code of Conduct, in each case, as amended from time to time and which are publicly available on the WHO website at the following links: <http://www.who.int/about/finance-accountability/procurement/en/> for the UN Supplier Code of Conduct and at <http://www.who.int/about/ethics/en/> for the other WHO Policies.

12. ZERO TOLERANCE FOR SEXUAL EXPLOITATION AND ABUSE

WHO has zero tolerance towards sexual exploitation and abuse in this regard, and without limiting any other provisions contained herein:
- The Institution warrants that it will:
(a) take all reasonable and appropriate measures to prevent sexual exploitation or abuse as described in the WHO Policy on Sexual Exploitation and Abuse Prevention and Response by any of its employees and any other persons engaged by it to perform any services under this Agreement; and
(b) promptly report to WHO and respond to, in accordance with the terms of the Policy, any actual or suspected violations of the Policy of which the Institution becomes aware; and
- The Principal Investigator warrants that he/she will:
(a) not engage in any conduct that would constitute sexual exploitation or abuse as described in the WHO Policy on Sexual Exploitation and Abuse Prevention and Response; and
(b) promptly report to WHO, in accordance with the terms of the Policy, any actual or suspected violations of the Policy of which the Principal Investigator becomes aware.

13. TOBACCO- AND ARMS-RELATED DISCLOSURE

The Institution is required to disclose relationships it may have with the tobacco and/or arms industry through completion of the WHO Tobacco / Arms Disclosure Statement. The Institution undertakes not to permit work under this Agreement to commence until WHO has assessed the disclosed information and confirmed to the Institution in writing that the work can commence.

14. ANTI-TERRORISM AND UN SANCTIONS; FRAUD AND CORRUPTION

14.1 The Institution and Principal Investigator warrant for the entire duration of this Agreement that:
(a) they are not and will not be involved in, or associated with, any person or entity associated with terrorism, as designated by any UN Security Council sanctions regime; that they will not make any payment or provide any other support to any such person or entity; and that they will not enter into any employment or

9/7/2019

Technical Services Agreement

Sensitivity: Internal & Restricted

ATTESTED

Page 3 of 6

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



**World Health
Organization**

**TECHNICAL SERVICES
AGREEMENT
ACCORD DE SERVICES
TECHNIQUES**

the Project and/or related activities

4.4 The final technical and financial reports must be submitted within 90 days after the expiry of this Agreement.

5. RELATIONSHIP AND RESPONSIBILITY OF PARTIES

The relationship of the Institution to WHO shall be that of an independent contractor. The employees of the Institution are not entitled to describe themselves as staff members of WHO. The Institution shall be solely responsible for the manner in which work on the project is carried out and accordingly shall assume full liability for any damage arising from research or other technical services under this Agreement. No liability shall attach to WHO, its advisers, agents or employees.

6. USE OF RESULTS, EXPLOITATION OF RIGHTS.

6.1 The results of the project funded under this Agreement may be freely used or disclosed by either party provided that, without the consent of the other party, no use may be made for commercial purposes and confidentiality shall be maintained with respect to results that may be eligible for protection by proprietary rights. The Institution shall provide WHO with the results, in the form of relevant know how and other information, and to the extent feasible, tangible products.

6.2 The industrial or commercial exploitation of any intellectual property rights, including the ownership of know-how, arising from the project shall be designed to achieve, in so far as circumstances permit, the following objectives in the following order of priority:

- (a) the general availability of the products of creative activity;
- (b) the availability of those products to the public health sector on preferential terms, particularly in developing countries;
- (c) the grant to each party of additional benefits, including royalties, account being taken of the relative value of each party's financial, intellectual and other contribution to the research.

6.3 The rights referred to in paragraph 6.2 shall belong to the Institution, or to the Principal Investigator if the Institution and WHO so agree. To the extent that the former do not intend to exercise them, the rights shall be promptly transferred to WHO, if it so requests. Each party shall provide the other with its full cooperation to permit the effective exercise of the rights. The party in which the corresponding rights are vested may file applications for industrial property protection, promptly furnishing copies of the applications and other patent documents to the other party. All rights other than the right to file applications shall be exercised in accordance with an agreement which shall be negotiated in good faith between the Institution and WHO.

7. PUBLICATIONS

7.1 Subject to any proprietary rights of WHO and/or third parties collaborating with WHO, the work supported by WHO under this Agreement may be published by the Institution and/or the Principal Investigator. In order to avoid prejudicing proprietary rights, the Institution or the Principal Investigator shall transmit to WHO for its review the material intended to be published at least 60 working days before a proposed publication is submitted to any editor, publisher, referee or meeting organizer. In the absence of any objection by WHO within that 60 working day period concerning prejudice to its proprietary rights, the publication may proceed.

7.2 Any publication by the Institution or the Principal Investigator of the work supported by WHO under this Agreement shall be published in accordance with the WHO policy on open access, which is available at the following link: <http://www.who.int/about/policy/en/>.

7.3 In any publication by the Institution or the Principal Investigator relating to the results of the project, the responsibility for the direction of the work shall not be ascribed to WHO. Unless WHO advises otherwise, all publications shall include a notice indicating that the underlying investigation received financial support from WHO. Two off-prints or copies of each publication shall be sent to WHO unless another number is stipulated. WHO funds may not be used for publication costs unless specifically authorized.

8. RESEARCH INVOLVING HUMAN SUBJECTS

8.1 Ethical Aspects

It is the responsibility of the Institution and the Principal Investigator to safeguard the rights and welfare of human subjects involved in research supported in whole or in part by funds from WHO, in accordance with the appropriate national code of ethics or legislation, if any, and in the absence thereof, the Helsinki Declaration and any subsequent amendments.

**Global Procurement
and Logistics**
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS

WHO Reference 2019/928926-0
Purchase Order 202319732
Unit Reference A65913

subcontracting relationship with any such person or entity; and
(b) They shall not engage in any illegal, corrupt, fraudulent, collusive or coercive practices (including bribery, theft and other misuse of funds) in connection with the execution of this Agreement.

14.2 The Institution and Principal Investigator shall take all necessary precautions to prevent the financing of terrorism and/or any illegal, corrupt, fraudulent, collusive or coercive practices (including bribery, theft and other misuse of funds) in connection with the execution of this Agreement.

14.3 Any funds used by the Institution and/or Principal Investigator for the promotion of any terrorist activity or any illegal, corrupt, fraudulent, collusive or coercive practice shall be repaid to WHO without delay.

15. BREACH OF ESSENTIAL TERMS

The Institution and Principal Investigator acknowledge and agree that each of the provisions in Sections 11, 12, 13 and 14 hereof constitutes an essential term of this Agreement, and that in case of breach of any of these provisions, WHO may, in its sole discretion, decide to:

- (a) terminate this Agreement and/or any other contract concluded by WHO with the Institution and/or Principal Investigator, immediately upon written notice to them, without any liability for termination charges or any other liability of any kind; and/or
- (b) exclude the Institution and/or Principal Investigator from participating in any ongoing or future tenders and/or entering into any future contractual or collaborative relationships with WHO.

WHO shall be entitled to report any breach of such provisions to WHO's governing bodies, other UN agencies, and/or donors.

16. PUBLICITY; USE OF WHO NAME AND EMBLEM

16.1 The Institution and the Principal Investigator shall not refer to the relationship of WHO to the project, or to products or processes connected with the project, in any statement or material of an advertising or promotional nature, including but not limited to any statements or materials issued for commercial purposes or with a view to financial benefit.

16.2 Without WHO's prior written approval, the Institution and/or the Principal Investigator shall not, in any statement or material of an advertising or promotional nature, refer to this Agreement or to the Institution's and/or Principal Investigator's relationship with WHO, or otherwise use the name (or any abbreviation thereof) or emblem of the World Health Organization.

17. PUBLICATION OF AGREEMENT

Subject to considerations of confidentiality, WHO may acknowledge the existence of this Agreement to the public and publish and/or otherwise publicly disclose the name of the Institution and/or Principal Investigator, the Institution's country of incorporation, general information with respect to the work supported under this Agreement, and this Agreement's value. Such disclosure will be made in accordance with WHO's Information Disclosure Policy and shall be consistent with the terms of this Agreement.

18. SURVIVING PROVISIONS

Those provisions of this Agreement that are intended by their nature to survive its expiration or earlier termination shall continue to apply.

19. SETTLEMENT OF DISPUTES

Any matter relating to the interpretation or application of this Agreement which is not covered by its terms shall be resolved by reference to Swiss law. Any dispute relating to the interpretation or application of this Agreement shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or, in the absence of agreement, with the Rules of Arbitration of the International Chamber of Commerce. The parties shall accept the arbitral award as final.

20. PRIVILEGES AND IMMUNITIES

Nothing contained in or relating to this Agreement shall be deemed to constitute a waiver of any of the privileges and immunities enjoyed by WHO under national or international law, and/or as submitting WHO to any national court jurisdiction.

SP 9/7/2019

ATTESTED

k

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act 1956) 6
Belagavi-590 010,Karnataka

Technical Services Agreement



TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

Global Procurement and Logistics
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS

WHO Reference 2019/928926-0
Purchase Order 202319732
Unit Reference A65913

CONDITIONS GENERALES

Les conditions générales énoncées ci-après s'appliquent au présent Accord sur l'appui de l'OMS aux recherches ou autres services techniques. Cet appui vise à aider une institution à entreprendre pour le compte de l'OMS, des investigations portant sur un problème particulier ou des travaux convenus entre l'institution et l'OMS. Si l'appui au titre du présent Accord provient d'une subvention principale accordée à l'OMS, le présent Accord est conclu sous réserve que le montant total de la subvention principale soit payé à l'OMS. Dans l'éventualité où l'OMS ne recevrait pas le montant total de la subvention principale, l'OMS se réserve le droit d'annuler le présent Accord ou d'ajuster le montant de l'appui à l'institution (à la seule discrétion de l'OMS et sans encourir aucune responsabilité vis-à-vis de l'institution).

1. INSTITUTION ET CHERCHEUR PRINCIPAL

1.1 L'institution et le Chercheur principal (ou l'Administrateur technique responsable), lequel doit être employé par l'institution, sont conjointement responsables de l'ensemble des aspects techniques et administratifs des travaux visés par le présent Accord.

1.2 L'institution est tenue d'aviser immédiatement l'OMS lorsqu'elle apprend que le Chercheur principal va cesser, ou a cessé, d'être employé par elle, ou bien qu'il ne continue pas à exercer les fonctions visées par le présent Accord. En pareil cas, l'OMS peut:

- (a) soit résilier le présent Accord;
- (b) soit accepter de poursuivre le projet sous la conduite d'un nouveau Chercheur principal proposé par l'institution et approuvé par l'OMS.

2. DISPOSITIONS FINANCIERES

2.1 Des versements seront faits au(x) compte(s) bancaire(s) de l'institution comme il est stipulé dans le présent Accord et conformément au calendrier qui y figure. Si, après communication du rapport financier final mentionné plus loin au paragraphe 4.4, il apparaît que l'institution détient un solde non utilisé, ce solde reste payable à l'OMS. En cas de restitution du présent Accord, quelles qu'en soient les circonstances, l'institution restituera à l'OMS les sommes non encore engagées. Les sommes fournies en vertu du présent Accord ne pourront être dépensées que conformément aux dispositions dudit Accord.

2.2 Les fonds versés à l'institution en vertu du présent Accord ne peuvent être utilisés pour verser des émoluments quelconques à un fonctionnaire de l'OMS, couvrir ses frais de voyage ou lui rembourser toute autre dépense.

2.3 Sauf dispositions contraires du présent Accord, les fonds versés à l'institution en vertu des présentes ne peuvent être utilisés pour couvrir:

- (a) les dépenses administratives et les frais généraux normaux de l'institution;
- (b) le coût de l'entretien, de la réparation, de l'exploitation ou de l'assurance de matériels ou d'appareils existants qui appartiennent à l'institution;
- (c) le coût de la construction de nouveaux bâtiments, ou de la transformation ou de la modification de bâtiments et locaux existants, ou
- (d) le versement d'un complément de traitement au Chercheur principal.

3. MATERIEL ET FOURNITURES; ACHAT

3.1 Sauf convention contraire et sous réserve des dispositions de l'alinéa 3.2 ci-après, tout matériel et toutes fournitures obtenus en vertu du présent Accord sera la propriété de l'institution. L'institution et le Chercheur principal seront conjointement responsables du bon état de conservation, de la maintenance et de l'entretien de tout matériel et de toutes fournitures acquis en application du présent Accord.

3.2 Nonobstant les dispositions de l'alinéa 3.1 ci-dessus et si l'OMS en fait la demande, l'institution transférera à celle-ci, lors de la restitution ou de l'expiration du présent Accord, les droits de propriété afférents à tout matériel et à toutes fournitures acquis au titre dudit Accord. L'institution expédiera alors ce matériel et ces fournitures vers toute destination que lui aura indiquée l'OMS, les frais d'expédition étant à la charge de cette dernière.

3.3 Dans la mesure où l'institution doit acheter des biens et/ou des services dans le cadre de l'exécution du présent Accord, elle devra veiller à ce que l'achat de ces biens et/ou services soit effectué sur la base du principe du meilleur rapport qualité-prix. On entend par « meilleur rapport qualité-prix » l'offre qui présente la meilleure combinaison du point de vue des spécifications techniques, de la qualité et du prix.

4. RAPPORTS ; AUDIT

L'institution soumettra à l'OMS des rapports techniques et financiers concernant ses travaux, chaque fois qu'il y a lieu et au moins une fois par an, selon les modalités suivantes:

4.1 Les rapports techniques seront établis par le Chercheur principal, envoyés sous couvert du responsable de l'institution ou de son représentant l'un et l'autre dûment autorisés, et contresignés par eux. Chaque rapport annuel résumera les résultats du projet et en exposera les conclusions positives ou négatives de façon assez détaillée pour permettre d'apprécier la valeur des travaux.

4.2 Les rapports financiers devront être envoyés, après avoir été visés conjointement par le Chef des Services financiers de l'institution et par le Chercheur principal. Les rapports devront indiquer l'utilisation des fonds provenant de l'OMS au regard des prévisions de dépenses initiales dont avaient convenu l'institution et l'OMS.

4.3 L'OMS peut demander qu'un examen ou un audit de type financier et opérationnel du projet et des activités y afférentes, soit effectué par l'OMS et/ou par des parties autorisées par l'OMS, et l'institution s'engage à faciliter cet examen ou cet audit. Cet examen ou cet audit peut être effectué à tout moment pendant la mise en œuvre du projet ou titre du présent Accord, ou dans les cinq ans suivant son achèvement. L'institution permettra à l'OMS et/ou aux parties autorisées par celle-ci, sans restriction:

- (a) de consulter ses livres, archives et systèmes (y compris l'ensemble des

- (a) les droits et le bien-être des sujets impliqués sont protégés comme il convient;
- (b) le consentement libre et éclairé des intéressés a été obtenu;
- (c) un groupe d'experts indépendants désignés par l'institution ont pesé les risques et les avantages potentiels et ont jugé qu'ils s'équilibraient de manière acceptable; et
- (d) toute exigence particulière de la réglementation nationale a été satisfaite.

8.2 Dispositions réglementaires

Il incombe à l'institution et au Chercheur principal de respecter la réglementation nationale relative aux recherches impliquant l'étude de sujets humains.

8.3 Protection des sujets d'expérience

Sans préjudice des obligations qui lui incombent aux termes des lois en vigueur, l'institution prendra des dispositions appropriées en vue d'éliminer ou d'atténuer les conséquences des expériences pour les sujets ou leur famille en cas de décès, de traumatisme ou de maladie résultant de la conduite des recherches mentionnées au paragraphe 8.1. Ces dispositions comprendront, dans la mesure du possible, un traitement médical et un dédommagement financier. L'institution et le Chercheur principal s'engagent à protéger le caractère confidentiel des informations qui pourraient permettre d'identifier les sujets impliqués dans les études effectuées en vertu du présent Accord.

9. RECHERCHES IMPLIQUANT L'UTILISATION D'ANIMAUX DE LABORATOIRE

L'institution s'engage à veiller à ce que les animaux vertébrés vivants qu'il sera nécessaire d'utiliser comme animaux de laboratoire pour des recherches entreprises en vertu du présent Accord soient traités conformément aux principes généralement admis destinés à assurer un traitement humain des animaux et à leur épargner toute souffrance inutile.

10. SECURITE DES RECHERCHES

Il incombe à l'institution d'établir et d'appliquer des politiques et pratiques visant à préserver et garantir la sécurité de ses employés, celle du public et de de l'environnement pendant le déroulement des recherches qui seront effectuées au titre du présent Accord. Si les travaux impliquent l'utilisation de substances biologiques dangereuses, l'institution établira et appliquera un plan de sécurité approprié.

11. RESPECT DES POLITIQUES DE L'OMS

En signant le présent Accord, l'institution et le Chercheur principal reconnaissent avoir lu les politiques de l'OMS (telles que définies ci-après) et, par les présentes, acceptent ces politiques et conviennent de s'y conformer. En lien avec ce qui précède, l'institution et le Chercheur principal prendront les mesures appropriées afin de prévenir et répondre à toute violation des normes de conduite, telles que décrites dans les politiques de l'OMS, par les employés de l'institution ou toute autre personne que l'institution et/ou le Chercheur principal aura engagée en vue de fournir un quelconque service au titre du présent Accord. Sans limiter la portée de ce qui précède, l'institution et le Chercheur principal signaleront immédiatement à l'OMS, conformément aux dispositions des politiques de l'OMS applicables, toute violation réelle ou présumée dont ils ont connaissance concernant toute politique de l'OMS. Aux fins du présent Accord, l'expression « politiques de l'OMS » désigne, collectivement :

- (a) le Code d'éthique et de déontologie de l'OMS;
- (b) la Politique de l'OMS relative à la prévention et à la lutte contre l'exploitation et les abus sexuels;
- (c) le Code de conduite pour une recherche responsable;
- (d) la Politique de l'OMS sur le signalement des actes répréhensibles et la protection contre les représailles et
- (e) le Code de conduite des fournisseurs des Nations Unies, y compris leurs modifications éventuelles et qui sont publiquement accessibles sur le site internet de l'OMS aux liens suivants : <http://www.who.int/about/finances-accountability/procurement/en/> (pour ce qui est du Code de conduite des fournisseurs des Nations Unies) et <http://www.who.int/about/ethics/en/> (pour ce qui est des autres politiques de l'OMS).

12. TOLERANCE ZERO POUR L'EXPLOITATION ET LES ABUS SEXUELS

L'OMS applique la tolérance zéro en matière d'exploitation et d'abus sexuels. À cet égard, et sans limiter la portée de toute autre disposition du présent Accord :

- l'institution garantit:
 - (a) qu'elle prendra toutes les mesures raisonnables et appropriées pour prévenir tout acte d'exploitation ou d'abus sexuels tels que décrits dans la Politique de l'OMS relative à la prévention et à la lutte contre l'exploitation et les abus sexuels, par l'un quelconque de ses employés et toute autre personne engagée par elle en vue de fournir un quelconque service au titre du présent Accord; et
 - (b) qu'elle signalera immédiatement à l'OMS et donnera suite à toute violation réelle ou présumée de cette Politique dont elle a connaissance, conformément aux dispositions de la Politique; et
- le Chercheur principal garantit:
 - (a) qu'il n'adoptera aucun comportement qui relèverait de l'exploitation ou l'abus sexuels tels que décrits dans la Politique de l'OMS relative à la prévention et à la lutte contre l'exploitation et les abus sexuels; et
 - (b) qu'il signalera immédiatement à l'OMS toute violation réelle ou présumée de la Politique dont il a connaissance, conformément aux dispositions de la Politique.

13. DECLARATION RELATIVE A L'INDUSTRIE DU TABAC/DE L'ARMEMENT

L'institution est tenue de déclarer ses éventuelles relations avec l'industrie du tabac et/ou de l'armement en remplissant la déclaration requise par l'OMS relative à l'industrie du tabac/de l'armement. Elle s'engage à ne pas autoriser le commencement des travaux tant que l'OMS n'a pas évalué les informations

Technical Services Agreement

Sensitivity: Internal & Restricted

ATTESTED

Page 5 of 6

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

9/7/2019



World Health Organization

**TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES**

Global Procurement and Logistics
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS

WHO Reference 2019/928926-0
Purchase Order 202319732
Unit Reference A65913

informations financières et opérationnelles pertinentes) relatifs au projet et aux activités y afférentes; et

(b) d'avoir un accès raisonnable à ses locaux et à son personnel. Afin de faciliter l'établissement de rapports financiers et la réalisation d'un audit financier, l'Institution tiendra des comptes et des registres exacts et systématiques concernant le projet et les activités y afférentes. L'Institution fournira des explications satisfaisantes en réponse à toutes les questions découlant de l'audit et des droits d'accès susmentionnés.

L'OMS pourra demander à l'Institution de lui communiquer des informations complémentaires concernant le projet et les activités y afférentes qui sont raisonnablement à sa disposition, y compris les conclusions et les résultats d'un audit (interne ou externe) effectué par l'Institution et relatif au projet et/ou aux activités y afférentes.

4.4 Les rapports techniques et financiers finaux devront être présentés dans les 90 jours suivant l'expiration du présent Accord.

5. RELATIONS ENTRE LES PARTIES ET LEURS RESPONSABILITES

L'Institution agira à l'égard de l'OMS en tant qu'entrepreneur indépendant; ses employés ne pourront se prévaloir de la qualité de membres du personnel de l'OMS. L'Institution sera seule responsable de la façon dont s'exécute le projet et, partant, assumera l'entière responsabilité de tout dommage résultant de recherches ou d'autres services techniques visés par le présent Accord. Aucune responsabilité ne pourra incomber à l'OMS, ses conseillers, agents ou employés.

6. UTILISATION DES RESULTATS, EXPLOITATION DES DROITS

6.1 Les résultats du projet financé en vertu du présent Accord pourront être librement utilisés ou divulgués par l'une ou l'autre partie. Toutefois, à défaut du consentement de l'autre partie, les résultats ne pourront être utilisés à des fins commerciales et, s'ils sont susceptibles d'être protégés par des droits de propriété, ils conserveront leur caractère strictement confidentiel. L'Institution communiquera à l'OMS les résultats des recherches, sous forme de savoir-faire et autres informations pertinents et, dans la mesure du possible, lui fournira des produits concrets.

6.2 L'exploitation industrielle ou commerciale de tout droit de propriété intellectuelle, y compris les droits qui s'attachent au savoir-faire, découlant du projet, devra permettre, dans toute la mesure du possible, d'atteindre les objectifs suivants énoncés par ordre de priorité:

- (a) mise à la disposition générale de tous les produits de l'activité créatrice;
- (b) leur mise à la disposition auprès du secteur de la santé publique, à des conditions préférentielles, en particulier dans les pays en développement;
- (c) octroi à chaque partie d'avantages additionnels, y compris sous formes de royalties, compte tenu de la valeur relative de ses contributions financières, intellectuelles et autres.

6.3 Les droits mentionnés plus haut au paragraphe 6.2 seront la propriété de l'Institution, ou du Chercheur principal si l'Institution et l'OMS en conviennent ainsi. Dans la mesure où l'Institution n'entend pas les exercer, les droits seront promptement transmis à l'OMS, si celle-ci le demande. Chaque partie coopérera pleinement avec l'autre pour lui permettre d'exercer effectivement ses droits. La partie détentrice des droits pourra déposer des demandes de propriété industrielle et devra alors remettre à l'autre partie copie de ces dépôts et des autres documents relatifs au brevet. Tous les droits autres que celui de déposer des demandes s'exercent aux termes d'un accord qui sera négocié de bonne foi entre l'Institution et l'OMS.

7. PUBLICATIONS

7.1 Sous réserve des droits de propriété de l'OMS et/ou de tiers qui collaboreront avec elle, les travaux financés par l'OMS au titre du présent Accord peuvent être publiés par l'Institution et/ou le Chercheur principal. Afin d'éviter de porter atteinte à des droits de propriété, l'Institution ou le Chercheur principal transmettra à l'OMS, pour examen, le document qu'il est prévu de publier, au moins 60 jours ouvrables avant qu'une proposition de publication ne soit présentée à un quelconque éditeur, maison d'édition, arbitre scientifique ou organisateur d'une réunion. Si l'OMS ne formule aucune objection pendant ces 60 jours ouvrables concernant une violation de ses droits de propriété, la publication peut avoir lieu.

7.2 Toute publication, par l'Institution ou le Chercheur principal, des travaux financés par l'OMS au titre du présent Accord se fera conformément à la politique de l'OMS en matière de libre accès, qui peut être consultée à l'adresse suivante: <http://www.who.int/about/policy/fr/>.

7.3 Dans aucune de ses publications concernant les résultats du projet, l'Institution ou le Chercheur principal n'attribuera à l'OMS la responsabilité de la direction des travaux. Sauf instructions contraires de l'OMS, toutes les publications comporteront une note indiquant que les recherches qui sont à l'origine des résultats ont reçu un appui financier de l'OMS. A moins qu'un autre chiffre n'ait été stipulé, deux exemplaires ou tirages de chaque publication seront envoyés à l'OMS. Sauf autorisation expresse, les fonds de l'OMS ne pourront être utilisés pour couvrir les coûts de publication.

8. RECHERCHES IMPLIQUANT L'ETUDE DE SUJETS HUMAINS

8.1 Aspects éthiques

Il incombe à l'Institution et au Chercheur principal de s'assurer qu'au cours des travaux financés totalement ou en partie par l'OMS et impliquant l'étude de sujets humains, les droits et le bien-être de ces derniers soient protégés conformément au code éthique ou à la législation appropriés du pays, ou, à défaut, à la Déclaration d'Helsinki et aux amendements qui pourraient lui être ultérieurement apportés. Les fonds ne peuvent être utilisés pour financer des recherches que si les conditions suivantes sont remplies:

communiquées et confirmé par écrit à l'Institution que ces travaux peuvent commencer.

14. ANTI-TERRORISME ET SANCTIONS DE L'ONU; FRAUDE ET CORRUPTION

14.1 L'Institution et le Chercheur principal garantissent, pour toute la durée du présent Accord:

(a) qu'ils ne sont ni ne seront impliqués à l'égard de, ni associés à, aucune personne ou entité que le régime de sanctions du Conseil de sécurité des Nations Unies a désignée comme étant associée au terrorisme, qu'ils ne feront aucun paiement à, ou ne soutiendront d'aucune autre manière, à une telle personne ou entité, et qu'ils ne concluront aucune relation d'emploi ni de sous-traitance avec une telle personne ou entité; et

(b) qu'ils ne prendront part à aucune pratique illégale, de corruption, de fraude, de collusion ou de coercition (y compris pots de vin, vol ou autre utilisation abusive de fonds) en lien avec l'exécution du présent Accord.

14.2 L'Institution et le Chercheur principal prendront toutes les précautions nécessaires pour empêcher le financement du terrorisme et/ou toute pratique illégale, de corruption, de fraude, de collusion ou de coercition (y compris, pots de vin, vol ou autre utilisation abusive de fonds) en lien avec l'exécution du présent Accord.

14.3 Toute somme que l'Institution et/ou le Chercheur principal utiliseraient pour promouvoir une quelconque activité terroriste ou une quelconque pratique illégale, de corruption, de fraude, de collusion ou de coercition sera remboursée à l'OMS sans délai.

15. VIOLATION DE CLAUSES ESSENTIELLES

L'Institution et le Chercheur principal reconnaissent et acceptent que chacune des dispositions des sections 11, 12, 13 et 14 des présentes constitue une clause essentielle du présent Accord et qu'en cas de manquement à l'une quelconque de ces dispositions, l'OMS peut, à sa seule discrétion, décider:

(i) de résilier immédiatement le présent Accord, et/ou tout autre contrat conclu par l'OMS avec l'Institution et/ou le Chercheur principal, moyennant une notification écrite adressée à ceux-ci, sans être redevable d'aucune pénalité au titre d'une telle résiliation et sans que sa responsabilité ne soit engagée d'une quelconque manière que ce soit; et/ou

(ii) d'exclure l'Institution et/ou le Chercheur principal de toute participation à des appels d'offres en cours ou à venir et/ou de toute relation contractuelle ou de collaboration future avec l'OMS.

L'OMS sera en droit de rapporter toute violation de ces dispositions à ses organes directeurs, aux autres organismes des Nations Unies et/ou aux donateurs.

16. PUBLICITE ; UTILISATION DU NOM ET DE L'EMBLEME DE L'OMS

16.1 L'Institution et le Chercheur principal ne pourront faire mention, dans un quelconque écrit ou déclaration à caractère publicitaire ou promotionnel, y compris, sans s'y limiter, ceux qui sont diffusés à des fins commerciales, ou en vue d'un avantage financier, du lien existant entre l'OMS et le projet, ou les produits ou procédés en découlant.

16.2 Ni l'Institution ni le Chercheur principal n'auront le droit, dans une déclaration ou support à caractère publicitaire ou promotionnel, de faire référence au présent Accord ou à leur relation avec l'OMS, ni d'utiliser d'une autre manière le nom (ou toute abréviation de celui-ci) et/ou l'emblème de l'Organisation mondiale de la Santé, sans l'autorisation écrite préalable de l'OMS.

17. PUBLICATION DE L'ACCORD

Sous réserve de considérations relatives à la confidentialité, l'OMS a le droit de divulguer l'existence du présent Accord et de publier, et/ou rendre public d'une autre manière, le nom de l'Institution et/ou du Chercheur principal, le pays d'enregistrement de l'Institution, des informations générales concernant les travaux financés au titre des présentes et la valeur du présent Accord. Cette divulgation se fera conformément à la politique de l'OMS sur la divulgation des informations et aux dispositions du présent Accord.

18. DISPOSITIONS RESTANT EN VIGUEUR APRES LA FIN DE L'ACCORD

Les dispositions du présent Accord qui sont, de par leur nature, destinées à survivre à l'expiration ou à la résiliation anticipée de l'Accord continueront de s'appliquer.

19. REGLEMENT DES DIFFERENDS

Toute question concernant l'interprétation ou l'application du présent Accord que les dispositions de ce dernier ne permettent pas de résoudre doit être résolue par référence au droit suisse. Tout différend relatif à l'application ou à l'interprétation du présent Accord qui n'aurait pu être résolu à l'amiable, fera l'objet d'une conciliation. En cas d'échec de celle-ci, le différend sera réglé par arbitrage. Les modalités de l'arbitrage seront convenues entre les parties ou, en l'absence d'accord, seront déterminées selon le Règlement d'arbitrage de la Chambre de commerce internationale. Les parties reconnaissent que la sentence arbitrale sera finale.

20. PRIVILEGES ET IMMUNITES

Aucun des termes du présent Accord ni rien qui s'y rapporte ne sera considéré comme constituant une renonciation à quelque privilège ou immunité que ce soit dont jouit l'OMS en vertu du droit national ou international et/ou interprété comme une soumission de l'OMS à la compétence d'une quelconque juridiction nationale.

SP
9/7/2019

Technical Services Agreement

Sensitivity: Internal & Restricted

ATTESTED

[Signature]

Page 6 of 6

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



**World Health
Organization**

**COVERING LETTER
LETTRE D'ACCOMPAGNEMENT**

Global Procurement
and Logistics
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS

WHO Reference	2017/716530-0
Purchase Order	201737246
Unit Reference	

DR. Shivaprasad Goudar
PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM (JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM)
KARNATAKA
Nehru Nagar
Belgaum
Karnataka
India

TECHNICAL SERVICES AGREEMENT (TSA)

Re: To conduct preparatory activities for WHO ACTION-1 and ACTION-2 Trials. To initiate participant recruitment for WHO ACTION-1 Trial. To initiate participant recruitment for WHO ACTION-2 Trial (pending receipt of all necessary approval)

We are enclosing the Technical Services Agreement between the World Health Organization and PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM (JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM), KARNATAKA, in the amount of INR 28,889,270.16 (Twenty-Eight Million Eight Hundred Eighty-Nine Thousand Two Hundred Seventy), for conducting the above-mentioned work. We also enclosed five attachment(s) referenced in the Agreement.

Kindly acknowledge your acceptance of this contract by returning the email with a copy of duly signed Purchase Order (all pages).

For any technical or scientific questions related to this Agreement, please contact the responsible technical officer, Joshua VOGEL, vogeljo@who.int.

On behalf of the World Health Organization, we thank you for your collaboration.

Cc: WHO Representative, India

WHO Global Service Centre

Concerne: To conduct preparatory activities for WHO ACTION-1 and ACTION-2 Trials. To initiate participant recruitment for WHO ACTION-1 Trial. To initiate participant recruitment for WHO ACTION-2 Trial (pending receipt of all necessary approval)

Veillez trouver ci-joint l'Accord de Services Techniques entre l'Organisation Mondiale de la Santé et PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM (JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM), KARNATAKA, pour un montant de INR 28,889,270.16 (Twenty-Eight Million Eight Hundred Eighty-Nine Thousand Two Hundred Seventy), vous permettant de mener à bien le travail susmentionné. Veillez également trouver five pièces jointes mentionnées dans l'Accord.

Merci de confirmer votre acceptation de ce contrat en nous retournant le courriel et une copie dûment signée du Bon de Commande (complet)

Pour toutes questions à caractère scientifique ou technique ayant trait à cet Accord, veuillez contacter le responsable technique Joshua VOGEL, vogeljo@who.int.

Au nom de l'Organisation Mondiale de la Santé, nous vous remercions de votre collaboration.

Centre de Soutien Administratif Mondial de l'OMS

Cc: Représentant de l'OMS, India

SP 12/5/2017
Research Co-Ordinator
JNMC - Women's & Children's
Health Research Unit,
J.N. Medical College, BELAGAVI.



M 12/5/2017
Principal
JNMC, BELAGAVI

ATTESTED

k
Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



World Health Organization

Global Procurement and Logistics
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS

WHO Reference 2017/716530-0
Purchase Order 201737246
Unit Reference

**TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES**

The WORLD HEALTH ORGANIZATION hereby agrees to provide to L'ORGANISATION MONDIALE DE LA SANTÉ s'engage par la présente à fournir à INSTITUTION:

PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM (JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM) KARNATAKA
PRINCIPAL INVESTIGATOR
Karnataka
India

Principal Investigator: DR.Shivaprasad Goudar
Telephone:
Fax:
Email/Courriel:

The Amount of/Un Montant de: INR 28,889,270.00 (Twenty-Eight Million Eight Hundred Eighty-Nine Thousand Two Hundred Seventy)

in respect of/en vue de: To conduct preparatory activities for WHO ACTION-1 and ACTION-2 Trials. To initiate participant recruitment for WHO ACTION-1 Trial. To initiate participant recruitment for WHO ACTION-2 Trial (pending receipt of all necessary approval)

For the period financed by this Agreement From/De : 15-MAY-2017
Période du projet financée par le présent accord To/A : 31-JUL-2018

Summary of work/ Description sommaire des travaux:

1. Description of work under this Agreement/ Description des travaux faisant l'objet du présent accord:

A65913 (ACTION 1)
A65916 (ACTION 2)

See attached protocol

2. Contribution of the Institution and/or other sources for the project (Staff, equipment, supplies, etc. excluding general facilities). The Institute will provide all facilities, equipment and personnel not covered by this Agreement.

Contribution de l'Institution ou de tout autre organisme à l'exécution du projet (personnel, matériel, fournitures, etc. à l'exclusion des services d'ordre général). L'Institution s'engage à fournir les locaux, équipement et personnels non couverts par cet accord.

Financial Arrangements/ Dispositions financiers:

1. Payments will be made as follows/Les versements seront effectués comme suit:

	Deliverable/ Résultat	Due Date/ Date Remise	%	Currency Amount/ Montant en Devise
1	Upon signature	22-MAY-2017	100.00	28,889,270.16
2	Financial Report	31-JUL-2018	0.00	0.00
3	Technical report	31-JUL-2018	0.00	0.00

2. INR 0.00 will be used by WHO for the purchase of equipment and supplies to be ordered by the Institution as soon as practicable, but not beyond 31 December of the year following the end of the Agreement period as indicated above at which time any uncommitted balance will revert to WHO.

INR 0.00 seront affectés par l'OMS à l'achat de matériels et de fournitures à commander par l'Institution dès que possible, mais au plus tard avant le 31 décembre de l'année suivant la fin de la période susmentionnée d'exécution de l'accord, étant entendu qu'à ce moment tout solde non engagé fera retour à l'OMS.

Annexes

The following annexes form an integral part of this Agreement/ Les annexes listées ci-dessous font partie intégrante de cet accord:

Annex	File Description/Description de fichier
1	2017/716530 Contractual - Statement of Work
2	2017/716530 Contractual - Statement of Work
3	2017/716530 Contractual - Budget Breakdown Budget ACTION 1 AND 2
4	2017/716530 Contractual - Terms of Reference
5	2017/716530 Contractual - Statement of Work

In the event that the terms of the annexes contain any provisions which are contrary to the terms of this Agreement, the terms of this Agreement shall take precedence/ En cas de contradiction entre les termes apparaissant sur les annexes et ceux de l'Accord, les dispositions de l'Accord prévaudront dans tous les cas.

Technical Services Agreement



Principal
JNMC, BELAGAVI

ATTESTED

Dr. V.A.Kothiwale
Registrar

Page 1 of 5

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

12/5/2017
Research Co-Ordinator
JNMC - Women's & Child Health Research Unit
J.N. Medical College, BELAGAVI



World Health Organization

Global Procurement and Logistics
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS	
WHO Reference	2017/716530-0
Purchase Order	201737246
Unit Reference	

**TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES**

General

The parties accept the "General Conditions" overleaf, which constitute an integral part of this Agreement. The Institution certifies the correctness of the banking instructions provided on Page 1.

All necessary arrangements to comply with national regulations relating to this project and relevant to the Institution's responsibilities shall have been under-taken by the Institution; failure to do so will nullify this Agreement. The responsibility of the World Health Organization is limited only to the financial support as specified in this Agreement.

Généralités

Les parties acceptent les "Conditions générales" reproduites au verso, lesquelles font partie intégrante du présent accord. L'Institution certifie l'exactitude des instructions bancaires indiquées à la page 1.

Toutes les dispositions relevant des responsabilités de l'Institution et nécessaires à la mise en conformité de ce Projet avec la réglementation nationale, devront avoir été prises par l'Institution, faute de quoi l'accord sera nul. La responsabilité de l'Organisation Mondiale de la Santé se limite au soutien financier spécifié dans le présent accord.

ON BEHALF OF WHO/ POUR L'OMS

Responsible WHO Technical Officer:
Fonctionnaire technique responsable de l'OMS:

Joshua Vogel
Technical Officer
HQ/RHR - Reproductive Health and Research

Responsible Divisional Director
Directeur de division responsable

Flavia BUSTREO
Asst Director-General
HQ/FWA FWC ADGO Office of the Assistant DG

Authorized Signatory:
Signataire autorisé:

Mr. Motohiro Ogita
Coordinator
Global Procurement and Logistics
(WHO/GMG/GSC/GPL)

Motohiro Ogita
Coordinator
HQ/GSC Global Service Centre
06-MAY-2017

PRINCIPAL INVESTIGATOR/ CHERCHEUR PRINCIPAL

Principal Investigator or Technical Officer responsible for the project.

Chercheur Principal ou membre du personnel technique responsable de l'exécution du projet.

Signature : 12/5/2017
DR. Shivaprasad Goudar

ON BEHALF OF THE INSTITUTION/ POUR L'INSTITUTION

Responsible Administrative Authority*
*Autorité administrative responsable**

Signature :
Name/nom : DR. N.S. MAHANTSHETI
Division : Principal, JNMC, BELAGAVI
Date : 12.05.2017



Principal
JNMC, BELAGAVI

* An official of the Institution - other than the Principal Investigator - fully empowered to enter into contracting arrangements on behalf of the Institution. / *Un responsable de l'Institution autre que le Chercheur principal - ayant pleins pouvoirs pour passer un contrat au nom de l'Institution.*

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



World Health Organization

**TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES**

Global Procurement and Logistics
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gss-procurement@who.int

WHO Reference/ Référence OMS

WHO Reference 2017/716530-0
Purchase Order 201737246
Unit Reference

GENERAL CONDITIONS

The following are the general conditions relating to this Agreement concerning WHO support for research or other technical services. The purpose of such support is to assist an Institution to undertake, for WHO, investigations on a particular problem or other work which has been agreed upon by the Institution and WHO.

1 INSTITUTION AND PRINCIPAL INVESTIGATOR

1.1 The Institution and the Principal Investigator (or Responsible Technical Officer), who must be an employee of the Institution, shall be jointly responsible for all the technical and administrative aspects of the work referred to in this Agreement.

1.2 The Institution is required to notify WHO immediately of knowledge that the Principal Investigator will cease or ceases to be an employee of the Institution or is no longer continuing the responsibilities covered by this Agreement. Under such circumstances WHO has the right to:

- a. cancel this Agreement or
- b. agree to continue the project under a new Principal Investigator proposed by the Institution and approved by WHO.

2. FINANCIAL ARRANGEMENTS

2.1 Payments shall be made to the bank account(s) of the Institution as specified in this Agreement and in accordance with the schedule of payments contained therein. If, after the submission of the final financial report referred to in paragraph 4.3 below, there remains an unused balance of funds with the Institution, this balance shall be due to WHO. In the event of this Agreement being cancelled under any circumstances, the Institution shall refund to WHO the balance of uncommitted funds. The funds provided under this Agreement shall be spent only in accordance with its terms.

2.2 The funds transferred to the Institution under this Agreement may not be used to meet any form of emoluments, travel costs or any other reimbursements of expenditure to a staff member of WHO.

2.3 Unless otherwise provided in this Agreement the funds may not be used to cover:

- a. normal administrative and overhead expenses of the Institution;
- b. cost of maintenance, repair, running or insurance of existing equipment and machinery belonging to the Institution;
- c. cost of construction of new buildings or alterations and modifications of existing buildings and premises;
- d. salary support of the Principal Investigator.

3. EQUIPMENT AND SUPPLIES

3.1 Unless otherwise agreed, and subject to subparagraph 3.2 below, any equipment acquired under this Agreement shall become the property of the Institution. The Institution and the Principal Investigator shall be jointly responsible for the proper safeguard, maintenance and care of all equipment acquired under this Agreement.

3.2 Notwithstanding subparagraph 3.1 above, the Institution shall transfer ownership of any equipment acquired under this Agreement to WHO, if so requested by WHO, upon termination or expiry of this Agreement. In such cases the Institution shall dispatch the equipment to any destination chosen by WHO, the cost of which will be borne by WHO.

4. REPORTS

The Institution shall submit technical and financial reports to WHO on the work as required, or at least annually, in accordance with the following provisions:

4.1 Technical reports shall be prepared by the Principal Investigator and forwarded through and countersigned by the authorized official of the Institution or his authorized representative. Each annual report shall summarize the results of the project and give in sufficient detail its positive and negative findings so that the value of the work can be assessed.

4.2 Financial reports shall be forwarded after being jointly certified by the Institution's Chief Financial Officer and the Principal Investigator, using form WHO 782. The reports must show the use of the funds provided by WHO compared with the original budget expenditure pattern agreed between the Institution and WHO.

4.3 All Financial and Technical reports are subject to audit by WHO, including examination of supporting documentation and relevant accounting entries in the Institution's books. In order to facilitate such reporting and audit, the Institution shall ensure that accurate and systematic accounts and records are kept in respect of the project. The final Technical and Financial reports must be submitted within 90 days after the expiry of this Agreement.

5. RELATIONSHIP AND RESPONSIBILITY OF PARTIES

The relationship of the Institution to WHO shall be that of an independent contractor. The employees of the Institution are not entitled to describe themselves as staff members of WHO. The Institution shall be solely responsible for the manner in which work on the project is carried out and accordingly shall assume full liability for any damage arising from research or other technical services under this Agreement. No liability shall attach to WHO, its advisers, agents or employees.

6. USE OF RESULTS, EXPLOITATION OF RIGHTS, AND PUBLICATION

6.1 The results of the project funded under this Agreement may be freely used or disclosed by either party provided that, without the consent of the other party, no use may be made for commercial purposes and confidentiality shall be maintained with respect to results that may be eligible for protection by proprietary rights. The Institution shall provide WHO with the results, in the form of relevant know how and other information, and to the extent feasible, tangible products.

6.2 The industrial or commercial exploitation of any intellectual property rights,

including the ownership of know-how, arising from the project shall be designed to achieve, in so far as circumstances permit, the following objectives in the following order of priority:

- a. the general availability of the products of creative activity;
- b. the availability of those products to the public health sector on preferential terms, particularly in developing countries;
- c. the grant to each party of additional benefits, including royalties, account being taken of the relative value of each party's financial, intellectual and other contribution to the research.

6.3 The rights referred to in para. 6.2 shall belong to the Institution, or to the Principal Investigator if the Institution and WHO so agree. To the extent that the former do not intend to exercise them, the rights shall be promptly transferred to WHO, if it so requests. Each party shall provide the other with its full cooperation to permit the effective exercise of the rights. The party in which the corresponding rights are vested may file applications for industrial property protection, promptly furnishing copies of the applications and other patent documents to the other party. All rights other than the right to file applications shall be exercised in accordance with an agreement which shall be negotiated in good faith between the Institution and WHO.

6.4 In any publication by the Institution or the Principal Investigator relating to the results of the project, the responsibility for the direction of the work shall not be ascribed to WHO. Unless WHO advises otherwise, all publications shall include a notice indicating that the underlying investigation received financial support from WHO. Two off-prints or copies shall be sent to WHO unless another number is stipulated. WHO funds may not be used for publication costs unless specifically authorized.

7. RESEARCH INVOLVING HUMAN SUBJECTS

7.1 Ethical Aspects

It is the responsibility of the Institution and the Principal Investigator to safeguard the rights and welfare of human subjects involved in research supported in whole or in part by funds from WHO, in accordance with the appropriate national code of ethics or legislation, if any, and in the absence thereof, the Helsinki Declaration and any subsequent amendments. Such funds may be used only to support investigations where (a) the rights and welfare of the subjects involved in the research are adequately protected, (b) freely given informed consent has been obtained, (c) the balance between risk and potential benefits involved has been assessed and deemed acceptable by a panel of independent experts appointed by the Institution and (d) any special national requirements have been met.

7.2 Regulatory Requirements

It is the responsibility of the Institution and the Principal Investigator to comply with the relevant national regulations pertaining to research involving human subjects.

7.3 Protection of Subjects

Without prejudice to obligations under applicable laws, the Institution shall make appropriate arrangements to eliminate or mitigate the consequences to subjects or their families in the case of death, injury or illness resulting from the conduct of research referred to in paragraph 7.1. Such arrangements shall, to the extent feasible, include medical treatment and financial relief. The Institution and Principal Investigator undertake to protect the confidentiality of the information relating to the possible identification of subjects involved in the research involving human subjects conducted under the auspices of this Agreement.

8. RESEARCH INVOLVING THE USE OF LABORATORY ANIMALS

The Institution undertakes that living vertebrate animals, required for use as laboratory animals for the research to be carried out under this Agreement, shall be handled in accordance with generally accepted principles for the humane treatment of such animals and the avoidance of unnecessary suffering.

9. RESEARCH SAFETY

It is the responsibility of the Institution to establish and implement policies and practices to assure and provide for the safety of its employees, the public, and the environment during the conduct of the supported research. If the supported research involves the use of dangerous biological agents, the Institution shall establish and implement an appropriate safety plan.

10. PUBLICITY

The Institution and the Principal Investigator shall not refer to the relationship of WHO to the project, or to products or processes connected with the project, in any statement or material of a publicity or promotional nature issued for commercial purposes, or with a view to financial benefit.

11. SETTLEMENT OF DISPUTES

Any matter relating to the interpretation or application of this Agreement which is not covered by its terms shall be resolved by reference to Swiss law. Any dispute relating to the interpretation or application of this Agreement shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or, in the absence of agreement, with the Rules of Arbitration of the International Chamber of Commerce. The parties shall accept the arbitral award as final.

12. PRIVILEGES AND IMMUNITIES

Nothing contained in or relating to this Agreement shall be deemed to constitute a waiver of any of the privileges and immunities enjoyed by WHO and/or as submitting WHO to any national court jurisdiction.

12/5/2017
Research Co-Ordinator
JNMC - Women's & Children's
Health Research Unit
Technical Services Agreement
J.N. Medical College, BELAGAVI.



12/5/2017
Principal
JNMC, BELAGAVI

ATTESTED

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



World Health Organization

**TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES**

Global Procurement and Logistics
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS

WHO Reference 2017/716530-0
Purchase Order 201737246
Unit Reference

CONDITIONS GENERALES

Les conditions générales énoncées ci-après s'appliquent au présent Accord sur l'appui de l'OMS aux recherches ou autres services techniques. Cet appui vise à aider une institution à entreprendre pour le compte de l'OMS, des investigations portant sur un problème particulier ou des travaux convenus entre l'institution et l'OMS.

1. INSTITUTION ET CHERCHEUR PRINCIPAL

1.1 L'institution et le Chercheur principal (ou l'Administrateur technique responsable), lequel doit être employé par l'institution, sont conjointement responsables de l'ensemble des aspects techniques et administratifs des travaux visés par le présent Accord.

1.2 L'institution est tenue d'aviser immédiatement l'OMS lorsqu'elle apprend que le Chercheur principal va cesser, ou a cessé, d'être employé par elle, ou bien qu'il ne continue pas à exercer les fonctions visées par le présent Accord. En pareil cas, l'OMS peut:

- a. soit annuler le présent Accord;
- b. soit accepter de poursuivre le projet sous la conduite d'un nouveau Chercheur principal proposé par l'institution et approuvé par l'OMS.

2. DISPOSITIONS FINANCIERES

2.1 Des versements seront faits au(x) compte(s) bancaire(s) de l'institution comme il est stipulé dans le présent Accord et conformément au calendrier qui y figure. Si, après communication du rapport financier final mentionné plus loin au paragraphe 4.3, il apparaît que l'institution détient un solde non utilisé, ce solde reste payable à l'OMS. En cas d'annulation du présent Accord, quelles qu'en soient les circonstances, l'institution restituera à l'OMS les sommes non encore engagées. Les sommes fournies en vertu du présent Accord ne pourront être dépensées que conformément aux dispositions dudit Accord.

2.2 Les fonds versés à l'institution en vertu du présent Accord ne peuvent être utilisés pour verser des émoluments quelconques à un fonctionnaire de l'OMS, couvrir ses frais de voyage ou lui rembourser toute autre dépense.

2.3 Sauf dispositions contraires du présent Accord, ces fonds ne peuvent être utilisés pour couvrir:

- a. les dépenses administratives et les frais généraux normaux de l'institution;
- b. le coût de l'entretien, de la réparation, de l'exploitation ou de l'assurance de matériels ou d'appareils existants qui appartiennent à l'institution;
- c. le coût de la construction de nouveaux bâtiments, ou de la transformation ou de la modification de bâtiments et locaux existants;
- d. le versement d'un complément de traitement au Chercheur principal.

3. MATERIEL ET FOURNITURES

3.1 Sauf convention contraire, et sous réserve des dispositions de l'alinéa 3.2 ci-après, tout matériel obtenu en vertu du présent Accord sera la propriété de l'institution. L'institution et le Chercheur principal seront conjointement responsables du bon état de conservation et d'entretien de tout matériel acquis en application du présent Accord.

3.2 Nonobstant les dispositions de l'alinéa 3.1 ci-dessus et si l'OMS en fait la demande, l'institution transfèrera à celle-ci, lors de la résiliation ou de l'expiration du présent Accord les droits de propriété afférents à tout matériel acquis au titre dudit Accord. L'institution expédiera alors ce matériel vers toute destination que lui aura indiquée l'OMS, les frais d'expédition étant à la charge de cette dernière.

4. RAPPORTS

L'institution soumettra à l'OMS des rapports techniques et financiers concernant ses travaux, chaque fois qu'il y a lieu et au moins une fois par an, selon les modalités suivantes.

4.1 Les rapports techniques seront établis par le Chercheur principal, envoyés sous couvert du responsable de l'institution ou de son représentant l'un et l'autre dûment autorisés, et contre-signés par eux. Chaque rapport annuel résumera les résultats du projet et en exposera les conclusions positives ou négatives de façon assez détaillée pour permettre d'apprécier la valeur des travaux.

4.2 Les rapports financiers devront être envoyés, après avoir été visés conjointement par le Chef des Services financiers de l'institution et par le Chercheur principal qui utiliseront à cette fin la formule WHO 782. Les rapports devront indiquer l'utilisation des fonds provenant de l'OMS au regard des prévisions de dépenses initiales dont étaient convenues l'institution et l'OMS.

4.3 Tous les rapports financiers et techniques sont soumis par l'OMS à une vérification comprenant l'examen de toutes pièces justificatives ainsi que des écritures comptables correspondantes dans les livres de l'institution. En vue de faciliter l'établissement et la vérification de ces rapports, l'institution veillera à la tenue de comptes et de registres exacts et systématiques pour tout ce qui concerne le projet. Les rapports techniques et financiers finaux devront être présentés dans les 90 jours suivant l'expiration du présent Accord.

5. RELATIONS ENTRE LES PARTIES ET LEURS RESPONSABILITES

L'institution agira à l'égard de l'OMS en tant qu'entrepreneur indépendant; ses employés ne pourront se prévaloir de la qualité de membres du personnel de l'OMS. L'institution sera seule responsable de la façon dont s'exécute le projet et, partant, assumera l'entière responsabilité de tout dommage résultant de recherches ou d'autres services techniques visés par le présent Accord. Aucune responsabilité ne pourra incomber à l'OMS, ses conseillers, agents ou employés.

6. UTILISATION DES RESULTATS, EXPLOITATION DES DROITS, ET PUBLICATION

6.1 Les résultats du projet financé en vertu du présent Accord pourront être librement utilisés ou divulgués par l'une ou l'autre partie. Toutefois, à défaut de l'assentiment de l'autre partie, les résultats ne pourront être utilisés à des fins commerciales et, s'ils sont susceptibles d'être protégés par des droits de propriété, ils conserveront leur caractère strictement confidentiel. L'institution communiquera à l'OMS les résultats des recherches, sous forme de savoir-faire et autres

intellectuelle, y compris les droits qui s'attachent au savoir-faire, découlant du projet, devra permettre, dans toute la mesure du possible, d'atteindre les objectifs suivants énoncés par ordre de priorité:

- a. mise à la disposition de tous les produits de l'activité créatrice;
- b. leur mise à la disposition du secteur de la santé publique, notamment dans les pays en développement à des conditions préférentielles;
- c. octroi à chaque partie d'avantages additionnels, y compris sous formes de redevances, compte tenu de la valeur relative de ses contributions financières, intellectuelles et autres.

6.3 Les droits mentionnés plus haut au paragraphe 6.2 seront la propriété de l'institution, ou du Chercheur principal si l'institution et l'OMS en conviennent ainsi. Dans la mesure où l'institution n'entend pas les exercer, les droits seront promptement transmis à l'OMS, si celle-ci le demande. Chaque partie coopérera pleinement avec l'autre pour lui permettre d'exercer effectivement ses droits. La partie détentrice des droits pourra déposer des demandes de propriété industrielle et devra alors remettre à l'autre partie copie de ces dépôts et des autres documents relatifs au brevet. Tous les droits autres que celui de déposer des demandes s'exercent aux termes d'un accord qui sera négocié de bonne foi entre l'institution et l'OMS.

6.4 Dans aucune de ses publications concernant les résultats du projet, l'institution ou le Chercheur principal n'attribuera à l'OMS la responsabilité de la direction des travaux. Sauf instructions contraires de l'OMS, toutes les publications comporteront une note indiquant que les recherches qui sont à l'origine des résultats ont reçu un appui financier de l'OMS. A moins qu'un autre chiffre n'ait été stipulé, deux exemplaires ou tirés à part de ces publications seront envoyés à l'OMS et, sauf autorisation expresse, les fonds de l'OMS ne pourront être utilisés pour couvrir les coûts de publication.

7. RECHERCHES IMPLIQUANT L'ETUDE DE SUJETS HUMAINS.

7.1 Aspects déontologiques

Il incombe à l'institution et au Chercheur principal de s'assurer qu'au cours des travaux financés totalement ou en partie par l'OMS et impliquant l'étude de sujets humains, les droits et la santé de ces derniers soient protégés conformément au code de déontologie ou à la législation du pays, ou, à défaut, à la Déclaration d'Helsinki et aux amendements qui pourraient lui être ultérieurement apportés. Les fonds ne peuvent être utilisés pour financer des recherches qui si les conditions suivantes sont remplies:

- a. les droits et le bien-être des sujets impliqués sont suffisamment protégés;
- b. le consentement libre et éclairé des intéressés a été obtenu;
- c. des experts indépendants désignés par l'institution ont pesé les risques et les avantages potentiels et ont jugé qu'ils s'équilibrent de manière acceptable; et
- d. il ait satisfait à toute exigence particulière de la réglementation nationale.

7.2 Dispositions réglementaires

Il incombe à l'institution et au Chercheur principal de respecter la réglementation nationale relative aux recherches impliquant l'étude de sujets humains.

7.3 Protection des sujets d'expérience

Sans préjudice des obligations qui lui incombent aux termes des lois en vigueur, l'institution prendra des mesures appropriées en vue d'éliminer ou d'atténuer les conséquences des expériences pour les sujets ou leur famille en cas de décès, de traumatisme ou de maladie résultant de la conduite des recherches mentionnées au paragraphe 7.1. Ces mesures comprendront, dans la mesure du possible, un traitement médical et un dédommagement financier. L'institution et le Chercheur principal s'engagent à protéger le caractère confidentiel des informations qui pourraient permettre d'identifier les sujets impliqués dans les études effectuées en vertu du présent Accord.

8. RECHERCHES IMPLIQUANT L'UTILISATION D'ANIMAUX DE LABORATOIRE

L'institution s'engage à veiller à ce que les animaux vertébrés vivants qu'il sera nécessaire d'utiliser comme animaux de laboratoire pour des recherches entreprises en vertu du présent Accord soient traités conformément aux principes universellement reconnus qui veulent que l'on épargne à ces animaux toute souffrance inutile.

9. SECURITE DES RECHERCHES

Il incombe à l'institution d'arrêter et d'appliquer des politiques et pratiques préservant et garantissant la sécurité de ses employés et du public ainsi que celle de l'environnement pendant les recherches soutenues par l'OMS. Si les travaux impliquent l'utilisation de substances biologiques dangereuses, l'institution établira et appliquera un plan de sécurité approprié.

10. PUBLICITE

L'institution et le Chercheur principal ne pourront faire mention, dans un quelconque écrit ou déclaration à caractère publicitaire ou promotionnel diffusé à des fins commerciales, ou en vue d'un avantage financier, du lien existant entre l'OMS et le projet ou les produits ou procédés en découlant.

11. REGLEMENT DES LITIGES

Toute question concernant l'application ou l'interprétation du présent Accord que les dispositions de ce dernier ne permettent pas de résoudre doit être résolue par référence au droit suisse. Tout différend relatif à l'application ou à l'interprétation du présent Accord qui n'aurait pu être résolu à l'amiable, fera l'objet d'une conciliation. En cas d'échec de celle-ci, le différend sera réglé par arbitrage. Les modalités de l'arbitrage seront convenues entre les parties ou, en absence d'accord, seront déterminées selon le règlement d'arbitrage de la Chambre de Commerce Internationale. Les parties reconnaissent que la sentence arbitrale sera finale.

12. PRIVILEGES ET IMMUNITES

Aucun des termes du présent Accord ne sera considéré comme constituant une

ATTESTED

12/5/2017
Principal

JNMC, BELAGAVI

Dr. V.A.Kothiware
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Research Co-Ordinator
JNMC - Women's & Children's
Health Technical Services Agreement
J.N. Medical College, BELAGAVI.





**World Health
Organization**

**TECHNICAL SERVICES
AGREEMENT
ACCORD DE SERVICES
TECHNIQUES**

Global Procurement
and Logistics
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS

WHO Reference 2017/716530-0
Purchase Order 201737246
Unit Reference

informations pertinentes et, dans la mesure du possible, lui fournira des produits concrets.
6.2 L'exploitation industrielle ou commerciale de tout droit de propriété

renonciation à quelque privilège ou immunité que ce soit dont jouit l'OMS et/ou comme constituant une soumission de l'OMS à la compétence d'un quelconque tribunal national.

[Signature]
12/5/2017

Research Co- Ordinator
JNMC - Women's & Children's
Health Research Unit,
J.N. Medical College, BELAGAVI,



[Signature]
12/5/2017

Principal
JNMC, BELAGAVI

ATTESTED

[Signature]



26 May 2020

Jawaharlal Nehru Medical College, KLE Academy of Higher Education and Research (KAHER)
Belgaum-590010, Karnataka, INDIA

Attn: Dr. N.S. Mahantashetti, Dean, JN Medical College, KAHER

Federal Award Number: NIH Award No.UH3CA189923

Project Name: Performance, safety, and efficacy of a new cryotherapy device for cervical dysplasia

Subject: Fixed Amount Award between Jhpiego Corporation ("Jhpiego") and KLE Academy of Higher Education and Research, hereinafter referred to as "KAHER"

Jhpiego Document Number: 20-SBA-094

CFDA: 93.396

Dear Dr. N.S. Mahantashetti:

Jhpiego Corporation (hereinafter referred to as "Jhpiego"), with offices at 1615 Thames Street, Baltimore, Maryland 21231, a Maryland corporation affiliated with the Johns Hopkins University, requests to issue KAHER, with offices at **Belgaum-590010, Karnataka, INDIA**, (hereinafter referred to as "Subrecipient") the sum of \$216,125 USD, as a Fixed Amount Award (FAA) as more fully described in the Program Description at Attachment 2. This FAA agreement upon signature by authorized officials of Jhpiego and Subrecipient on page three of this letter is effective as of 4 March 2020.

Maximum Award Ceiling Amount:	\$216,125 USD
Type:	Fixed Amount Award
Subaward Expiration Date:	31 July 2020
Payment Method:	Milestone Payments

By signing this FAA agreement, the Subrecipient agrees:

1. The Subrecipient will comply with the terms and conditions as set forth in the attachments listed following the signature below, which are incorporated as part of the Grant Agreement.
2. Subrecipient will maintain records of transactions related to the Grant Subagreement for at least three years after payment of the final milestone. After the end of the agreement, Jhpiego and NIH retains the right, at its discretion, to examine all or a sample of the Subrecipient's records or transactions related to the Grant Subagreement where concerns of implementation irregularities arise.
3. Jhpiego is not liable for reimbursing the Subrecipient for any amount in excess of the obligated amount, or outside of the grant period, as provided in the Schedule.

ATTESTED

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

4. Unless otherwise provided in the Schedule, title to any equipment or personal property purchased to accomplish any milestones under this Grant Subagreement vests in the Subrecipient upon acquisition, with the condition that the Subrecipient must use the equipment or property for the grant as long as it is needed for such.
5. Subrecipient will obtain Jhpiego's written approval prior to any changes to: 1) the activities being supported by this Grant; 2) the fixed amount of this grant; 3) the milestones; or 4) change in the Grant Sub-agreement completion date.
6. Jhpiego will conduct monitoring of the grant program, including site visits as appropriate.
7. On submission of the voucher for payment for the final milestone, the Subrecipient must certify that the grant is completed and the Subrecipient will make no further claim against Jhpiego after final payment.
8. Either party may terminate this Grant Subagreement at any time, in whole or in part, 30 calendar days after receipt of written notification by the other party. If Jhpiego terminates this award, the Subrecipient may submit a claim within 90 calendar days of such termination for any costs incurred in performance of any unpaid or incomplete milestones. Jhpiego must determine the amount(s) to be paid by Jhpiego to the Subrecipient under such claim in accordance with the legally applicable Cost Principles, 2 CFR 200.
9. Jhpiego will decide any dispute under this award. Notwithstanding any other term of this award, sub awardees and contractors have no right to submit claims directly to NIH and NIH assumes no liability for any third party claims against the Subrecipient.

If you concur with the terms and conditions stipulated herein, please sign below and return an electronic version of this signed letter to Jhpiego. Jhpiego is pleased to be working with KAHER on this important program and looks forward to a successful endeavor.

<p>Jhpiego Corporation</p> <p><u>Abhishek Bhasin</u> Abhishek Bhasin (May 26, 2020 08:48 EDT)</p> <p>BY: (signature)</p> <p>Abhishek Bhasin Chief Operating and Financial Officer</p> <p><u>26-May-2020</u></p> <p>Date</p>	<p>KLE Academy of Higher Education and Research (KAHER)</p> <p><u>[Signature]</u></p> <p>BY: (signature)</p> <p>Dr. N.S. Mahantashetti Dean, JN Medical College, KAHER</p> <p><u>27-May-2020</u></p> <p>Date</p>
---	--

ATTESTED

[Signature]
Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



**World Health
Organization**

**COVERING LETTER
LETTRE D'ACCOMPAGNEMENT**

**GLOBAL
PROCUREMENT AND
LOGISTICS**

Global Service Centre
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS

WHO Registration	2020/1037753-0
Purchase Order	202570446
Unit Reference	WCO-NB&CH

DR.Niranjana S. Mahantashetti
PRINCIPAL, J.N. MEDICAL COLLEGE,
BELGAUM (JAWAHARLAL NEHRU MEDICAL
COLLEGE, BELGAUM)
KARNATAKA
Nehru Nagar
Belgaum
Karnataka
India

AGREEMENT FOR PERFORMANCE OF WORK (APW)

Re: Jawaharlal Nehru Medical College (JNMC), Belgaum - Standardizing reporting and evidence generation on clinical characteristics and outcomes of COVID-19 and Pregnancy, 27 July 2020 to 27 January 2021

We are enclosing the Agreement for Performance of Work between the World Health Organization and PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM (JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM), KARNATAKA, in the amount of INR 1,838,823.00 (One Million Eight Hundred Thirty-Eight Thousand Eight Hundred Twenty-Three), for conducting the above-mentioned work. We also enclosed two attachment(s) referenced in the Agreement.

Kindly acknowledge your acceptance of this contract by returning the email with a copy of duly signed Purchase Order (all pages).

For any technical questions relating to this Agreement, please contact the responsible technical officer, Deepti AGRAWAL, agrawald@who.int.

Invoicing Instructions for Contractors who are legal entities (Company Contractors):

Invoices must be sent via email to accountspayable@who.int. Other than invoices, please do not send any enquiry to this email address. You may contact the above responsible technical officer for enquiries.

In order to ensure timely and accurate payment, invoices must include:

- Invoice number
- Purchase Order number against each invoice line;
- Invoice descriptions matching with PO descriptions
- Invoice currency same as the Purchase Order Currency also corresponding with the currency of the bank account provided to WHO;
- Supplier name as in the PO

Invoices shall be clearly readable and stamps or any other additional markings should not obscure the original invoice content. Invoices shall not be handwritten.

On behalf of the World Health Organization, we would like to thank you for your collaboration.

cc: WHO India

WHO Global Service Centre

Concerne: Jawaharlal Nehru Medical College (JNMC), Belgaum - Standardizing reporting and evidence generation on clinical characteristics and outcomes of COVID-19 and Pregnancy, 27 July 2020 to 27 January 2021

Veuillez trouver ci-joint l' Accord pour Exécution de Travaux entre l'Organisation Mondiale de la Santé et PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM (JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM), KARNATAKA, pour un montant de INR 1,838,823.00, vous permettant de mener à bien le travail susmentionné. Veuillez également trouver 2 pièce(s) jointe(s) mentionnée(s) dans l'Accord.

Merci de confirmer votre acceptation de ce contrat en nous retournant le courriel et une copie dûment signée du Bon de Commande (

MK
31/7/2020

ATTESTED

[Signature]
Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka



World Health Organization

AGREEMENT FOR PERFORMANCE OF WORK ACCORD POUR EXECUTION DE TRAVAUX

GLOBAL PROCUREMENT AND LOGISTICS

Global Service Centre
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS

WHO Registration	2020/1037753-0
Purchase Order	202570446
Unit Reference	WCO-NB&CH

complet)

Pour toutes questions à caractère technique ayant trait à cet Accord, veuillez contacter le responsable Deepti AGRAWAL, agrawald@who.int.

Instructions concernant la facturation pour les contractants qui sont des personnes morales.(Personne Morale):
Les factures doivent être envoyées par courriel à accountspayable@who.int. Outre les factures, n'envoyez aucune enquête à cette adresse de courrier électronique. Vous pouvez contacter le responsable technique responsable ci-dessus pour toute demande de renseignements.

De manière à garantir un paiement exact et ponctuel, les factures doivent impérativement comporter:

- Le Numéro de facture
- Le Numéro du bon de commande, répété à chaque ligne de facturation
- Des descriptifs des produits identiques à ceux du Bon de commande
- Une devise de facturation identique à celle du Bon de commande et à celle du compte en banque fourni à l'OMS
- Un intitulé de facture (nom de fournisseur) identique à celui du Bon de commande.

Les factures doivent être parfaitement lisibles. Le contenu de la facture ne doit en aucun cas être masqué par un tampon ou tout autre marquage. La facture ne doit pas être manuscrite.

Au nom de l'Organisation mondiale de la Santé, nous vous remercions de votre collaboration.

cc: OMS India

Centre mondial de services de l'OMS

MK
31/7/2020



World Health Organization

AGREEMENT FOR PERFORMANCE OF WORK ACCORD POUR EXECUTION DE TRAVAUX

GLOBAL PROCUREMENT AND LOGISTICS

Global Service Centre
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS

WHO Registration 2020/1037753-0
Purchase Order 202570446
Unit Reference WCO-NB&CH

The WORLD HEALTH ORGANIZATION hereby agrees to provide to
L'ORGANISATION MONDIALE DE LA SANTÉ s'engage par la présente à fournir à
PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM
(JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM)
KARNATAKA
Principal
Karnataka
INDIA

The Maximum amount of/Un montant Maximum de: INR 1,838,823.00 (One Million Eight Hundred Thirty-Eight Thousand Eight Hundred Twenty-Three) in respect of/en vue de: Jawaharlal Nehru Medical College (JNMC), Belgaum - Standardizing reporting and evidence generation on clinical characteristics and outcomes of COVID-19 and Pregnancy, 27 July 2020 to 27 January 2021

For the period financed by this Agreement From/De: 27-JUL-2020
Période du projet financée par le présent Accord To/A: 27-JAN-2021

Summary of work/ Description sommaire des travaux:

Description of work under this Agreement/ Description des travaux faisant l'objet du présent Accord:

Jawaharlal Nehru Medical College (JNMC), Belgaum - Standardizing reporting and evidence generation on clinical characteristics and outcomes of COVID-19 and Pregnancy, 27 July 2020 to 27 January 2021, as per the Terms of Reference at Annex 1 and within the approved budget at Annex 2. Both these Annexes form an integral part of this agreement.

During the course of the contract and on its conclusion, the contractual partner shall ensure to submit the stipulated deliverables mentioned under "Financial arrangements".

Financial arrangements/ Dispositions financières:

Payments will be made as follows/Les versements seront effectués comme suit:

	Deliverable/ Résultat	Due date/ Date remise	%	Currency amount/ Montant en devise
1	Upon submission of countersigned contract	27-JUL-2020	50.00	919,411.50
2	Upon submission of retrospective data	27-SEP-2020	25.00	459,705.75
3	Upon submission of monthly report	27-NOV-2020	15.00	275,823.45
4	Upon submission of certified financial Statement of Expenditure (SoE)	27-JAN-2021	10.00	183,882.30
5	Upon submission of the final report	27-JAN-2021	0.00	0.00

Annexes

The following annexes form an integral part of this Agreement/ Les annexes listées ci-dessous font partie intégrante de l'Accord:

Annex/Annexes	File Name/ Nom du fichier
1	2020/1037753 Contractual - Budget Breakdown
2	2020/1037753 Contractual - Terms of Reference

AGREEMENT FOR PERFORMANCE OF WORK

Sensitivity: Internal & Restricted

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



World Health Organization

**AGREEMENT FOR PERFORMANCE OF WORK
ACCORD POUR EXECUTION DE TRAVAUX**

GLOBAL PROCUREMENT AND LOGISTICS

Global Service Centre
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS

WHO Registration 2020/1037753-0
Purchase Order 202570446
Unit Reference WCO-NB&CH

In the event that the annexes contain any provisions which are contrary to the terms of this Agreement, the terms of this Agreement shall take precedence/ En cas de contradiction entre les dispositions des annexes et celles de l'Accord, les dispositions de l'Accord prévaudront dans tous les cas.

The undersigned parties, having read the terms and General Conditions, hereby conclude the present Agreement and confirm their agreement and acceptance thereof.

ON BEHALF OF WHO/ POUR L'OMS

Responsible WHO Technical Officer:

Fonctionnaire technique responsable de l'OMS:

Deepti Agrawal
National Professional Officer (New Born and Child Health)
SE_IND WR Office, India

Approved by:

Approuvé par:

Roderico OFRIN
WHO Representative
SE_IND WR Office, India

Authorized Signatory:

Signataire autorisé:

Mr Prem Prakash Chopra
Team Lead, a.i.

Global Procurement, Processing and Logistics
(WHO BOS/SUP/GPL)

Processed by:

Traité par:

Piramila Devi Apalasy
Procurement Assistant
HQ/BOS Business Operations

PO Approved Date:
PO approuvé le:
29-JUL-20

Les parties soussignées, ayant lu les modalités et les Conditions Générales, ratifient l'Accord et confirment leur acceptation.

CONTRACTOR/ CONTRACTANT

Signature :

Date :

31/7/2020

Name & Title/ Nom & Fonction :

Dr. N.S. Mohantashetti

Principal
JNMC, BELAGAVI



ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



World Health Organization

AGREEMENT FOR PERFORMANCE OF WORK ACCORD POUR EXECUTION DE TRAVAUX

GLOBAL PROCUREMENT AND LOGISTICS

Global Service Centre
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS

WHO Registration 2020/1037753-0
Purchase Order 202570446
Unit Reference WCO-NB&CH

GENERAL CONDITIONS

1. **Relationship of the Parties.** It is understood that the execution of the work does not create any employer/employee relationship. In this respect, the contractor shall be solely responsible for the manner in which the work is carried out. Thus, WHO shall not be responsible for any loss, accident, damage or injury suffered by any person whatsoever arising in or out of the execution of this work, including travel. Insurance coverage for any such loss, accident, damage or injury will be the contractor's responsibility, including where appropriate, insurance coverage for persons used by the contractor to carry out the work.

Without prejudice to the foregoing, WHO may in certain cases provide insurance coverage for the contractor for travel in WHO vehicles. WHO declines all responsibility for non-payment by the insurance company of all or part of a claim submitted by or for the contractor for any accident. In case of such non-payment, the contractor shall be obliged to immediately reimburse all or part of any advance which WHO may have paid to the contractor.

2. **Rights.** All rights in the work, including ownership of the original work and copyright thereof, shall be vested in WHO, which reserves the right (a) to revise the work, (b) to use the work in a different way from that originally envisaged, or (c) not to publish or use the work.

3. **Payment and use of funds.** If the option, on the face of this agreement, for payment of a fixed sum applies, that sum is payable in the manner provided, subject to proper performance of the work.

If the option for payment of a maximum amount applies:

- (i) the funds shall be used exclusively for the work specified in this agreement and any unspent balance shall be refunded to WHO. In this latter case, any financial statement required shall reflect expenditures according to the relevant main categories of expenditure; and
- (ii) to the extent the contractor is required to purchase any goods and/or services in connection with its performance of this agreement, the contractor shall ensure that such goods and/or services shall be procured in accordance with the principle of best value for money. "Best value for money" means the responsive offer that is the best combination of technical specifications, quality and price.

Contractors who are legal entities (hereinafter referred to as "Company Contractors") must submit an invoice to the contracting WHO department or the WHO Global Service Center in order to receive payment. Invoices are not required from contractors who are individuals (hereinafter referred to as "Individual Contractors"), who can be paid upon receipt by the contracting WHO department of the required deliverables (including any required technical reports and financial statements) in a satisfactory manner.

The invoice from Company Contractors shall reflect any tax exemption to which WHO may be entitled by reason of the immunity it enjoys. WHO is, as a general rule, exempt from all direct taxes, custom duties and the like, and the Company Contractor will consult with WHO so as to avoid the imposition of such charges with respect to this agreement and the work performed hereunder. As regards excise duties and other taxes imposed on the provision of goods and services (e.g. value added tax), the Company Contractor agrees to verify in consultation with WHO whether in the country where the tax would be payable, WHO is exempt from such tax at the source, or entitled to claim reimbursement thereof. If WHO is exempt from value added tax, this shall be indicated on the invoice, whereas if WHO can claim reimbursement thereof, the Company Contractor agrees to list such charges on its invoices as a separate item and, to the extent required, cooperate with WHO to enable reimbursement thereof.

WHO shall have no responsibility whatsoever for any taxes, duties or other contributions payable by contractors. Payment of any taxes, duties and other contributions which a contractor may be required to pay shall be the sole responsibility of that contractor who shall not be entitled to any reimbursement thereof by WHO.

4. **Satisfactory performance.** If the work is not satisfactorily completed (and, where applicable, delivered) by the date fixed in this agreement and/or if any financial statement required is not satisfactorily submitted to WHO in accordance with general condition 5 below, WHO may specify an additional period within which this agreement must be satisfactorily performed. Normally such additional period should be of at least one week's

CONDITIONS GENERALES

1. **Relation entre les Parties.** Il n'est pas institué de relations d'employeur à employé aux fins de l'exécution des travaux. A cet égard, le contractant est seul responsable de la manière dont les travaux sont exécutés. Ainsi, l'OMS ne saurait assumer, à l'égard de quelque personne que ce soit, aucune responsabilité pour toute perte, tout accident, tout dommage ou toute blessure subis au cours ou en raison de l'exécution des travaux ou d'un déplacement les concernant. La mise en place d'une couverture d'assurance pour toute perte, tout accident, tout dommage ou toute blessure subis au cours ou en raison de l'exécution des travaux sera de la responsabilité du contractant y compris le cas échéant, toute couverture d'assurance pour les personnes auxquelles le contractant recourt pour l'exécution des travaux.

Sans préjudice de ce qui précède, l'OMS peut, dans certains cas, fournir une couverture d'assurance au contractant en cas de déplacement dans un véhicule de l'OMS. L'OMS décline toute responsabilité pour le non-paiement par la compagnie d'assurance de la totalité ou d'une partie d'une demande d'indemnisation soumise par ou pour le contractant suite à un accident. En cas de non-paiement, le contractant sera obligé d'immédiatement rembourser la totalité ou une partie des avances que l'OMS pourrait lui avoir versées.

2. **Droits.** Tous les droits attachés aux travaux, y compris la propriété des travaux originaux et le droit d'auteur y afférent, seront dévolus à l'OMS qui se réserve le droit (a) de réviser les travaux, (b) d'utiliser les travaux d'une autre manière que celle initialement envisagée, ou (c) de ne pas publier ni utiliser les travaux.

3. **Paiement et utilisation des fonds.** Si l'option applicable - prévue au recto du présent accord - est celle du paiement d'une somme fixe, cette somme est payable dans les conditions prévues, sous réserve de l'exécution satisfaisante des travaux.

Si l'option applicable est celle du paiement d'un montant maximum :

- (i) les fonds seront utilisés exclusivement aux fins des travaux précisés dans l'accord et tout solde non utilisé sera remboursé à l'OMS. Dans ce dernier cas, les états financiers requis devront indiquer les montants engagés pour les principaux postes de dépense ; et
- (ii) dans la mesure où le contractant doit acheter des biens et/ou des services quelconques dans le cadre de l'exécution du présent accord, il devra veiller à ce que l'achat de ces biens et/ou services soit effectué sur la base du principe du meilleur rapport qualité-prix. On entend par « meilleur rapport qualité-prix » l'offre qui présente la meilleure combinaison du point de vue des spécifications techniques, de la qualité et du prix.

Afin d'être payé, les contractants qui sont des personnes morales (ci-après dénommées « Personnes Morales ») doivent présenter une facture au département contractant de l'OMS ou au centre mondial de services de l'OMS. Les contractants qui sont des personnes physiques (ci-après dénommées « Personnes Physiques ») ne sont pas tenus de présenter de facture et peuvent être payés au moment de la réception, sous une forme satisfaisante, des livrables requis (y compris tout rapport technique et état financier requis) par le département contractant de l'OMS.

La facture des Personnes Morales devra refléter toute exonération d'impôt à laquelle l'OMS pourrait avoir droit en vertu de l'immunité dont elle jouit. De manière générale, l'OMS est exonérée de tout impôt direct, de tout droit de douane et de tous droits et taxes similaires, et la Personne Morale devra se mettre en rapport avec l'OMS afin d'éviter l'application des dites charges en rapport avec le présent accord et les travaux qui en résultent. En ce qui concerne les impôts et autres charges indirectes imposés sur la fourniture de biens et de services, (par ex: taxe à la valeur ajoutée), la Personne Morale accepte de vérifier en consultation avec l'OMS si, dans le pays où la charge serait exigible, l'OMS est exonérée de ladite charge à la source ou est en droit d'en réclamer le remboursement. Si l'OMS est exonérée de la taxe à la valeur ajoutée, cela devra être indiqué sur la facture, tandis que si l'OMS est en droit d'en réclamer le remboursement, la Personne Morale accepte de mentionner cette charge de façon séparée sur ses factures et, si nécessaire, de coopérer avec l'OMS afin d'en obtenir le remboursement.

L'OMS n'encourra aucune responsabilité pour quelque taxe, droit ou autre contribution dû par les contractants. Le paiement de quelque taxe, droit ou autre contribution qu'un contractant pourrait être tenu de payer sera de l'entière responsabilité de celui-ci et il n'aura droit à aucun remboursement de la part de l'OMS à ce titre.

4. **Exécution satisfaisante.** Si les travaux ne sont pas accomplis correctement (et, le cas échéant, fournis) à la date prévue par l'accord ou si tout état financier requis n'est pas soumis de façon satisfaisante à l'OMS conformément à la condition générale 5 ci-dessous, l'OMS peut accorder un délai supplémentaire à l'expiration duquel l'accord doit être exécuté de façon satisfaisante. En règle générale, ce délai supplémentaire est d'une semaine au moins, à moins

AGREEMENT FOR PERFORMANCE OF WORK

Sensitivity: Internal & Restricted

Page 4 of 7

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



World Health Organization

AGREEMENT FOR PERFORMANCE OF WORK ACCORD POUR EXECUTION DE TRAVAUX

GLOBAL PROCUREMENT AND LOGISTICS

Global Service Centre
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS

WHO Registration 2020/1037753-0
Purchase Order 202570446
Unit Reference WCO-NB&CH

duration, unless it is clear from the agreement that it was particularly important that the performance be completed on the date specified, in which case WHO may specify a shorter period or refuse to grant any additional period at all. In the event that the work is not satisfactorily completed and delivered on the date fixed, or any additional period granted by WHO and/or if any financial statement required is not satisfactorily submitted to WHO in accordance with general condition 5 below, WHO may immediately terminate this agreement (in addition to the other remedies), in accordance with general condition 13 below (without being held to grant the contractor an additional period of thirty (30) days to perform, complete and deliver the work).

qu'il ne ressorte clairement de l'accord qu'il était particulièrement important d'achever les travaux à la date initialement prévue, auquel cas l'OMS peut accorder un délai plus court ou refuser la moindre prorogation. Si les travaux ne sont pas achevés et livrés de façon satisfaisante à la date prévue ou à l'expiration de tout délai supplémentaire accordé par l'OMS, et/ou si tout état financier requis n'est pas soumis de façon satisfaisante à l'OMS conformément à la condition générale 5 ci-dessous, l'Organisation peut immédiatement résilier le présent accord (sans préjudice d'autres recours dont elle peut disposer), conformément à la condition générale 13 ci-dessous (sans être tenue d'accorder au contractant une période supplémentaire de trente (30) jours pour exécuter, achever et livrer les travaux).

5. Completion and delivery. The contractor shall complete and deliver the work to WHO (including any technical report that may be required) by the date fixed in this agreement or any additional period that may be granted by WHO under general condition 4 above. Any financial statement required shall be submitted within thirty (30) days thereafter at the latest. If the payment schedule on the face of this agreement provides for a final payment upon completion of the work, this final payment shall be made only after satisfactory receipt of all deliverables called for under this agreement, including any technical report and financial statement.

5. Achèvement et livraison. Le contractant achève et livre les travaux à l'OMS (y compris tout rapport technique qui pourrait être requis) à la date prévue par l'accord ou à l'expiration de tout délai supplémentaire accordé par l'OMS en application de la condition générale 4 ci-dessus. Tout état financier requis est soumis au plus tard dans les trente (30) jours qui suivent. Si le calendrier de paiement prévu au recto de l'accord prévoit le paiement à la fin des travaux, celui-ci n'est effectué qu'après réception, sous une forme satisfaisante, de tous les livrables exigés aux termes de l'accord, y compris les rapports techniques et les états financiers.

6. Certification of status of individual contractors. Each Individual Contractor certifies that he/she does not presently, and will not during the term of this agreement, hold any form of contractual relationship with WHO (including any WHO regional, country or project office, as well as any programme, center or other entity where staff is subject to WHO Staff Regulations and Rules) that confers upon the Individual Contractor the status of a WHO staff member. The Individual Contractor understands that a false statement may result in the cancellation of any or all contracts, and/or the withdrawal of any offer of a contract with WHO.

6. Certification du statut des personnes physiques. Toute Personne Physique certifie qu'elle n'a pas actuellement et n'aura pas pour la durée du présent accord, de relation contractuelle avec l'OMS (y compris les bureaux régionaux de l'OMS, les bureaux de pays ou de projet, les programmes, centres ou entités où le personnel est soumis au Statut et au Règlement du Personnel de l'OMS) lui conférant le statut de membre du personnel de l'OMS. Toute Personne Physique comprend qu'une fausse déclaration de sa part peut entraîner l'annulation de tous les contrats, et/ou le retrait de toute offre de contrat, avec l'OMS.

7. Research involving human participants. If and to the extent the work to be performed under this agreement includes surveys or interviews involving human participants (hereinafter referred to as "research"), the following shall apply:

7. Recherches impliquant des êtres humains. Si et dans la mesure où les travaux à effectuer dans le cadre du présent accord incluent des études ou interviews impliquant des êtres humains (ci-après dénommés "recherches" ou "étude de sujets humains"), les points suivants sont applicables:

7.1 Ethical Aspects

It is the responsibility of the contractor to safeguard the rights and welfare of human subjects involved in research performed under this agreement, in accordance with the appropriate national code of ethics or legislation, if any, and in the absence thereof, the Helsinki Declaration and any subsequent amendments. Prior to commencing any such research, the contractor shall ensure that (a) the rights and welfare of the subjects involved in the research are adequately protected, (b) freely given informed consent has been obtained for all participants, (c) the balance between risk and potential benefits involved has been assessed and deemed acceptable by a panel of independent experts appointed by the contractor, and (d) any special national requirements have been met.

7.1 Aspects éthiques

Il incombe au contractant de s'assurer qu'au cours des travaux effectués dans le cadre de cet accord et impliquant l'étude de sujets humains, les droits et la santé de ces derniers soient protégés conformément au code d'éthique ou à la législation du pays, ou, à défaut, à la Déclaration d'Helsinki et aux amendements qui pourraient lui être ultérieurement apportés. Avant de commencer toute recherche, le contractant doit s'assurer que: a. les droits et le bien-être des sujets impliqués sont suffisamment protégés; b. le consentement libre et éclairé a été obtenu pour tous les participants; c. des experts indépendants désignés par le contractant ont évalué les risques et les avantages potentiels et ont jugé qu'ils s'équilibrent de manière acceptable et; d. toute exigence particulière de la réglementation nationale a été satisfaite.

7.2 Regulatory Requirements

It is the responsibility of the contractor to comply with the relevant national regulations pertaining to research involving human subjects.

7.2 Exigences réglementaires

Il incombe au contractant de respecter la réglementation nationale relative aux recherches impliquant l'étude de sujets humains.

7.3 Protection of Subjects

Without prejudice to obligations under applicable laws, the contractor shall make appropriate arrangements to eliminate or mitigate any negative consequences to subjects or their families resulting from the conduct of the research under this agreement. Such arrangements shall to the extent feasible include appropriate counseling, medical treatment and financial relief. The contractor furthermore undertakes to protect the confidentiality of the information relating to the possible identification of subjects involved in the research.

7.3 Protection des sujets humains

Sans préjudice des obligations lui incombant aux termes des lois en vigueur, le contractant prendra des mesures appropriées en vue d'éliminer ou d'atténuer toute conséquence négative pour les sujets ou leur famille résultant de la conduite des recherches dans le cadre de cet accord. Ces mesures comprendront, dans la mesure du possible, des conseils appropriés, un traitement médical et un dédommagement financier. Le contractant s'engage en outre à protéger le caractère confidentiel des informations qui pourraient permettre d'identifier les sujets impliqués dans les études.

8. Compliance with WHO Policies. By entering into this agreement, the contractor acknowledges that it has read, and hereby accepts and agrees to comply with, the WHO Policies (as defined below). In connection with the foregoing:

8 Respect des politiques de l'OMS. En concluant cet accord, le contractant reconnaît qu'il a lu les Politiques de l'OMS (telles que définies ci-dessous), et qu'il les accepte et convient de s'y conformer. En lien avec ce qui précède:

- Company Contractors shall take appropriate measures to prevent and respond to any violations of the standards of conduct, as described in the WHO Policies, by their employees and any other persons engaged by them to perform the work under the agreement; and

- les Personnes Morales doivent prendre des mesures appropriées afin de prévenir et répondre à toute violation des normes de conduite, telles que décrites dans les Politiques de l'OMS, par leurs employés et par toute autre personne qu'elles ont engagées pour exécuter les travaux en vertu de cet accord; et

- Individual Contractors shall not engage in any conduct that would constitute a violation of the standards of conduct, as described in the WHO Policies.

- les Personnes Physiques ne doivent pas adopter un comportement pouvant constituer une violation des normes de conduite, telles que décrites dans les Politiques de l'OMS.

Without limiting the foregoing, the contractor shall promptly report to WHO, in accordance with the terms of the applicable WHO Policies, any actual or suspected violations of any WHO Policies of which the contractor becomes aware. For purposes of this agreement, the term "WHO Policies" means collectively: (i) the WHO Code of Ethics and Professional Conduct; (ii) the WHO Policy on Sexual Exploitation and Abuse Prevention and Response; (iii) the WHO Code of Conduct for responsible Research; (iv) the WHO Policy on Whistleblowing and Protection Against Retaliation; and (v) the UN Supplier Code of Conduct, in each case, as amended from time to time and which are publicly available on the WHO website at the following links:

Sans limiter la portée de ce qui précède, le contractant doit immédiatement signaler à l'OMS, conformément aux dispositions des Politiques de l'OMS applicables, toute violation réelle ou présumée dont il a connaissance concernant toute Politique de l'OMS. Aux fins du présent accord, l'expression « Politiques de l'OMS » signifie collectivement: (i) le Code d'éthique et de déontologie de l'OMS, (ii) la Politique de l'OMS relative à la prévention et à la lutte contre l'exploitation et les abus sexuels, (iii) le Code de conduite pour une recherche responsable, (iv) la Politique de l'OMS sur le signalement des actes répréhensibles et la protection contre les représailles, et (v) le Code de conduite des fournisseurs des Nations Unies, y compris leurs modifications éventuelles et qui sont publiquement accessibles sur le site internet de l'OMS aux liens suivants: <http://www.who.int/about/finances-accountability/procurement/en/> pour ce

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Handwritten signature and date: 31/7/2020



World Health Organization

AGREEMENT FOR PERFORMANCE OF WORK ACCORD POUR EXECUTION DE TRAVAUX

GLOBAL PROCUREMENT AND LOGISTICS

Global Service Centre
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS

WHO Registration 2020/1037753-0
Purchase Order 202570446
Unit Reference WCO-NB&CH

<http://www.who.int/about/finances-accountability/procurement/en/> for the UN Supplier Code of Conduct and at <http://www.who.int/about/ethics/en/> for the other WHO Policies.

qui est du Code de conduite des fournisseurs des Nations Unies, et <http://www.who.int/about/ethics/en/> pour ce qui est des autres Politiques de l'OMS.

9. Zero tolerance for sexual exploitation and abuse. WHO has zero tolerance towards sexual exploitation and abuse. In this regard, and without limiting any other provisions contained herein:

- each Company Contractor warrants that it will: (i) take all reasonable and appropriate measures to prevent sexual exploitation or abuse as described in the WHO Policy on Sexual Exploitation and Abuse Prevention and Response by any of its employees and any other persons engaged by it to perform the work under the agreement; and (ii) promptly report to WHO and respond to, in accordance with the terms of the Policy, any actual or suspected violations of the Policy of which the Company Contractor becomes aware; and
- each Individual Contractor warrants that he/she will: (i) not engage in any conduct that would constitute sexual exploitation or abuse as described in the WHO Policy on Sexual Exploitation and Abuse Prevention and Response; and (ii) promptly report to WHO, in accordance with the terms of the Policy, any actual or suspected violations of the Policy of which the Individual Contractor becomes aware.

10. Tobacco/Arms Related Disclosure Statement. Company Contractors may be required to disclose relationships they may have with the tobacco and/or arms industry through completion of the WHO Tobacco/Arms Disclosure Statement. In the event WHO requires completion of this Statement, the Company Contractor undertakes not to permit work on the agreement to commence, until WHO has assessed the disclosed information and confirmed to the Company Contractor in writing that the work can commence.

11. Anti-terrorism and UN sanctions; Fraud and Corruption. The contractor warrants for the entire duration of the agreement that:

- (i) it is not and will not be involved in, or associated with, any person or entity associated with terrorism, as designated by any UN Security Council sanctions regime, that it will not make any payment or provide any other support to any such person or entity and that it will not enter into any employment or subcontracting relationship with any such person or entity;
- (ii) it shall not engage in any illegal, corrupt, fraudulent, collusive or coercive practices (including bribery, theft and other misuse of funds) in connection with the execution of the agreement; and
- (iii) the contractor shall take all necessary precautions to prevent the financing of terrorism and/or any illegal, corrupt, fraudulent, collusive or coercive practices (including bribery, theft and other misuse of funds) in connection with the execution of the agreement.

Any payments used by the contractor for the promotion of any terrorist activity or any illegal, corrupt, fraudulent, collusive or coercive practice shall be repaid to WHO without delay.

12. Breach of essential terms. The contractor acknowledges and agrees that each of the provisions of general conditions 8, 9, 10 and 11 above constitutes an essential term of this agreement, and that in case of breach of any of these provisions, WHO may, in its sole discretion, decide to:

- (i) terminate this agreement, and/or any other contract concluded by WHO with the contractor, immediately upon written notice to the contractor, without any liability for termination charges or any other liability of any kind; and/or
- (ii) exclude the contractor from participating in any ongoing or future tenders and/or entering into any future contractual or collaborative relationships with WHO.

WHO shall be entitled to report any violation of such provisions to WHO's governing bodies, other UN agencies, and/or donors.

13. Termination. WHO may terminate this agreement or any part thereof with immediate effect (in addition to any other rights or remedies to which WHO may be entitled, including the right to claim damages), on written notice to the contractor if the contractor is:

- (i) in breach of any material obligation(s) under this agreement and, to the extent such breach is capable of being remedied, fails to correct such breach within a period of thirty (30) days after having received a written notification to that effect from WHO; or
- (ii) adjudicated bankrupt or formally seeks relief of its financial obligations.

14. Use of WHO name and emblem. Without WHO's prior written approval, the contractor shall not, in any statement or material of an advertising or promotional nature,

9. Tolérance zéro pour l'exploitation et les abus sexuels. L'OMS applique la tolérance zéro en matière d'exploitation et d'abus sexuels. À cet égard, et sans limiter la portée de toute autre disposition du présent accord :

- chaque Personne Morale garantit: i) qu'elle prendra toutes les mesures raisonnables et appropriées pour prévenir tout acte d'exploitation ou d'abus sexuels tels que décrits dans la Politique de l'OMS relative à la prévention et à la lutte contre l'exploitation et les abus sexuels, par l'un quelconque de ses employés et toute autre personne engagée par elle pour exécuter les travaux prévus au titre du présent accord; et (ii) qu'elle signalera immédiatement à l'OMS et donnera suite à toute violation réelle ou présumée de cette Politique dont elle a connaissance, conformément aux dispositions de la Politique; et
- chaque Personne Physique garantit: i) qu'elle n'adopte aucun comportement qui relèverait de l'exploitation ou d'abus sexuels tels que décrits dans la Politique de l'OMS relative à la prévention et à la lutte contre l'exploitation et les abus sexuels; et (ii) qu'elle signalera immédiatement à l'OMS toute violation réelle ou présumée de la Politique dont elle a connaissance, conformément aux dispositions de la Politique.

10. Déclaration relative à l'industrie du tabac/de l'armement. Il peut être demandé aux Personnes Morales de déclarer leurs éventuelles relations avec l'industrie du tabac et/ou de l'armement en remplissant la déclaration requise par l'OMS relative à l'industrie du tabac/de l'armement. Dans les cas où l'OMS demande une telle déclaration, la Personne Morale s'engage à ne pas autoriser le commencement des travaux au titre de l'accord tant que l'OMS n'a pas évalué les informations communiquées et confirmé par écrit à la Personne Morale que ces travaux peuvent commencer.

11. Anti-terrorisme et sanctions de l'ONU; fraude et corruption. Le contractant garantit, pour toute la durée de l'accord :

- (i) qu'il n'est ni ne sera impliqué à l'égard de, ni associé à, aucune personne ou entité que le régime de sanctions du Conseil de sécurité de l'ONU a désignée comme étant associée au terrorisme, qu'il ne fera aucun paiement à, ou ne soutiendra d'aucune autre manière, une telle personne ou entité, et qu'il ne conclura aucune relation d'emploi ni de sous-traitance avec une telle personne ou entité ;
- (ii) qu'il ne prendra part à aucune pratique illégale, de corruption, de fraude, de collusion ou de coercition (y compris, pots de vin, vol ou autre utilisation abusive de fonds) en lien avec l'exécution de l'accord ; et
- (iii) le contractant prendra toutes les précautions nécessaires pour empêcher le financement du terrorisme et/ou toute pratique illégale, de corruption, de fraude, de collusion ou de coercition (y compris, pots de vin, vol ou autre utilisation abusive de fonds) en lien avec l'exécution de l'accord.

Tout paiement utilisé par le contractant pour la promotion de toute activité terroriste ou de toute pratique illégale, de corruption, de fraude, de collusion ou de coercition doit être immédiatement remboursé à l'OMS.

12. Violation de clauses essentielles. Le contractant reconnaît et accepte que chacune des dispositions des conditions générales 8, 9, 10 et 11 ci-dessus constitue une clause essentielle du présent accord, et qu'en cas de manquement à l'une quelconque de ces dispositions, l'OMS peut, à sa seule discrétion, décider :

- (i) de résilier immédiatement cet accord, et/ou tout autre contrat conclu par l'OMS avec le contractant, moyennant une notification écrite adressée au contractant, sans être redevable d'aucune pénalité au titre d'une telle résiliation et sans que sa responsabilité ne soit engagée d'une quelconque manière que ce soit; et/ou
- (ii) d'exclure le contractant de toute participation à des appels d'offres en cours ou à venir et/ou de toute relation contractuelle ou de collaboration future avec l'OMS.

L'OMS sera en droit de rapporter toute violation de ces dispositions aux organes directeurs de l'OMS, aux autres organismes des Nations Unies et/ou aux donateurs.

13. Résiliation. L'OMS peut résilier avec effet immédiat le présent accord ou toute partie de celui-ci (en plus de tous les autres droits ou recours dont l'OMS peut se prévaloir, y compris celui de réclamer des dommages-intérêts), moyennant une notification écrite adressée au contractant, si ce dernier :

- (i) est en violation d'une (ou plusieurs) obligation(s) importante(s) du présent accord et, dans le cas d'une violation susceptible d'être réparée, manque de remédier à une telle violation dans les trente (30) jours suivant la réception d'une notification écrite de l'OMS envoyée à cet effet ; ou
- (ii) s'est déclaré en faillite ou a demandé officiellement à être exonéré de ses obligations financières.

31/7/2020



World Health Organization

AGREEMENT FOR PERFORMANCE OF WORK ACCORD POUR EXECUTION DE TRAVAUX

GLOBAL PROCUREMENT AND LOGISTICS

Global Service Centre
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ Référence OMS

WHO Registration	2020/1037753-0
Purchase Order	202570446
Unit Reference	WCO-NB&CH

refer to this agreement or the contractor's relationship with WHO, or otherwise use the name (or any abbreviation thereof) and/or emblem of the World Health Organization.

15. **Publication of agreement.** Subject to considerations of confidentiality, WHO may acknowledge the existence of this agreement to the public and publish and/or otherwise publicly disclose the contractor's name and for Company Contractors, the country of incorporation, general information with respect to the work described herein and the agreement's value. Such disclosure will be made in accordance with WHO's Information Disclosure Policy and shall be consistent with the terms of this agreement.

16. **Audit.** WHO may request a financial and operational review or audit of the work performed by Company Contractors under this agreement, to be conducted by WHO and/or parties authorized by WHO, and the Company Contractor undertakes to facilitate such review or audit. This review or audit may be carried out at any time during the implementation of the work performed under this agreement, or within five years of completion of the work. In order to facilitate such financial and operational review or audit, the Company Contractor shall keep accurate and systematic accounts and records in respect of the work performed under this agreement. The Company Contractor shall make available, without restriction, to WHO and/or parties authorized by WHO:

- (i) the Company Contractor's books, records and systems (including all relevant financial and operational information) relating to this agreement; and
- (ii) reasonable access to the Company Contractor's premises and personnel.

The Company Contractor shall provide satisfactory explanations to all queries arising in connection with the aforementioned audit and access rights.

WHO may request the Company Contractor to provide complementary information about the work performed under this agreement that is reasonably available, including the findings and results of an audit (internal or external) conducted by the Company Contractor and related to the work performed under this agreement.

17. **Surviving provisions.** Those provisions of this agreement that are intended by their nature to survive its expiration or earlier termination shall continue to apply.

18. **Settlement of disputes.** Any matter relating to the interpretation or application of this agreement which is not covered by its terms shall be resolved by reference to Swiss law. Any dispute relating to the interpretation or application of this agreement shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or, in the absence of agreement, with the Rules of Arbitration of the International Chamber of Commerce. The parties shall accept the arbitral award as final.

19. **Privileges and immunities.** Nothing contained in or relating to this agreement shall be deemed to constitute a waiver of any of the privileges and immunities enjoyed by WHO and/or as submitting WHO to any national court jurisdiction.

14. **Utilisation du nom et de l'emblème de l'OMS.** Le contractant n'a pas le droit, dans aucune déclaration ni aucun support à caractère publicitaire ou promotionnel, de faire référence au présent accord ou à sa relation avec l'OMS, ni d'utiliser d'une autre manière le nom (ou toute abréviation de celui-ci) et/ou l'emblème de l'Organisation mondiale de la Santé, sans l'autorisation écrite préalable de l'OMS.

15. **Publication de l'accord.** Sous réserve de considérations relatives à la confidentialité, l'OMS a le droit de divulguer l'existence de cet accord et de publier, et/ou rendre public d'une autre manière, le nom du contractant ainsi que, le pays d'enregistrement si le contractant est une Personne Morale, des informations générales concernant les travaux décrits dans le présent accord et la valeur de l'accord. Cette divulgation se fera conformément à la politique de l'OMS sur la divulgation des informations et aux dispositions du présent accord.

16. **Vérification.** L'OMS peut demander qu'un examen ou une vérification de type financier et opérationnel des travaux effectués par les Personnes Morales en vertu du présent accord soit effectué(e) par l'OMS et/ou par des parties autorisées par l'OMS, et la Personne Morale s'engage à faciliter cet examen ou cette vérification. Cet examen ou cette vérification peut être effectué(e) à tout moment pendant l'exécution des travaux effectués au titre du présent accord, ou dans les cinq ans suivant l'achèvement des travaux. Afin de faciliter cet examen ou cette vérification de type financier et opérationnel, la Personne Morale doit tenir des comptes et des registres précis et systématiques sur les travaux effectués en vertu du présent accord. La Personne Morale doit mettre à la disposition de l'OMS et/ou des parties autorisées par l'OMS, sans restriction:

- (i) les livres, les archives et les systèmes de la Personne Morale concernant le présent accord (y compris l'ensemble des informations financières et opérationnelles pertinentes); et
- (ii) un accès raisonnable aux locaux et au personnel de la Personne Morale.

La Personne Morale doit fournir des explications satisfaisantes en réponse à toutes les questions découlant de la vérification et des droits d'accès susmentionnés.

L'OMS peut demander à la Personne Morale de lui communiquer des informations complémentaires concernant les travaux exécutés au titre du présent accord qui sont raisonnablement à sa disposition, y compris les conclusions et les résultats d'une vérification (interne ou externe) effectuée par la Personne Morale au sujet des travaux exécutés au titre du présent accord.

17. **Dispositions restant en vigueur après la fin du contrat.** Les dispositions du présent accord qui sont, de par leur nature, destinées à survivre à l'expiration ou à la résiliation anticipée dudit accord continueront de s'appliquer.

18. **Règlement des différends.** Toute question concernant l'interprétation ou l'application du présent accord que les dispositions de ce dernier ne permettent pas de résoudre doit être résolue par référence au droit suisse. Tout différend relatif à l'application ou à l'interprétation du présent accord qui n'aurait pu être résolu à l'amiable fera l'objet d'une conciliation. En cas d'échec de celle-ci, le différend sera réglé par arbitrage. Les modalités de l'arbitrage seront convenues entre les parties ou, en l'absence d'accord, déterminées selon le Règlement d'arbitrage de la Chambre de Commerce internationale. Les parties reconnaissent que la sentence arbitrale sera finale.

19. **Privilèges et immunités.** Aucun des termes du présent accord ne sera considéré comme constituant une renonciation à quelque privilège ou immunité que ce soit dont jouit l'OMS en vertu du droit national ou international et/ou interprété comme une soumission de l'OMS à la compétence d'une quelconque juridiction nationale.

ATTESTED

Sensitivity: Internal & Restricted

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Handwritten signature and date:
31/7/2020



गुजरात गुजरात GUJARAT

नं. 14539 रु. 100

BU 943836

तारीख : १५ माहे ०५ २०१८

नाम : LAMBDA THERAPEUTIC RESEARCH LTD.
Plot No. 38, Near Silver Oak Club,

ठेकाणुं : S.G. Highway, Gota,
Ahmedabad-380061

ड. क. इतरीया

दा. नं. अ.स.पी. ४२८, ४२८/१९९९

भे. इ. सोला क्लब, मुंगलूर, अमरावती ना सखेंदी

बेनामनी सखेंदी *(Signature)*

Clinical Trial Agreement

BETWEEN

Lambda Therapeutic Research Ltd.
Lambda House, Plot No. 38,
Survey-No. 388, Near Silver Oak Club,
S.G. Highway, Gota,
Ahmedabad-382481,
Gujarat, India.

(Hereinafter referred to as "LAMBDA" or "CRO")

Acting as agent for

Intas Pharmaceuticals Limited
Corporate House, Near Sola Bridge,
S.G. Highway, Thaltej, Ahmedabad -380054
Gujarat, India.

Dr. Santosh Hajare, Belagavi



ATTESTED

(Signature)
Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

AND

Dr. Santosh Dhananjay Hajare

KLES Dr. Prabhakar Kore Hospital & Medical Research Centre,
Nehrunagar, Belagavi-590010, Karnataka, India.
(Hereinafter referred to as the "Investigator")

AND

KLES Dr. Prabhakar Kore Hospital & Medical Research Centre,

Nehrunagar, Belagavi-590010, Karnataka, India.
(Hereinafter referred to as the "Institute")

AND

Doclin Clinical Research Services

445, Maruti Galli, Main Road, Hangarge, Mandoli, Belagavi Karnataka-590008
(Hereinafter referred to as the "SMO")

THIS AGREEMENT shall come into effect on the date of signature of all the parties.

BETWEEN

Lambda Therapeutic Research Ltd.

Lambda House, Plot No. 38,
Survey No. 388, Near Silver Oak Club,
S.G. Highway, Gota,
Ahmedabad-382481,
Gujarat, India.
(Hereinafter referred to as "LAMBDA" or "CRO")

Acting as agent for

Intas Pharmaceuticals Limited

Corporate House, Near Sola Bridge,
S.G. Highway, Thaltej, Ahmedabad -380054
Gujarat, India.
(Hereinafter referred to as the "Sponsor")

AND

Dr. Santosh Dhananjay Hajare

KLES Dr. Prabhakar Kore Hospital & Medical Research Centre,
Nehrunagar, Belagavi-590010, Karnataka, India.
(Hereinafter referred to as the "Investigator")

AND

KLES Dr. Prabhakar Kore Hospital & Medical Research Centre,

Nehrunagar, Belagavi-590010, Karnataka, India.
(Hereinafter referred to as the "Institute")

Dr. Santosh Hajare, Belagavi



ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

AND

Doclin Clinical Research Services

445, Maruti Galli, Main Road, Hangarge, Mandoli, Belagavi Karnataka-590008
(Hereinafter referred to as the "SMO")

WHEREAS:

LAMBDA is acting as a Contract/Clinical Research Organization (CRO) under a Service Agreement on behalf of **Intas Pharmaceuticals Ltd.;**

Intas Pharmaceuticals Ltd. has asked LAMBDA to handle and negotiate site Agreements on its behalf;

LAMBDA on behalf of Sponsor wishes the Investigator and Institute to participate in a clinical trial entitled "A randomized, multi-centre, open label, two-arm, parallel, clinical study to evaluate the efficacy, safety and tolerability of tacrolimus lipid suspension for enema of Intas Pharmaceuticals Limited, India against CORTENEMA® (Hydrocortisone retention enema) of Anip Acquisition Company, USA in adult patients with mild to moderately active left-sided/distal ulcerative colitis refractory to mesalamine treatment." and, The Principal Investigator, having reviewed the Protocol for the Clinical Trial, the Investigator brochure and sufficient information regarding the Investigational Product in order to evaluate and determine its interest in participating in the Clinical Trial, wishes to participate in the Clinical Trial and the Principal Investigator assures that he/she has sufficient authority, Competence and experience in conducting clinical trials.

The Institution has facilities and personnel with the requisite skills, experience, and knowledge required to support the performance of the Clinical Trial by the Principal Investigator; and the Institute is willing to participate in the Clinical Trial; and,

The Investigator is authorized to conduct the clinical trial at the Institution. The Investigator will review the Clinical Trial for patient safety, scientific validity, and utilization of hospital resources.

IN CONSIDERATION of the mutual promises and covenants herein, the parties agree as follows:

1. Definitions


1.1 In this Agreement, the following terms shall have the following meanings:

<u>Term</u>	<u>Meaning</u>
"Compound"	Tacrolimus Lipid Suspension for enema 4 mg/vial (Test Product)
"CRF"	means the case report form in a format prepared by Sponsor and documenting the administration of the Investigational Product to Clinical Trial Subjects as well as all tests and observations related to the Clinical Trial;
"CRO"	Contract/Clinical Research Organization

Dr. Santosh Hajare, Belagavi


LAMBDA
 Research Accelerated
ATTESTED

Page 3 of 23


 Dr. V.A. Kothiwale
 Registrar

KLE Academy of Higher Education and Research,
 (Deemed-to-be-University u/s 3 of the UGC Act, 1956)
 Belagavi-590 010, Karnataka

“Declaration of Helsinki”	The 2013 version of the Helsinki Declaration of the World Medical Association and amendments.
“DCGI”	Drug Controller General of India.
“Ethics Committee”	The relevant properly constituted ethics committee as organized by the Hospital Authority or independent, which has reviewed or will review the application for conducting the Clinical Trial.
“ICH GCP”	ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) as may be amended from time to time.
“Site Investigator File”	The file maintained by the Investigator containing the documentation specified in section 8 of ICH GCP.
“Payment Agreement”	The payment agreement set out in Schedule “B”.
“Protocol”	The protocol together with its amendments as agreed between the parties from time to time (Schedule “A”).
“SAE”	Serious Adverse Event as defined by ICH GCP.
“Site”	The site at which the Clinical Trial is conducted.
“Study”	The study to be undertaken by the Investigator and the Institution in accordance with the Protocol, ICH-GCP and applicable regulatory requirements.
Agent	shall include, but shall not be limited to, any person providing services to a Party under a contract for services or otherwise, to include without limitation any pharmacist, clinical chemist, nurse or other health professional.
Agreement	means this agreement comprising its clauses, schedules and any appendices attached to it, including the Protocol and including any amendments to the Agreement agreed between the Parties;
Auditor	means a person who is authorized to carry out a systematic review and independent examination of clinical trial related activities and documents to determine whether the evaluated clinical trial related activities were conducted, and the data were recorded, analyzed and accurately reported according to the Protocol, the Standard Operating Procedures of Sponsor and/or CRO, ICH GCP and the applicable regulatory requirements.
Clinical Trial	means the investigation to be conducted at the Trial Site in accordance with the Protocol
Clinical Trial Subject	means a person enrolled to participate in the Clinical Trial

Dr. Santosh Hajare, Belagavi



ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Confidential Information means information provided by a Party (the Disclosing Party) to the other Party (the Receiving Party) or to any other of such Receiving Party's employees or agents, and means all information (including, without limitation, study protocols, case report forms, clinical data, other data, reports, specifications, computer programs or models and related documentation, know-how, trade secrets, or business or research plans) of the Disclosing Party or the Disclosing Party's Affiliates that are provided in connection with this Agreement or the Clinical Trial. Sponsor's Confidential Information shall include Clinical Trial data, results, or reports created by Institution, Principal Investigator, or Research Staff in connection with the Clinical Trial (except for a Clinical Trial Subject's medical records); and cumulative Clinical Trial data, results, and reports from all sites conducting the Clinical Trial.

Intellectual Property Rights means patents, trademarks, trade names, service marks, domain names, copyrights, rights in and to databases (including rights to prevent the extraction or reutilization of information from a database), design rights, topography rights and all rights or forms of protection of a similar nature or having equivalent or the similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered and including applications for registration of any of them;

Investigational Product Means the Study Drug identified above and the control material, as further detailed in the Protocol.

2. Investigator/Institution responsibilities

- 2.1 The Investigator in his personal capacity and as an authorized representative of the Institution and the Institution undertakes to adhere to the Protocol and general acceptable clinical practices for the conduct of the Clinical Trial.
- 2.2 The Investigator and the Institution will adhere to ICH GCP, Declaration of Helsinki, current Schedule Y of DCGI, and all applicable laws and regulations for the conduct of the Clinical Trial.
- 2.3 The Investigator and Institute is also responsible for supporting Sponsor and Lambda in resolving any technical issues encountered during the performance of the Clinical Trial and queries from national / international authorities in close coordination with Lambda in a timely manner. The provisions of this article shall remain in force for a period of 10 years even after expiry or termination of this agreement.
- 2.4 The Investigator is responsible for submitting to the Ethics Committee; the conduct of the Clinical Trial in accordance with the terms of the Protocol and for obtaining written approval from the Ethics Committee prior to the commencement of the Clinical Trial. The Investigator will deliver a copy of such approval to LAMBDA. Trial supplies to the Investigator or the Institution will not be delivered until LAMBDA has received a copy of such approval. The said approval must indicate the date of approval and contain the name and signature of the Chairperson/member secretary of the Ethics Committee.
- 2.5 The Investigator is responsible for training and supervision of sub-investigators and other site study team members on the procedures specified in the Protocol to ensure scientific, technical

Dr. Santosh Hajare, Belagavi



Page 5 of 23

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

and ethical conduct of the Clinical Trial. In case of any personnel changes, the Investigator is responsible for notifying LAMBDA of such change in a timely manner.

- 2.6 The Investigator shall communicate all relevant aspects of the Clinical Trial to the patients intending to participate in the trial and their legally acceptable representatives and shall obtain voluntary signed written informed consent from all prospective patients and their legally acceptable representatives prior to start of any study related procedures.
- 2.7 During the performance of the Clinical Trial and for a period of 10 years after expiry/termination of the agreement, the Investigator and/or Institute is responsible for, but are not limited to, the following aspects:
- a) provision of required study documents (e.g. curriculum vitae(s), medical registration certificates and/or other relevant documents evidencing qualifications of investigator(s) and sub-investigator(s), confirmation of adequate site facilities, etc.);
 - b) progress reporting (including recruitment figures) to ethics committee and LAMBDA on a regular basis;
 - c) ensuring direct access by monitors, auditors and regulatory authority to original study documents, medical records, study materials, etc and providing appropriate working conditions for monitors, auditors and regulatory authority to perform study-related monitoring, audit and inspection respectively;
 - d) to allow any regulatory audit by DCGI or any applicable regulatory authority within 15 years of submission of report and ensure compliance of any regulatory deficiency raised by such authorities in reasonable period of time; If Investigator is to submit any information to such regulatory authorities agencies, such submissions shall not be made without Lambda's prior review and written approval, and any changes (other than entry of required information) also shall be subject to such prior written approval.
 - e) safe handling, storage, transportation and disposal of infectious materials and wastes involved in the Clinical Trial;
 - f) Inform the Ethics Committee of study closure.
 - g) Maintenance of drug accountability records, study documents including study drug acknowledgement receipts, study supply receipts, payment receipts, EC approvals etc.;
 - h) Handling and storage of compound according to protocol.
 - i) In case if any of the delegated research staff at site gets relieved from his/ her services the Investigator/ Institution shall appoint the relevant function or make the alternate arrangement in shortest possible time so as the trial related activity does not get affected.
 - j) The Investigator / institution shall make and retain records (study documents including source data/patient medical documents) of the Clinical Trial as required by the Protocol, applicable Law, and in accordance with the Institution's standard archiving procedures (SOP). Institution will retain such records for a minimum of fifteen (15) years from the date of database closure or as per the local regulatory requirements. Such archival shall be done either at the institution or at the third party agency. At least Sixty (60) days prior to the expiry of such retention period, Sponsor/ CRO will contact Institution. If requested by

ATTESTED



Dr. V.A. Kothiwale
Registrar

Sponsor/CRO, Institution shall retain the records for a longer period of time at Sponsor's expense.

- k) Place of archival of retention records and the amount incurred should be discussed during the CTA execution as per Institution's standard archiving procedures (SOP). Cost of Archival fees, if applicable will be paid at the time of close out before close out visit.
- l) If any services or activities including the diagnostic test or clinical procedure required by the protocol are being outsourced by Investigator /Institution to the other facilities/ institutions then this should clearly be documented via an agreement / MOU. The Investigator /Institution shall provide LAMBDA with a copy of the said agreement / MOU.

2.8 All SAEs has to be promptly reported by the Investigator to LAMBDA and/or Sponsor and to the Ethics Committee. The Investigator is responsible for reporting, and shall report, all such findings in the manner and within the time limits as set out in the applicable provisions of ICH GCP and the applicable legislation i.e. within 24 hours (of occurrence or knowledge or becoming aware) to LAMBDA, IEC and Institution by Investigator; and further follow up reporting will be done as per the regulatory guidelines prescribed in Schedule-Y(of occurrence or knowledge or becoming aware) to ethics committee and Regulatory Authority (DCGI) via first draft report. LAMBDA and/or Sponsor confirms an effective system for centralized tracking and notification to investigators and to applicable regulatory authorities of all findings that could adversely affect the safety of Clinical Trial subject, including, without limitation, all unexpected serious adverse drug reactions experienced by any subject taking part in the Clinical Trial at any site has been established. Notwithstanding anything in this Agreement to the contrary, the Investigator and the Institution shall have the right to disclose findings that could adversely affect the safety of Clinical Trial subjects to the Ethics Committees of participating sites, and appropriate regulatory authorities if they deemed necessary to protect the health of study participants, provided that Sponsor is copied on such reports.

2.9 The Investigator and the Institution shall indemnify, defend and hold harmless Lambda and the Sponsor against any and all claims arising out of or in connection with the performance of this agreement, allegedly arising from Investigator's and / or his team's negligence or reckless or intentional misconduct, breach or failure to perform its obligations and responsibilities under this agreement. Lambda undertakes to provide timely written notice after such claim is served upon Lambda / Sponsor. The Investigator shall have the right to defend the same at his own expenses including selection of counsel, control of the proceedings and settlement of the claim. Lambda shall fully cooperate and aid in such defense. In the event that a claim or suit is or may be asserted, Lambda shall have the right to select and to obtain representation by separate counsel, at its own expense. Investigator may not settle or compromise a claim or suit without the express prior written approval of Lambda.

2.10 The Investigator is responsible for supporting LAMBDA in development of the Clinical Trial Report.

3. CRO responsibilities

3.1 LAMBDA will adhere to and confirms the Sponsor will adhere to ICH GCP, the Declaration of Helsinki, requirements of DCGI, and all applicable guidelines, laws and regulations for the conduct of the Clinical Trial.

3.2 LAMBDA confirms that the Sponsor has committed to provide Lambda with the Compound and with guidelines and descriptions for the safe and proper handling regarding the use, storage

Dr. Santosh Hajare, Belagavi



ATTESTED

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

Page 7 of 23

and disposal of the Compound. Sponsor/Lambda will be responsible for shipment of drug supplies and investigational products to the PI or Site. The Compound is the property of Sponsor and is being provided only for the purposes of the performance of the Clinical Trial by the PI or by individuals working under his direct supervision at the Institution. The Compound shall not be used for any other research or study activities other than outlined in this Agreement.

- 3.3 LAMBDA and/or Sponsor is responsible for obtaining and maintaining all applicable government or regulatory approvals for the Clinical Trial in India, and warrants that these will be obtained before the Clinical Trial begins at the Institution. Development and improvement of the Protocol is the responsibility of LAMBDA and Sponsor.
- 3.4 LAMBDA on behalf of the Sponsor will provide the study-specific documents, e.g. Investigator Site File, Case Report Form, etc. to the Investigator before commencement of the Clinical Trial.
- 3.5 LAMBDA on behalf of the Sponsor will provide the Investigator with documentation, which describes the Compound being tested in the Clinical Trial and its known effects and safety information (e.g. Prescribing Information / Summary of Product Characteristics, an Investigator Brochure equivalent document). LAMBDA on behalf of Sponsor will, to the best of its knowledge; answer any questions the Investigator or the Institution may have regarding the Protocol or the Compound being tested, whether such questions are asked before the commencement of the Clinical Trial or during its conduct. Sponsor is responsible for reporting of relevant new information regarding the investigational Compound.
- 3.6 LAMBDA will transfer on behalf of Sponsor the financial support to the Institution or Investigator according to the budget agreed by Sponsor, Investigator and the Institution as set out in Schedule B subject to the terms of this Agreement.

4. Performance standards of the work to be conducted by the Investigator

- 4.1 The Investigator and/or the Institution shall use all reasonable endeavors to enroll at least **2-3 Eligible Patients** within **1 month**; minimum expected recruitment rate from the site is **2-3 patients per month** on average. The parties may agree in writing to extend the time for recruitment of eligible patients if so desired. Recruitment period will be of **10 months** depending on the complexity of the project and date of initiation; however recruitment will be competitive among participating sites hence the site may have recruitment period even less or more than specified.

"Eligible Patients" is defined as those who fulfill inclusion and exclusion criteria specified in the Protocol which is verifiable from source documents.

- 4.2 In the event that the study is part of a multi-center trial, Sponsor may amend the number of Eligible Patients to be recruited as follows:
- if in the reasonable opinion of LAMBDA or Sponsor recruitment of Eligible Patients is proceeding at a rate below that required for the relevant timelines to be met, LAMBDA may by notice to the Investigator or the Institution require recruitment at the Site to cease and the terms of this Agreement shall relate to the number of patients that have been accepted for entry into the Study at the date of such notice; or
 - If recruitment of Eligible Patients is proceeding at a rate above that required meeting the relevant timelines, LAMBDA may, with the agreement of the Investigator or the Institution increase the number of cases to be recruited.

Dr. Santosh Hajare, Belagavi



ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Page 8 of 23

- 4.3 The Investigator or the Institution shall use all reasonable endeavors to comply with the time frames as agreed with LAMBDA.
- 4.4 The Investigator shall enter the data into the eCRF within 3 working days after completion of each visit.
- 4.5 The Investigator shall participate in teleconference and meeting as required by LAMBDA or Sponsor to update the Compound information and to resolve issues, if any.
- 4.6 The Investigator shall strictly adhere to the SAE reporting timelines in accordance with requirement of ICH GCP, current Schedule Y and standard operating procedure ("SOP") of LAMBDA, whichever is tightest.

5. Payment terms

- 5.1 LAMBDA confirms the Sponsor agrees to support the Clinical Trial as outlined in the Protocol and as described in and in accordance with the provisions of this Agreement and the Payment Agreement as set out in Schedule B.
- 5.2 3 Original wet ink copies of the CTA would be in place.

6. Period of validity of the Agreement

- 6.1 This Agreement shall be effective as of the date executed by all the parties and shall continue in full force and effect until the site is closed, Clinical Trial and Clinical Trial Report are completed unless otherwise extended, renewed, or amended by mutual written consent or unless terminated earlier in accordance with Section 14 of this Agreement. In any event, the terms of this Agreement shall not be longer than fifteen (15) years from the date of commencement.
- 6.2 However following matters shall survive even after expiry/termination of the agreement:
- Archival of study documents including source data as referred to in para 2.7 and 14
 - Reasonable access by monitors, auditors and regulatory authority to original study documents and source data and providing appropriate working conditions for monitors, auditors and regulatory authority to perform study-related monitoring, audit and inspection;
 - Confidentiality as per para 11
- 6.3 In case of early termination of trial at site, due to any clause, data and documents are to be archived at Site (PI's /Institution /third party). This shall be discussed during the execution of CTA and should be clearly documented in the CTA. The said data must be archived for at least fifteen (15) years or for the period required by applicable regulatory authority following termination of the study at the Site or such other facilities as agreed between Sponsor and the Investigator. Sponsor shall also keep all clinical trial data and documents according to the relevant regulatory requirements. In case of early close out/termination the validity of the agreement would remain for 5 years.

7. Data ownership / Intellectual property rights

- 7.1 LAMBDA, the Institution and the Investigator undertake to be bound by applicable laws and regulations on the protection of personal data.
- 7.2 The Investigator undertakes to transfer data to Sponsor, LAMBDA, Ethics Committee, and the regulatory authority. In the event of an audit/inspection, LAMBDA, the Sponsor, Ethics Committee, and regulatory authority may obtain information that includes patient identification.

Dr. Santosh Hajare, Belagavi



ATTESTED

Page 9 of 23

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- 7.3 All data and results derived from the Study and any inventions or discoveries made as a result of the Clinical Trial will be the property of Sponsor. Disclosure to LAMBDA, Ethics Committee, or regulatory authority does not transfer the ownership thereof.
- 7.4 All intellectual property rights owned by, or licensed to, the Investigator / Institute prior to and after the date of this Agreement, other than intellectual property rights arising from the Clinical Trial is and shall remain the property of the Investigator / Institution.
- 7.5 All intellectual property rights owned by, or licensed to, Sponsor prior to and after the date of this Agreement, other than intellectual property rights arising from the Clinical Trial is and shall remain the property of Sponsor.
- 7.6 All intellectual property rights in the data and results derived from the Clinical Trial shall be the property of Sponsor and shall be assigned to Sponsor.
- 7.7 The Investigator/Institute is obliged to report any inventions or discoveries promptly to Sponsor and/or LAMBDA.
- 7.8 Investigator and Institute agree that Sponsor may utilize the data at its own discretion in compliance with the applicable data protection rules, including but not be limited to, submission to government regulatory authorities.
- 7.9 The Investigator and the Institution shall assist Sponsor in making any patent applications and shall execute, complete, deliver and perform any and all instruments necessary to make all such applications.
- 7.10 It would be the primary responsibility of the institution to maintain custody of study records and all other applicable study items in purview of the study protocol and this agreement, irrespective of the PI presence in the institution. Institution will allow regulatory authorities, sponsor and CRO to perform inspections of study data. In case the PI has to leave the institution, the PI should handover charge of the study to any other designee in form of document and forward all future communications received to institute pertaining to trial. PI is responsible to update CRO and / or sponsor for this change and all applicable communications, henceforth. Designee will execute all PI responsibilities, henceforth. In case of change in institution management, the institute will inform CRO and / or sponsor

8. **Publication**

- 8.1 Study results are Sponsor's property and as a result of this, no publication can be performed without the written approval by the sponsor.

9. **Indemnity / Liability**

- 9.1 In no event, shall LAMBDA, Sponsor, Investigator or Institution/Site be liable for any indirect, incidental, special, or consequential damages or lost profits arising under or as a result of this agreement (or the termination hereof).
- 9.2 In the event of a material error by Investigator/Institute in the performance of the Services, which renders the Services invalid, Investigator/Institute shall repeat the Services at no additional expense to LAMBDA, if Lambda requests or Investigator/ Institute should reimburse the payment already made by Lambda. Lambda has the right to terminate the services of Investigator due to any breach of this agreement.

Dr. Santosh Hajare, Belagavi



ATTESTED

Page 10 of 23

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

- 9.3 Sponsor (on behalf of LAMBDA) will indemnify the Investigator and/or Institution from any claims due to acts of omission or wrong by Sponsor.
- 9.4 Sponsor (on behalf of LAMBDA) will indemnify liability arising from design or manufacture of the Compound, sale and use of the Compound following the Clinical Trial and injury to study subject directly attributable to Compound, which is jointly identified by a medical monitor/ Sponsor's medical expert and the Investigator.
- 9.5 The Investigator and/or the Institution will indemnify LAMBDA and Sponsor from any claims due to acts of negligence, omission or wrong by the Investigator or Institution.
- 9.6 The Investigator and/or the Institution are responsible and liable for conduct of the Clinical Trial at the Institution according to the Protocol and the Agreement.
- 9.7 Each party will notify other parties of any claim related to the Clinical Trial.
- 9.8 Sponsor (on behalf of LAMBDA) will cover medical expenses for the treatment of any SAE as identified by the Investigator, which arise from using the Compound and study procedures in accordance with the Protocol, to the extent not covered by any other insurance by patient and provided the patient did nothing to cause or contribute to the injury.
- 10. Compensation / Insurance**
- 10.1 Sponsor/LAMBDA shall maintain appropriate insurance coverage for the Study subjects against financial losses caused by personal injury, which are study and/or Compound related.
- 11. Confidentiality**
- 11.1 For a period of 10 (ten) years from the effective date of this Agreement, Recipient shall not disclose the Discloser's Confidential Information to any third party. Recipient shall use the Confidential Information solely for purpose of the terms of the agreement, unless otherwise mutually agreed in writing. Upon request, Recipient shall return or destroy, at the Discloser's option, all Confidential Information, including any copies and extracts thereof, will immediately cease using such Confidential Information and shall deliver to the disclosing party all such Confidential Information including all copies, reproduction, facsimiles and any other tangible records of such information.
- 11.2 Notwithstanding the performance, or the discharge for whatever reason including breach of this Agreement, the provisions of this article shall remain in force for a period of 10 years from the date of execution of this Agreement but shall, thereafter, cease to apply provided that the expiry of such period shall not entitle Investigator or Institution to sell or otherwise dispose of, or otherwise turn to use for its own or another's advantage, any confidential information received during the conduct of projects covered by this Agreement.
- 11.3 The Investigator may only to the extent is, as far as necessary for the performance of its obligations under this Agreement, but not further or otherwise, disclose confidential information to study staff or to any relevant committee, that need to know the same to undertake and/or participate in this study. Investigator shall ensure that all persons shall be made aware of the relevant terms and conditions of this Agreement and shall agree to be bound by them.
- 11.4 The Investigator/institution shall not disclose or use any confidential information, which is provided by Sponsor or LAMBDA or generated by Investigator as a result of the Study, for any

Dr. Santosh Hajare, Belagavi



ATTESTED

Dr. V.A. Kothiwale
Registrar

Page 11 of 23

purpose other than the conduct of the Clinical Trial as outlined in the Protocol and this Agreement.

11.5 Confidential information shall remain the confidential and proprietary property of Sponsor, and shall only be disclosed to those who have a need to know the same. Where it is necessary to disclose any confidential information to any third party for the performance of this Agreement, a confidentiality agreement with the same terms and conditions as this Agreement shall be entered into with such third party.

11.6 Each party will keep an updated list of all individuals who have received the other parties' confidential information, together with their contact information and job title, and will provide the list if it is legally requested. All confidential information must be identified as confidential at the time of disclosure, preferably provided in writing. If the disclosure is verbally, visually, or otherwise (e.g. an X-ray, a visit to a site or lab), then the information must be summarized in writing within thirty (30) days after the disclosure and provided to the receiving party.

11.7 Confidential information shall not include any information which:

- a) is already in the public domain at the time of disclosure
- b) becomes part of the public domain after receipt of the information through no fault of the Institution or the Investigator
- c) was previously known to the Institution or the Investigator as evidenced by written documents
- d) Is disclosed to the Institution/Investigator by a third party who has the right to disclose and who is not under a direct or indirect obligation of confidentiality to Sponsor.
- e) Has been permitted to be disclosed by Sponsor.

11.8 All Confidential Information disclosed to a party under this Agreement will remain the property of the disclosing party (or the Sponsor, if such information was disclosed through LAMBDA) and may be re-called and withdrawn by the disclosing party at any time. Upon receipt of a written request from the disclosing party for return or destroy of such Confidential Information, the receiving party will immediately cease using such Confidential Information and shall deliver to the disclosing party all such Confidential Information including all copies, reproduction, facsimiles and any other tangible records of such information.

11.9 Any previous Confidentiality Agreement between Sponsor and/or LAMBDA and the Investigator or the Institution shall be superseded by the confidentiality obligations in this Agreement.

12. Privacy

12.1 Sponsor, LAMBDA, the Investigator and the Institution will adhere to applicable privacy laws, regulations, and other standards.

12.2 The Investigator and Institute/Institution consents to LAMBDA and Sponsor and its affiliates collecting and/or otherwise processing personal data provided by or relating to the Investigator for purposes of any necessary sharing with regulatory authorities and for any use by Sponsor and its affiliates and their agents.

Dr. Santosh Hajare, Belagavi



ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Page 12 of 23

12.3 The Investigator and Institute consents to Sponsor or LAMBDA transferring such personal data to Sponsor's facilities, Sponsor's affiliated companies, regulatory authorities, and third party vendors that may be utilized in other countries. For such purposes, the Investigator and Institute acknowledge that such other countries may not provide the same level of data protection as the laws in India.

12.4 The Investigator and Institution will inform each study subject of the potential for disclosure of their personal or health information to Sponsor, Sponsor's affiliated companies, LAMBDA, the Ethics Committee, and the regulatory authorities and the measures being taken to ensure their privacy.

13. Independent Contractor

13.1 Investigator is an independent contractor engaged by LAMBDA to perform the Services in accordance with the provisions of this Agreement, and the relationship hereby created is specifically governed by, limited to, and subject to all of the terms and conditions contained in this Agreement. The parties further agree that LAMBDA does not have the authority to hire or fire employees of the Investigator / Institution, nor does LAMBDA determine the rate or method of pay of such employees. Additionally, nothing contained in this Agreement shall entitle Investigator/Institute to the right or authority to make any representation on behalf of LAMBDA or the Sponsor, bind LAMBDA or Sponsor to others in any manner, or use LAMBDA's / Sponsor's name or trademarks in any public disclosure, without LAMBDA's / Sponsor's prior written permission.

14. Termination

LAMBDA on behalf of Sponsor retains the right to terminate this Agreement on Institution or Investigator's involvement in the Study for any reason with or without cause including but not limited to the following;

- a) Investigator or Institution fails to recruit patients within **60 days** of site initiation visit.
- b) The incidence and/or severity of adverse drug reactions in this or other studies with the Compound indicate a potential health hazard.
- c) Adherence to the Protocol is poor or data recording is inaccurate or seriously incomplete.
- d) LAMBDA, the Principal Investigator and/or the Institution agree to terminate this Agreement.
- e) The total number of patients required to be randomised is reached before the end of the recruitment period.
- f) The Sponsor of the Study mandates the termination of the Study for any reason, with or without cause.
- g) The appropriate Regulatory Agency mandates the termination of the Study.

In case of termination of the agreement without any default on the part of Investigator or Institution, except in the event of non-recruitment of patients by the Institution or Principal Investigator, LAMBDA shall reimburse the Institution or Principal Investigator on a pro rata basis of the number of visits completed by patients. Should the Institution or the Principal Investigator have already received payments in excess of the actual pro rated amounts due then that overpayment will be promptly remitted to LAMBDA by the Institution or Principal Investigator. Payments should be payable to LAMBDA. On termination / completion of trial or expiration of this Agreement all unused Investigational Product shall, either be returned to the Lambda Pharmacy /

Sponsor or disposed of in accordance with the Protocol or the Sponsor's written Instructions.

Dr. Santosh Hajare, Belagavi



ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Page 13 of 23

14.1 On Completion, Early Termination of the Trial:

- a) Upon completion of the Clinical Trial (whether prematurely or otherwise) the Principal Investigator and Sponsor shall co-operate in producing a report of the Clinical Trial detailing the methodology, results and containing an analysis and drawing appropriate conclusions.
- b) The Investigator/ Institute shall permit authorized representatives of the Ethics Committee and Competent Authorities to have access to, copy and verify information relating to the Clinical Trial, as required by and in accordance with applicable Law. Furthermore Sponsor and/or CRO acknowledges and agrees that the Institution executive management (or a local review board appointed by such management) will have the right to audit the performance of the Clinical Trial at the Trial Site. Institution acknowledges that the Clinical Trial is subject to inspection by regulatory authorities worldwide and that such inspections may occur after the completion of the Clinical Trial.
- c) On completion, termination of the Trial, following termination or expiration of this Agreement Investigator/ Institution shall upon request immediately deliver to the LAMBDA/Sponsor all Confidential Information, except for copies to be retained in order to comply with Institution's archiving obligations or for evidential purposes. Furthermore the Site Parties shall immediately deliver to the Sponsor any equipment provided to them for the conduct of the trial at the site.
- d) Upon notice of termination of trial or this Agreement, Investigator/Institution will not recruit and/or enroll additional Clinical Trial subjects, and will cooperate with the Sponsor in the orderly discontinuation of the Clinical Trial, including, without limitation, discontinuing Investigational Product as soon as medically appropriate, allowing Sponsor and/or CRO access to records and facilities as required for Clinical Trial close-out procedures at mutually agreed times, and requiring Principal Investigator to complete any actions required in compliance to ICH GCP and Local regulations by the role Principal Investigator.
- e) In all circumstances causing the early termination of trial and, LAMBDA shall confer with the Principal Investigator/ Institution and use their best endeavours to minimize any inconvenience or harm to Clinical Trial Subjects caused by the premature termination of the Clinical Trial. Parties (LAMBDA, Investigator and Institution) agree that in case of early termination of this Agreement, they will in good faith make arrangements concerning the continuation of the treatment of the enrolled patients if such is in their medical best interest. Furthermore the Investigator and Institution shall ensure that the rights, safety and well-being of the trial subjects are protected in all circumstances.

14.2 Termination of Trial/ Trial Agreement by Investigator or Institution:

- a) The Institution and/or the Principal Investigator shall notify the Sponsor and/or CRO if the Principal Investigator ceases to be associated with the Institution where the Clinical Trial will be conducted or if he/she is otherwise unavailable to continue as Principal Investigator, and Institution and/or Principal Investigator shall use all reasonable endeavours to find a qualified successor acceptable to the LAMBDA, subject to the Principal Investigator's overriding obligations in relation to Clinical Trial Subjects and individual patient care. In the event Principal Investigator is for whatever reason unable or unwilling to appoint a successor personally, the Institution will have the right to recommend a suitable successor and the Institution will make all possible efforts to appoint the successor/ PI to conduct the study.
- b) In case if the Institution is unable to carry out the ongoing trial for any reasons the Institution will make all the necessary arrangement to ensure that the enrolled trial patient

Dr. Santosh Hajare, Belagavi



ATTESTED

Page 14 of 23

Dr. V.A. Kothiwale
RegistrarKLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

can receive the best medical care, In case if the patients still want to continue in the study, they can be referred to the other Institution/ Investigator. In all such cases Institute/investigator will be responsible for the safety follow and further medical care of the patients for the period as appropriate as per the study drug and the nature of the study. In case if the trail subject do not wish to continue with the trial at referred site and the site has to be closed data retention, patient safety and maintenance of study data for the required period as required by the applicable regulatory authority would be the responsibility of the Institution.

15. Record retention

- 15.1 The Investigator and/or the Institution shall provide Sponsor through LAMBDA any and all records and data in relation to the Clinical Trial in time and in full according to requirements of ICH GCP, Schedule Y and the Declaration of Helsinki, and all applicable guideline, laws and regulations.
- 15.2 The Investigator and/or the Institution, LAMBDA/CRO and Sponsor shall comply with all regulatory requirements relating to the retention of records and shall maintain all such records, and make them available for inspection, and shall allow Sponsor and all applicable authorities in charge of the Clinical Trial to inspect such records. The Investigator and /or the Institution shall inform Sponsor in the event of relocation or transfer of archiving responsibilities.
- 15.3 The Site Investigator File containing the essential documents, case report forms, informed consent forms and any other source data/document (like patient medical records) must be archived for at least fifteen (15) years following completion of the study at the Site or such other facilities as agreed between Sponsor and the Investigator. Sponsor shall also keep all clinical trial data and documents according to the relevant regulatory requirements.
- 15.4 In the event that the Institution and/or the Investigator is or are unable to maintain the Clinical Trial records due to any unforeseen event/s during the study or retention period, the Institution and/or the Investigator shall, no later than 30 days prior to the day when the Clinical Trial records were planned to be removed, notify Sponsor in writing of such occurrence to permit Sponsor to fulfill its record retention obligation in connection with the Clinical Trial.
- 15.5 In the event that Sponsor removes the Clinical Trial records, Institution and/or Investigator may nevertheless retain a copy of Clinical Trial records (1) as required by law, regulation, regulatory guidelines or ICH GCP and (2) in order to ascertain and fulfill their obligations of confidentiality under this Agreement.
- 15.6 In the event that the Investigator/Institute is to destroy the Site Investigator File or source data, the Investigator/Institute should inform LAMBDA prior to destruction to confirm it is acceptable for them to be destroyed.

16. Representation and Warranty

- 16.1 The Investigator and Institution represent and warrant that they have and will keep throughout the Clinical Trial study all such qualifications, approvals, permits, licenses and conditions as necessary for performance of the Clinical Trial hereunder as required by laws and regulations of India.

17. Laws and Jurisdiction

Dr. Santosh Hajare, Belagavi



ATTESTED


Dr. V.A. Kothiwale
Registrar

Page 15 of 23

17.1 This Agreement shall be governed by and interpreted in accordance with the laws of India in Ahmedabad.

18. Notice

18.1 All notices shall be delivered to the following addresses:

CRO

Address: Lambda Therapeutic Research Ltd
Lambda House, Plot No. 38, Survey No. 388
Near Silver Oak Club, S.G. Highway, Gota
Ahmedabad-382481, Gujarat, India
Telephone: +91 79 4020 2020
Fax: +91 79 4020 2021/22
Contact person: **Dr. Kiran Marthak**

Investigator : Dr. Santosh Dhananjay Hajare
Address : KLES Dr. Prabhakar Kore Hospital & Medical Research
Centre, Nehrunagar, Belagavi-590010, Karnataka, India.
Telephone : 0831-2470400
Fax : 0831-2493099

Institution Contact Person: : Dr. M.V.Jali
Address : KLES Dr. Prabhakar Kore Hospital & Medical Research
Centre,
Nehrunagar, Belagavi-590010, Karnataka, India.
Telephone :
Fax : NA

SMO Name : Doclin Clinical Research Services
Address : 445, Maruti Galli, Main Road, Hangarge, Mandoli,
Belagavi Karnataka-590008
Telephone : +91-9164256468
Contact Person : Mr. Maruti Patil

18.2 Either party should inform the other party of any change of the said addresses in writing within forty-eight (48) hours of the change.

18.3 Any notice shall be deemed to be given: a) If sent by courier - on the day when the recipient signs for the notice; b) If sent by registered letter - at 9:00 am on the five (5) working day of dispatch; or c) If sent by telefacsimile - at 9:00 am on the second day of delivery.

Dr. Santosh Hajare, Belagavi



ATTESTED

[Signature]
Dr. V.A. Kothiwale
Registrar

Page 16 of 23

18.4 Any notice one party delivered to other parties, which concerns important issues such as claims or amendments under this Agreement should be signed by the legal representative or the authorized representative of the delivering party.

19. **Miscellaneous**

19.1 Any unsettled issues of this Agreement shall be negotiated and agreed upon in separate supplementary agreement signed by all parties. The supplementary agreement and Schedules of this Agreement which form an integral part of this Agreement and have the same legal effect as this Agreement.

19.2 No party shall assign to any third party its rights and obligations hereunder without the prior written consent of the other parties except when Sponsor takes over some of the activities from Lambda. The Investigator and the Institution acknowledge that Lambda is acting as the agent of the Sponsor and hence in such case Sponsor will get into the shoes of Lambda for all rights and obligations contemplated under this agreement as between Lambda on one side and Investigator and the Institution on the other side.

19.3 This Agreement shall constitute the entire agreement among the parties and shall supersede all previous negotiations, discussions, understandings or agreements among the parties.

19.4 No amendment or modification to this Agreement shall be effective unless made in writing and signed by all the parties or their duly authorized representatives.

19.5 All infrastructures provided by Lambda on behalf of sponsor for the conduct of this clinical trial to the Institute/Investigator will be retrieved from the Institute/Investigator upon completion of the trial.

19.6 If SMO is involved in any study related activities, PI / Institution needs to provide the copy of MOU/Agreement to CRO during / before the time of execution of CTA. The MOU provided should have the clarity on the responsibilities of Investigator /Institute and SMO.

IN WITNESS hereof, the parties hereto have caused this Agreement to be executed by their respective duly authorized representatives and the Agreement shall come into effect on the date of signature of all the parties.

LAMBDA:

Sign: 

Mr. Rajiv Bhattacharya / Mr. Gautam Vaghela
Clinical Trial Management
Lambda Therapeutic Research Ltd.

Date: 3 Jul. 2019

Witness:

Sign: 

Witness Name : Mr. Naresh Khemani, AGM, Finance
Witness Address : Lambda Therapeutic Research Ltd.,
Lambda House, Plot No. 38,
Survey No. 388, Near Silver Oak Club,
S.G. Highway, Gota,
Ahmedabad-382481, Gujarat, India.


Date: 03/Jul/19

Dr. Santosh Hajare, Belagavi



ATTESTED

Page 17 of 23


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Institute: KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi-590010, Karnataka, India

Sign: _____

Date: 19.07.2019

Dr. M.V.Jali – MD & CEO

Witness:

Sign: _____

Date: 19-07-2019

Witness Name: Ravanna Speriandi

Designation: Assistant coordinator

Department/Work Unit:

Institute Name: KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi-590010, Karnataka, India.

SMO: Doclin Clinical Research Services

445, Maruti Galli, Main Road, Hangarge, Mandoli, Belagavi Karnataka-590008

Sign: _____

Date: 12 Jul 2019

Mr. Maruti Patil – Managing Director

Witness:

Sign: _____

Date: 12 Jul 2019

Witness Name: Akshay Thombare

Witness Address:

Investigator: Dr. Santosh Dhananjay Hajare

ACKNOWLEDGMENT: In signing below, I, the Investigator, acknowledge that there is no real or perceived conflict-of-interest in the execution of this clinical trial project (e.g. stock or equity in companies which manufacture products being tested in the clinical trial, or obligations or restrictions which will conflict with the performance of this Agreement). I hereby agree to act in accordance with all the terms and conditions of this Agreement and further agree to ensure that all participants in the clinical trial are informed of their obligations under such terms and conditions.

Principal Investigator: Dr. Santosh Dhananjay Hajare

Sign: _____

Date: 15-Jul-2019

Witness:

Sign: _____

Date: 15-Jul-2019

Witness Name: Dr. Arvind Jadhav

Witness Address: KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi-590010, Karnataka, India.

Dr. Santosh Hajare, Belagavi



ATTESTED

Page 18 of 23

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

Schedule A**Study Protocol****Protocol No: 0979-17**

A randomized, multi-centre, open label, two-arm, parallel, clinical study to evaluate the efficacy, safety and tolerability of tacrolimus lipid suspension for enema of Intas Pharmaceuticals Limited, India against CORTENEMA® (Hydrocortisone retention enema) of Anip Acquisition Company, USA in adult patients with mild to moderately active left-sided/distal ulcerative colitis refractory to mesalamine treatment.”

Dr. Santosh Hajare, Belagavi

**ATTESTED**

Page 19 of 23

Dr. V.A.Kothiwale
RegistrarKLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

Schedule B
Budget and Payment Agreement

(I) Budget

S.No	Visit Number	Screening washout	Treatment Period				Follow up period		Total	
		1	2	3	4	5	6	7		8
	Week Number	W-1	W-0 Baseline	W-1	W-2	W-3	W-4/EOT	W-6(2 Week post treatment follow up	W-8(EOS 4 week post treatment follow up	
	Days	D-7 TILL D-1	D-0	D-7(+ 2)	D-14(+ 2)	D-21(+ 2)	D-28(+ 2)	D-42(+ 2)	D-56(+ 2)	
	Activity									
1	PI Grant	7000	4000	4000	4000	4000	5000	5000	5000	0
2	CRC Grant	5000	3500	3500	3000	3000	3000	3000	3500	38000
3	ECG-12 lead	600								27500
4	Serum pregnancy test	650					600			1200
5	Urine pregnancy test		250				650		650	1950
6	Drug urine scan	200								250
7	Urine analysis	500								200
8	Stool test for CD toxins	600					500		500	1500
9	Hematology	800								600
10	Blood/serum Biochemistry(Including S.electrolytes)	1800					800		800	2400
11	X-ray (Chest PA view)	500					1800		1800	5400
12	Immunology (S.anti HIV antibodies, Hbsag, and antibodies against HCV)	2000								500
13	UCDAI Score(including colonoscopy)		10000							2000
14	PK assessment		800	800	800	800	800			20000
15	Histopathology (Biopsy) [Optional]		1000						800	4800
16	Institutional OverHeads (25%)	3000	1875	1875	1750	1750	2000	2000	2125	1000
17	Patient Conveyance	1000	1000	1000	1000	1000	1000	1000	1000	16375
	Total	23650	22425	11175	10550	10550	26150	11000	16175	8000

Note:

Archival Fees: LAMBDA will pay the Institute / Investigator/Payee towards archival fees INR 1,50,000/- for 15 yrs. on behalf of sponsor.

Screen Failures: LAMBDA will pay the Institute/Investigator towards screen failure payment of INR 10,000/- for each screen failure up to the maximum of 20% of total patients screened at the site. All screen failure patients payments will be made post LPLV.

PK Sample will be collected only from the patients randomized in test arm.

ATTESTED

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

(II) Payment Schedule

The parties hereto agree as follow on the basis of the Clinical Trial Agreement:

- a) LAMBDA will pay a sum Rs. **One Lakh Thirty One thousand Six hundred and Seventy Five** (in words) for every complete and evaluable patient as defined in the payment schedule.
- b) A complete and evaluable patient is defined as follows:
- all procedures must be performed according to the protocol
 - a patient will only be included according to the inclusion/exclusion criteria
 - all data are documented completely and accurately
 - baseline evaluations done as per protocol
- c) All payments will be on a *pro rata* basis as mentioned in budget above. For patients who do not complete (early termination, drop-out, etc), the budget will be evaluated according to the number of visits completed as per protocol. If any investigation is not performed during a visit then an equivalent amount mentioned in the above budget will be deducted.
- d) Invoice will be generated/requested for payment on monthly basis according to the actual work performed (after source data verification and CRFs review for completed visits). Invoice will be generated / requested according to days completed by patient as specified above.
- e) Any other parties designated by you (including Radiology, Local Laboratory & Cardiology, etc) will be managed and paid by you.
- f) The **Ethics Committee fee** will be paid by the Sponsor, and it is separate from per patient grant as mentioned in budget.
- g) Central Laboratory costs will be paid by Sponsor.
- h) For Screen failure patients, the payment will be paid **ONLY** if the patient is screen failure based on results or reports of laboratory investigations, ECG, radiological investigation or in case patient withdrew consent. Payment for patients withdrawn before dosing on Day 1 will be paid for screening visit. Reimbursement for screen failures will be at the amount indicated on the screening visit of the schedule-B budget, not to exceed One (1) screen failure(s) paid to four (4) subject(s) randomized. Reimbursement for discontinued or early termination subjects will be prorated based on the number of confirmed completed visits.
- i) If patient was randomized in the study deviating from protocol inclusion and exclusion criteria (without waiver, if applicable) then payment will not be made for such wrong randomization and subsequent visits, however screening visit can be paid, if performed according to protocol.
- j) **Patient conveyance/compensation** will be paid by Sponsor, and is included in budget as mentioned. TDS would not be deducted on Reimbursement only if original supporting are provided for full amount." **GST applicable as per union budget rules.**
- k) All Services provided by the site under this Agreement are taxable under the laws related to Goods & Service tax in India (GST) and it is required to be charged at the rate of 18%, as may be amended from time to time. The Sponsor / CRO (applicable word as per agreement should be used) undertake to provide Patient Visit Tracker on monthly basis (on last day of the month) to CRCs for the trial and on the basis of the tracker site shall raise invoice for the month. The invoice shall be in accordance with the terms of Rule 5 of the Tax Invoice, Debit and Credit Notes Rules of Goods & Service Rules 2017.

Dr. Santosh Hãjare, Belagavi



Page 21 of 23

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- l) Payment for the final invoice raised by the site will be released at the time of site close out. LAMBDA will release payment within 30 days from the receipt of invoice.
- m) LAMBDA will pay the Institute / Investigator/Payee towards archival fees **INR 1, 50,000/-** for 15 yrs. on behalf of sponsor.
- n) LAMBDA will pay the Institute/Investigator towards screen failure payment of **INR 10,000/-** for each screen failure up to the maximum of **20%** of total patients screened at the site.
- o) All medical and hospital bills related to SAE management for the SAEs related to IMP to be paid by the Sponsor/Lambda.
- p) The last amount payable will be considered as Final Payment. Final Payment will be paid during / after site close out visit. Sponsor will release payment within 40 days from the receipt of invoice.
- q) Payment reconciliation will be made before the final payment to sites.
- r) Adhoc payments will be made as per actuals (subjected to the approval from management and sponsor).
- Should the trial terminate prematurely, any payments made by Sponsor exceeding the amount actually earned will be promptly refunded to Sponsor (minus Ethics Committee fees, and patient conveyance/compensation).

Method of payment

Sponsor shall pay the relevant cost and fee as set out in this Payment Agreement to following payee through A/c Payee Cheque as agreed by the Institution & PI. Details of Payee are:

Payment through Cheque:	
Name of Payee:	Doclin Clinical Research Services
Address of Payee:	445, Maruti Galli, Main Road, Hangarge, Mandoli, Belagavi Karnataka-590008
PAN / TAN Number:	AZXPP8818R
GST Number:	29AZXPP8818R1ZP

Note: All the payments made to the payee are subject to Tax Deducted at Source (TDS) as per the applicable existing tax laws in the country. LAMBDA will deduct the tax at the time of making payments unless a valid Certificate from tax authority is made available.

(III) Per Patient Fee, Payment Schedule and Terms

- As consideration for performance under the terms of this Agreement, the Sponsor will provide financial support for the trial that will be transferred by the LAMBDA on behalf of the Sponsor to the Investigator / Institute at the rate specified above per patient grant, for each Subject completing all Protocol specified treatments.

The "Per patient grant" is a fixed fee per patient which includes all costs and honoraria, including, but not limited to:

Dr. Santosh Hajare, Belagavi

 **ATTESTED**

Page 22 of 23

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

- all study related activities such as conduct of visits and CRF completion
- time and effort of investigators and other site staff
- study coordinator salary
- electricity expenses for use of equipment for study conduct
- procurement of any study related material
- all diagnostic tests and other investigations (like ECG, X-ray, Slit lamp examination etc)
- housing/hospital stay (if applicable) and meals during housing for patient and patient's relative
- Phlebotomy expenses
- usage of internet while filling of eCRF
- miscellaneous (telephone, fax, courier, etc)
- all overhead or any incidental costs.

Not included are (which are separate and in addition to per patient payment):

- EC submission fee
2. In the event that the LAMBDA/Sponsor requests that additional Subjects be enrolled in the Trial, the Trial Cost will be equal to the Per patient grant multiplied by the number of complete and evaluable Subjects.
 3. All payments to be made by the Sponsor under this Agreement will be done within 30 days following receipt of the corresponding invoice (complete in all respects) from the Investigator to Sponsor through LAMBDA. All such payments will be made by A/C Payee Cheques to the Institution/Investigator. (Can also be paid through wire transfer under case to case basis)
 4. As regards tasks that are not specifically itemized in this Agreement, payments will not be made without prior written approval of the LAMBDA/Sponsor. These additional tasks will be submitted to LAMBDA/Sponsor in writing, with estimated completion dates and costs, if any. Any expenses not specified in this Agreement or any changes to the amounts mentioned in this agreement, will be communicated to LAMBDA/Sponsor and are subject to prior written approval by LAMBDA/Sponsor, which, in its turn, must obtain prior written approval from Sponsor.
 5. In the event that a randomized Subject is determined to be ineligible for the Trial, LAMBDA will decide, together with the Sponsor, if required, whether or not to pay to the Institution/Investigator the Per Subject Fee for such Trial Subjects. In the event that a Trial Subject withdraws voluntarily or is withdrawn from the Trial (a) by LAMBDA or (b) by the Investigator for any reason other than the Trial Subject failing to meet eligibility requirements for the Trial, then LAMBDA/Sponsor will pay the Institution/Investigator a prorated amount of the per patient grant through the date of such withdrawal. Further, if, at the completion of the Trial, Sponsor has advanced sums under the terms of this Agreement that exceed the adjusted Trial Cost, the Investigator/Institute will reimburse to Sponsor any amount by which amounts advanced by the Sponsor exceed the adjusted Trial Cost.
 6. The CRO/Sponsor may withhold all or part of any amounts in the event of:
 - (1) failure of the Investigator/Institute to complete the services according to the Protocol;
 - (2) failure to provide LAMBDA with requested documentation;
 - (3) Failure of the Investigator/Institute to comply with the terms of this Agreement.

Dr. Santosh Hajare, Belagavi



Page 23 of 23

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

2
Authorized Signatory

THE DECCAN MERCHANT CO-OP BANK LTD.
ANDAR BLD., BESHILLA BUILDING, FIRST FLOOR
BANDRA ROAD, DADAR(WEST)
MUMBAI - 400 028
D-5/SIPV/C.R.1093/01/10/705-00/10

भारत 62179
144283
SPECIAL ADHESIVE
महाराष्ट्र
JUL 18 2019
10:37
R. 0000200/- PB6584
INDIA STAMP DUTY MAHARASHTRA

CLINICAL STUDY AGREEMENT

This Clinical Agreement ("Agreement") is entered into as of 19th July 2019 ("Effective Date") between Novartis Healthcare Private Limited, a company registered under the Companies Act, 1956 and having its registered office at Sandoz House, Dr. Annie Besant Road, Worli, Mumbai - 400018 ("Novartis") which expression shall mean and include its successors and assigns of the ONE PART;

AND

KLES Dr. Prabhakar kore hospital and MRC, , located at *Nehru Nagar Belagavi* ("Institution") registered under the provisions of Bombay Public Trust Act, 1950 and having its address at *Nehru Nagar, Belagavi, Karnataka, 590010* which expression shall mean and include its successors and assigns of the SECOND PART;

AND *Dr. Shivakumar Patil* as clinical practitioner in the field of *Dermatology*, acting in the role of principal investigator ("Principal Investigator") which expression shall mean and include his/her heirs, executors, administrators and assigns of the THIRD PART;

Novartis and Institution and Principal Investigator are hereinafter individually referred to as the "Party" and jointly as the "Parties".

RECITALS:

WHEREAS, Novartis is to perform a clinical trial (hereinafter the "Study") to evaluate the following drug: QGE031 (hereafter the "Study Drug") in accordance with a protocol entitled A multi-center, randomized, double-blind, active and placebo-controlled study to investigate the efficacy and safety of ligelizumab (QGE031) in the treatment of Chronic Spontaneous Urticaria (CSU) in adolescents and adults inadequately controlled with H1-antihistamines, CQGE031C2302 and its amendments (hereinafter collectively the "Protocol") attached hereto in Annex 3, and,

WHEREAS, the Institution and the Principal Investigator having each reviewed the Protocol for the Study and sufficient information regarding the Study Drug to evaluate their interest in participating in the Study, wish to conduct in the Study and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Study,

WHEREAS, the Parties wish to set forth certain the terms and conditions under which the Study shall be conducted;

NOW THEREFORE, the Parties, in consideration of the above and the mutual promises set forth below, agree as follows:

1. CONFORMANCE WITH LAW AND ACCEPTED PRACTICE **ATTESTED**

The Institution and Principal Investigator shall carry out the Study in accordance with:

(a) the Protocol as amended from time to time,

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- (d) any applicable direction received from a regulatory authority (DCGI) or ethics committee with jurisdiction over the Study;
- (e) any "Applicable Law(s)" being hereinafter defined as : all regional, federal, state, and local directives, laws, including but not limited to Schedule Y of Drugs and Cosmetics Act 1940, those related to anti-bribery and promotion, rules, regulations, orders, published guidelines, operating procedures applicable to the Study and/or the Parties including but not limited to, legislation applicable to clinical Studies, the Parties, medical treatment and the processing of personal and medical data.
- (f) comply with all guidelines provided to it by Novartis from time to time individually but not limited to Code of Conduct, Novartis global Antibribery Policy and Professional Practices Policy

The Institution warrants that the Principal Investigator and the Institution's employees and collaborators involved in the Study will comply with all Applicable Laws.

PROTOCOL

- 2.1 The Parties agree that the Protocol, including any subsequent amendments and the Annexes form an integral part of this Agreement.
- 2.2 Institution and Principal Investigator agree to use their best efforts and professional expertise to perform the Study in accordance with the Protocol, all Applicable Laws, the identified timelines and the terms and conditions of this Agreement. Institution and Principal Investigator may not start the clinical trial without prior approval of the appropriate Ethics Committee and Regulatory Authority.

APPROVALS

The Study shall not commence until:

- (a) all the necessary approvals of the relevant regulatory authority hence been obtained by Novartis and the competent Ethics Committee have been obtained in writing by the Principal Investigator. Such approvals shall be forwarded to Novartis no sooner they are obtained;
- (b) the written approval of relevant authority or organisation that owns or is responsible for the administration of the facility in which the Study is to be performed has been obtained, if such authority or organisation is not the Institution.
- (c) the Informed Consent Form as defined in Section 6.4 provided by Novartis, has been approved by the Principal Investigator and/or the ethic committee.

DURATION OF THE STUDY

The Study shall commence on *1 Dec 2018*, subject to the requirements of Section 3 have been met prior to this date. The Institution shall use its best efforts to complete the Study and to perform its obligations under this Agreement by *27 July 2021* or as may be extended by a formal writing between the parties in that behalf

TERM OF THIS AGREEMENT

- 1 This Agreement shall be effective upon 9 May 2019 ('Effective Date') and shall expire upon 8 May 2022 (both days inclusive) unless extended or terminated in terms of this Agreement.
- 2 The following provisions shall survive the termination or expiry of this Agreement: Section 12 (Intellectual Property), Section 14 (Publication) and Section 15 (Confidentiality), as well as any other provisions which by their terms are understood to survive the termination or expiry of this Agreement, including compliance with Applicable Laws.
- 3 In the event that the Principal Investigator ~~no longer~~ ^{ATTESTED} no longer conduct the Study both Principal Investigator and the Institution shall provide written notice to Novartis as soon as possible, and ~~at least~~ ^{within} 30 days prior to such ~~departure~~. It is clarified that Principal Investigator shall

Dr. V.A.Kothiwale
Registrar

6. PERFORMANCE OF THE STUDY

Principal Investigator and the Institution shall jointly and severally be responsible for the performance of the Study, in particular for the following:

6.1 Principal Investigator may appoint individuals and investigational staff as they may deem appropriate as sub-investigator (the "Sub-Investigators") to assist in the conduct of the Study. All Sub-Investigators and investigational staff will be adequately qualified, timely appointed and an updated list will be maintained. Principal Investigator shall alone be responsible for hiring, leading, supervising and reimbursing such team of Sub-Investigators and investigational staff, who, in all respects, shall be bound by the same terms and conditions as the Principal Investigator under this Agreement. The Principal Investigator shall be responsible for the conduct of the clinical investigation in its entirety and the well-being of the study subjects ("Study Subjects") and undertake in particular to have it executed by competent resources.

6.2 Study Site

The Study shall be conducted at the premises of Institution at the *KLES Dr. Prabhakar kore hospital and MRC*, located at *Nehru Nagar, Belagavi* : (hereinafter the "Study Site").

6.3 Use of Study Drug:

Novartis shall provide QGE031 (hereinafter called "Study Drug") in sufficient quantity to conduct the Study. For purposes of this Agreement only, the Study Drug shall be supplied to Institution free of charge. In all events, the Study Drug shall remain the sole property of Novartis.

The Principal Investigator shall

- (a) at his/her risks, costs and expenses ensure the safe receipt, handling, storage, use and administration of the Study Drug and take all reasonable measures to ensure that it is kept secure;
- (b) not permit Study Drug to be used for any purpose other than the conduct of the Study in compliance with the Protocol;
- (c) shall not make the Study drug available to any third party other than as specified in the Protocol without Novartis' prior written consent;
- (d) shall fully comply with all the responsibilities set out under the law;
- (e) keep full and accurate records of who dispenses the Study Drug, the quantity dispensed, and the quantity returned which shall be available for review and /or collection by Novartis and/or designated monitor ("Novartis Monitor") at any scheduled monitoring visit; and
- (f) upon any earlier expiration or termination of this Agreement, at Novartis's expense, return any remaining quantities of the Study Drugs to Novartis.

6.4 Study Subject consent and entry into Study: Before entering a Study Subject into the Study, the Principal Investigator shall:

- (a) Exercise independent medical judgement as to the compatibility of each prospective Study Subject with the requirements of the Protocol;
- (b) advise Novartis of all instances in which, in the Principal Investigator's judgement, there is any question as to any prospective Study Subject's suitability for participation in the Study, and abide by Novartis's decision as to whether or not to enroll that Study Subject;
- (c) ensure that, before their participation in the Study, the Study Subject, and/or as the case may be, her/his legal representative, are duly informed in language understandable to them, about all aspects of the Study that are relevant to them, including: (i) the purpose, duration, nature, significance, implications, potential benefits and/or risks of the Study; and (ii) the processing, auditing, and monitoring of data (including personal data) under this Agreement;

ATTESTED
Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- (d) ensure that, before his/her participation in the Study, each Study Subject and/or as the case may be his/her legal representative has given his or her Informed Consent on the basis of the information described in Clause 6.4. (c) by signing a consent form ("Informed Consent Form" or "ICF") in accordance with the Protocol and without the undue influence or coercion of any person directly involved in the Study, and in accordance with Applicable Laws. An example ICF is attached hereto as Annex 3;
- (e) ensure that a copy of the signed Informed Consent Form be provided to the Study Subject, and/or as the case may be, his/her legal representative;
- (f) acknowledge that the use of the Informed Consent Form does not release the Principal Investigator from his or her legal, regulatory and contractual obligations relating to Informed Consent, and that it remains the Principal Investigator's responsibility to ensure that those obligations are complied with;
- (g) comply with the procedures described in the Protocol in relation to that Study Subject; and,
- (h) provide details of the proposed Study Subject to Novartis.

6.5 Study Subject Recruitment

Principal Investigator has estimated that he/she can recruit the number of Study Subjects as specified in Annex 1. This target of recruitment can be increased only upon written agreement of Novartis. The Principal Investigator undertakes to comply with these limitations and conditions for further recruitment at the Study Site as required by Novartis.

Novartis will review the Study Subjects recruitment on an on-going basis to ensure that the enrollment continues at an acceptable rate. Novartis is empowered to discontinue the Study at Institution medical facilities in case of no or poor enrollment.

In a multicentre study, Novartis reserves the right, at its sole discretion, to require Institution and Principal Investigator to cease enrollment of Study Subjects prior to enrollment of the targeted number of Study Subjects. Institution and Principal Investigator undertake to cease such enrollment upon request of Novartis and further undertake not to seek any compensation therefor.

6.6 Recordkeeping, Reporting, Access and Inspections

(a) Recordkeeping, Reporting

The Institution and the Principal Investigator shall perform the following recordkeeping and reporting obligations in a timely fashion:

- (i) Preparation and maintenance of complete, accurately written and electronic records, including accounts, notes, reports, Case Reports Forms, records of Study Subject identifications, medical notes, clinical observations, laboratory tests, and the receipt and disposition of the Study Drug and all supportive documentation and data for each Study Subject of this Study (hereinafter "Records").
- (ii) Maintain a copy of all documents related to this Study for the longer of a) fifteen (15) years after the Study is completed or discontinued by Novartis) as required by applicable laws and regulations.
- (iii) Meet with a representative of Novartis to discuss the progress of the Study; and Notify Novartis immediately upon discovering any significant violations of the Protocol.
- (iv) In accordance with the procedure set out in the Protocol : Complete a Case Report Form for each Study Subject; review and sign each of the Case Report Forms to ensure and confirm their accuracy and completeness; promptly submit the Case Report Forms to Novartis following their completion,
- (v) Cooperate with Novartis in all their efforts to monitor the Study and to support Novartis in all matters of data collection, verification and discrepancy resolution

ATTESTED

Dr. V.A. Kothiwale
Registrar

...in compliance with Data Privacy and Protection provisions set out in this Agreement. In the event of the insolvency or liquidation of Institution, Institution agrees to promptly transmit all copies of such records to Novartis in accordance with Novartis' written instructions and in line with the transfer and disclosure terms set out in the ICF signed by concerned trial participants, at Novartis' expense.

- (vii) Ensure the hospital records of Study Subjects are kept safely in a known and accessible location during the period defined here-above.
- (viii) Make all Records available to Novartis or its nominee promptly upon request for monitoring and/or auditing purposes;
- (ix) Be responsible for making any necessary applications for registration under the data protection legislation in connection with data obtained under this Agreement, as provided in Article 27.

(b) Access and Inspection

It is agreed that the authorized representatives of Novartis, and regulatory authorities to the extent required by law, shall be entitled to:

- (i) Examine and inspect the Institution's facilities required for performance of the Study; and
- (ii) Inspect and copy all data and work products relating to the Study (including, without limitation, access to records as necessary for study monitoring or to audit the conduct of the Study in accordance with Novartis standards). Sponsor will maintain the confidentiality of any subject-identifiable medical records.
- (iii) If any governmental or regulatory authorities notifies Institution or the Principal Investigator that it will inspect Institution's records, facilities, equipment, or procedures, or otherwise take action related to the Study, Institution shall promptly notify Novartis or any designated person within 24 hours, allow Novartis to be present at the inspection/action or participate in any response to the inspection/action, and provide Novartis with copies of any reports or information issued by the authority and Institution's proposed and final response.
- (iv) Grant access to Novartis or its representative to visit periodically, as frequently as required for the proper performance and oversight of the Study, the Study Site in order to proceed with any and all monitoring activities required for the Study.
- (v) The Institution and the Principal Investigator will use their best efforts to facilitate the performance of any audit and inspection and shall give Novartis and any person designated by them access to all necessary facilities, data and documents.
- (vi) The Institution and the Principal Investigator shall take appropriate measures required by Novartis to correct without delay all observations found during the audits or inspections.
- (vii) It is expressly agreed between the Parties that Novartis will not compensate the Institution or the Principal Investigator for the audits and inspection.

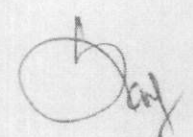
The rights and obligations under this Article shall remain in effect for fifteen (15) years after the end of the Study.

6.7 Reporting: The Principal Investigator shall, either by himself/herself or his/her duly authorized representative, on reasonable notice

- (a) Meet with a representative of Novartis to discuss the progress of the Study; and



ATTESTED
Dr. V.A. Kothiwale
Registrar



- (b) Make the hospital notes and Case Report Forms for each Study Subject available for source data verification or auditing purposes by representatives of Novartis representatives and the officers of any competent authority.
- (c) On discovering any significant violations of the Protocol, the Principal Investigator shall notify Novartis immediately.

6.8 Reporting of Safety Information:

The Principal Investigator shall notify Novartis of each Serious Adverse Event encountered in the Clinical Trial within twenty-four (24) hours of becoming aware of it in accordance with the instructions set forth in the Protocol as well as local regulatory requirements. Each such notice shall be given by telefax or e-mail on a Novartis Serious Adverse Event Report form, whether or not notification was initially given by telephone. Section 6.6 shall apply to both the original copy of each Serious Adverse Event Report form and the telefax confirmation sheet or e-mail reflecting its transmission to Novartis.

The Principal Investigator shall also ensure that any person involved in the conduct of the study shall:

- (a) Immediately report to Novartis according to the procedure set out in the Protocol, any new safety findings on the Study Drug, including Serious Adverse Event or Serious Adverse Reaction affecting or which could have an impact on the safety of the Study Subject or which could result in a re-assessment of the risk-benefit ratio of the Study Drug. The Principal Investigator shall follow up such immediate reports and provide the additional information in a detailed, written manner to Novartis in accordance with the Protocol and local regulatory requirements;
- (b) Report to Novartis all Adverse Events (refer definition of adverse event as per ICH E6 guidelines for Good Clinical Practice and/or as mentioned in the protocol) in accordance with the study Protocol, applicable study procedures for safety data reporting;
- (c) Cooperate with and supply any further information required by Novartis and/or any relevant ethics committee or Regulatory Authority with jurisdiction over the Study.-

These reporting obligations shall survive expiration or earlier termination of the Agreement.

Novartis shall further report the adverse events to the competent Regulatory Authorities, in accordance with the current Applicable Laws. Novartis will furthermore provide the Principal Investigator with safety-related information from other investigational sites in order to inform the ethics committees IRB/IEC, as required.

After completion of the Study and evaluation of the results, Novartis will inform the Principal Investigator about relevant safety-related findings in accordance with the guidelines and Study procedures.

6.9 Items supplied by Novartis

Novartis shall provide directly or indirectly the Principal Investigator and/or the Institution with all necessary information, documents and materials, including but not limited to:

- (a) the Investigator Brochure (IB)
- (b) the Protocol,
- (c) the CRF/e-CRF
- (d) the Study Drug
- (e) the study related equipments on returnable basis listed in Annexure 1

6.10 The Principal Investigator, or coordinating investigator for multicentre studies, shall sign the clinical Study reports, which form part of the marketing authorization submission.

7. LIABILITY-INDEMNIFICATION

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

In the case of any injury occurring to a clinical trial subject or in the event of clinical trial related death of the subject, Novartis assumes responsibility to the extent and in the manner under the applicable laws

The Institution and Principal Investigator ("Indemnifying Party") will indemnify and hold harmless Novartis from and against any and all liabilities, claims, damages, losses, settlements, penalties, fines, costs and expenses, including attorneys' fees, (collectively, "Damages") of whatever kind or nature (but not including taxes) arising from any third party demand, investigation, claim, action or suit in the based on (i) the gross negligence, bad faith or willful or intentional misconduct of the Indemnifying Party (ii) a material breach by the Indemnifying Party of any term of this Agreement, or (iii) a violation of any relevant law, rule or regulation by the Indemnifying Party in the performance of its duties under this Agreement.

INSURANCE

The Institution warrants that it has appropriate and adequate professional indemnity insurance to cover claims or damages including those arising out of negligence of the Principal Investigator for which it shall be liable under this Agreement. The Institution shall provide evidence of its insurance upon request by Novartis.

Novartis warrants that it has insurance for the Study Subjects included in the Study in place a Study start.

9. COMPENSATION

9.1 In consideration for the satisfactory performance of the Study according to this Agreement and the Protocol, The Principal Investigator agrees to Payment Schedule attached hereto as Annex 1

9.2 Novartis reserves the right to terminate the Agreement immediately if no subjects have been recruited at the Study Site by 16 Feb 2020.

9.3 Subjects not completing the Study will be paid for on a prorated basis according to the number of completed visits. All payment will be made for subject visits according to the above Payment Schedule attached as Annex 1. No payment will be made for any Study Subject excluded from analysis because of Protocol violations that were within the Institution or Principal Investigator control. Reimbursement for expenses related to screening failures, patient travel, and local lab test will be made according to the Payment Schedule in Annex 1.

9.4 The Principal Investigator shall send the invoices to:

Novartis Healthcare Private Limited

GDO Trial Monitoring, India

Novartis Healthcare Private Limited

Inspire BKC, 'G' Block,

6 & 7 Floor, BKC Main Road,

Bandra Kurla Complex,

Bandra (E) Mumbai 400051, India

9.5 Each invoice shall specify the Study Code. Novartis shall make payments into the account indicated by the Institution and Principal Investigator within 60 (sixty) days of receipt of invoice from the Institution.

10. EQUIPMENT

10.1 If necessary and based upon Novartis' assessment of Institution existing equipment, Novartis may provide equipment (the "Equipment") to the Institution and/or Investigator strictly on a returnable basis as detailed in Annex 1. The Equipment shall remain the sole and exclusive property of Novartis. It shall be used exclusively by the Institution and/or the Investigator. The Equipment shall only be used for the conduct of the Study in accordance with the Protocol and Novartis instructions and until the Study is completed or discontinued.

ATTESTED

Dr. V.A. Kothiwale

Registrar

purpose of this Study, the Institution and Investigator agree that the Equipment shall remain in the same condition during the Study, with the exception of ordinary depreciation.

- 11.3 During the term of the Study, Institution and/or Investigator shall be responsible for immediately notifying Novartis of any malfunctioning Equipment.
- 11.4 Following completion of the Study or upon discontinuation of the Study for any reason, the Institution and/or Investigator, as the case may be, shall return the Equipment to Novartis or alternatively, in the event the Equipment remains with the Institution and/or Investigator, the cost of such Equipment will be deducted from the last payment(s) to be made to either the Institution or Investigator, as the case may be.

11. TERMINATION

- 11.1 Either party may terminate this Agreement for any safety and/or efficacy concerns or other ethical grounds by giving written notice to the other party with immediate effect. In case of early termination the *KLES Dr. Prabhakar kore hospital and MRC/Dr. Shivkumar Patel* shall notify the relevant Ethics Committee of the early termination, and Novartis shall notify the regulatory authorities and any other competent authorities as relevant and appropriate within specified timelines
- 11.2 Novartis may terminate this Agreement for convenience by giving written notice to the Institution with immediate effect.
- 11.3 If Novartis terminates this Agreement, Novartis shall have no obligations under this Agreement except to reimburse the Institution for such reasonable costs and non-cancellable obligations which has been approved by Novartis incurred in the performance of the Study prior to receiving notice of termination.
- 11.4 The termination or expiry of this Agreement shall not affect the rights and obligations of the parties which accrue prior to the date of termination. In particular, the Institution/Principal Investigator shall provide all outstanding Case Report Forms to Novartis and return to Novartis all documents and Equipment provided by Novartis under this Agreement.

12. INTELLECTUAL PROPERTY

- 12.1 All data, information and documents provided to the Institution by or on behalf of Novartis, whether in paper, oral, electronic or other form, shall remain the sole property of Novartis.
- 12.2 All data, information, documents, inventions and discoveries, resulting from or developed in the performance of the Study or this Agreement shall be the sole property of Novartis and may be used and/or transferred by Novartis in its sole discretion with no further payment or other obligation to the Institution. The Institution shall have no rights whatsoever therein.
- 12.3 The Institution agrees to, and to cause its employees and collaborators and the Principal Investigator to, execute promptly all documents and take all such other action as may reasonably be requested by Novartis to enable Novartis to obtain the benefit of its rights under this Agreement. This includes without limitation taking all necessary steps for the transfer of ownership of all data, information, documents, inventions and discoveries to Novartis in accordance with this Agreement, and assisting Novartis in the preparation and prosecution of patent applications. Furthermore, Institution and Investigator shall execute, or procure the execution of, and enforce all documents and deeds and do, or procure the doing of, all things as Novartis including but not limited to assignment of any and all rights, title and interest in resulting intellectual property in Novartis.
- 12.4 The Institution shall ensure that the Principal Investigator and the Institution's employees and collaborators involved in the Study will comply with its obligations under this Agreement.

13. TAXES AND SOCIAL SECURITY CONTRIBUTIONS

It shall be the Institution's responsibility to comply with all obligations in respect of taxes and social security contributions, if applicable, which relate to the subject matter of this Agreement, including without limitation those which relate to the Principal Investigator, the Institution and its employees and/or collaborators.

ATTESTED
Dr. V. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

PUBLICATION

- 14.1 Novartis recognizes the Institution's interest in making publications and presentations relating to the Study in journals, at meetings or otherwise, and may therefore permit such publications and presentations, provided however that the Institution shall provide to Novartis any proposed presentation at least 15 (fifteen) working days prior to being disclosed and any other proposed publication at least 45 (forty-five) working days prior to being disclosed, and provided that Novartis shall have the right to require amendments to any such proposed presentation or publication on reasonable grounds including without limitation:
- (a) to ensure the accuracy of the presentation or publication;
 - (b) to ensure that proprietary information is not inadvertently divulged;
 - (c) to enable intellectual property rights to be secured;
 - (d) to enable relevant supplementary information to be provided.
- 14.2 Authorship of any publications relating to the Study shall be determined by mutual agreement.
- 14.3 Novartis may require any proposed publication or presentation to be delayed for up to 4 (four) months to enable a patent application to be prepared and filed. The 4 (four) month period shall commence on the date of receipt of the proposed publication or presentation, or from the date when all relevant data from the Study are made available to Novartis, whichever is later.
- 14.4 If the Study is a multi-centre study, the first publication of data shall be based on consolidated data from all centres analysed according to the Protocol, unless otherwise agreed in writing by all the Principal Investigators involved in the Study and Novartis.
- 14.5 Except as otherwise required by law or regulation, neither Party shall release or distribute any materials or information containing the name of the other Party or any of its officers, agents or employees without the prior written consent by an authorised representative of the non-releasing Party.

15. CONFIDENTIALITY

- 15.1 All information and data, trade secrets, privileged records and other confidential or proprietary information (including but not limited to the Protocol, CRFs and information on password-protected Novartis websites) disclosed to or collected or developed by the Institution, the Principal Investigator and/or the Institution's employees and/or collaborators in connection with this Agreement or the Study (collectively "Information") shall be treated as confidential. The Institution and/or the Principal Investigator agree not to disclose to any third parties or to use any Information for any purpose other than the performance of the Study. The Institution and/or the Principal Investigator shall ensure that the Institution's employees and collaborators are bound by confidentiality obligations not less strict than those set out herein prior to receiving any Information.
- 15.2 Upon termination or expiry of this Agreement, the Institution and / or Principal Investigator shall safely destroy (as set in the Data Privacy and Protection annexure to this Agreement) or return to Novartis, as per Novartis' request, all documents, samples and material containing or relating to Information, except for one copy of Information which is to be retained in the confidential files of the Institution for record purposes only. If requested by Novartis, such safe destruction shall be promptly confirmed in writing by the Institution to Novartis.
- 15.3 The confidentiality obligations set out above shall not apply to:
- (a) Information which is, at the time of disclosure, in the public domain or thereafter becomes part of the public domain otherwise than by the act or omission of the Institution, the Principal Investigator, or the Institution's employees and/or collaborators;
 - (b) Information that the Institution can demonstrate by written evidence was in its possession prior to its disclosure by Novartis or that said information, its collection or creation did not occur during or in connection with the Study;

ATTESTED
Dr. V.A.Kothiwale
Registrar

NOTICES

Any notice given in connection with this Agreement shall, unless otherwise provided herein, be in writing and shall be delivered personally, or sent by registered mail or facsimile to the address given in this Agreement

Mr. K. Muruganathan

GDO Trial Monitoring,

Novartis Healthcare Private Limited

Inspire BKC, 'G' Block,

6 & 7 Floor, BKC Main Road, Bandra Kurla Complex,

Bandra (E) Mumbai 400051, India

Email: muruganathan.k@novartis.com

or to such other address as may have notified to the other party in writing.

7. ASSIGNMENT

Neither Party may assign its rights and obligations under this Agreement without the other Party's prior written consent, except that Novartis may (a) assign its rights and obligations under this Agreement or any part hereof to one or more of its Affiliates; or (b) assign this Agreement in its entirety to a successor to all or substantially all of its business or assets to which this Agreement relates. Any permitted assignee will assume all obligations of its assignor under this Agreement (or related to the assigned portion in case of a partial assignment). Any attempted assignment in contravention of the foregoing will be void. Subject to the terms of this Agreement, this Agreement will be binding upon and inure to the benefit of the Parties and their respective successors permitted assigns.

18. SUBCONTRACTING

The Institution and /or Principal Investigator shall not retain any subcontractor to perform any of its obligations under this Agreement without the prior written consent of Novartis. Any such consent shall not relieve the Institution and/or Principal Investigator of its obligations hereunder.

19. SEVERABILITY

The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision hereof.

20. WAIVER

No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or of any other term, provision or condition of this Agreement.

21. ENTIRE AGREEMENT

This Agreement (including the Protocol) represents the entire understanding between the parties with respect to the subject matter hereof. No amendment to this Agreement will be effective unless it is in writing signed by both parties and refers to this Agreement.

22. DEBARMENT

Neither the Principal Investigator nor the Institution, nor any person employed thereby nor a collaborator who is involved in the performance of the Study has been debarred under the provisions including but not limited to provisions of the Indian Medical Council Act, 1956 as amended, Drugs and Cosmetics Act, 1940 and no debarred person will in the future be employed or engaged by the Institution in connection with any work to be performed for or on behalf of Novartis. If at any time after the execution of this Agreement, the Institution or the Principal Investigator

Dr. V.A. Kothiwale

Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

CONFLICT OF INTEREST, FINANCIAL DISCLOSURE

The Institution and the Principal Investigator confirm that there is no conflict of interests between the Parties that would inhibit or affect their performance of the work specified in this Agreement. The Institution and the Principal Investigator further certify that they will promptly inform Novartis in the event any conflict of interests arises during the performance of this Agreement and certify that their performance hereunder does not violate any other agreement they may have with any other third party.

TRANSPARENCY/DISCLOSURE

1. In all materials relating to Services intended for an external audience, Principal Investigator shall disclose:
 - (a) that Novartis has retained Principal Investigator for professional services in relation to the conduct of the Study; and
 - (b) any other relationships that Novartis has with Principal Investigator which a reasonable and ethical person would expect to be disclosed.
- 4.2 Both parties agree to make all other disclosures and/or notifications as may be required in connection with entering into, performing, or receiving compensation under this Agreement, and Principal Investigator shall follow all Applicable Laws in this respect, including those relating to Principal Investigator's professional relationships with decision-making authorities or bodies (if any), such as, for instance, recusal from any votes, discussions or recommendations regarding investigational or marketed products of Novartis, regardless of whether such are subject to the Services.
- 4.3 The Institution and Principal Investigator understand and agree that Novartis may be required to disclose certain information to governmental agencies in different jurisdictions in order to comply with local laws regulating clinical trials. The Institution and Principal Investigator consent to the disclosure of certain information that otherwise may constitute personal data in order to comply with laws regulating clinical trials, including but not limited to the Institution's and/or Principal Investigator's name, clinical trial Study Site contact information, name of the clinical trial, sponsor, copy of the Agreement, and costs and fees relating to Study Site's activities performed under the Agreement. Novartis will provide upon written request a list of any such disclosure made regarding the Institution and/or the Principal Investigator.

25. JURISDICTION AND APPLICABLE LAW

This Agreement shall be governed by and construed in accordance with the laws of India. The parties hereby submit to the exclusive jurisdiction of the competent courts of Mumbai, India without restricting any right of appeal.

26. DATA PROTECTION

A form regarding the disclosure of the Principal Investigator's personal data together with the general provisions regarding any personal information processed by the Institution under this Agreement is attached as Annex 2.

27. COUNTERPARTS

This Agreement may be executed in two or more counterparts each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

28. PRECEDENCE

To the extent that there may be any inconsistency between this Agreement and the Protocol, the Protocol shall take precedence in ONLY in relation with trial procedures while in all other instances the agreement shall prevail.

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

WITNESSETH, the Parties attending to be bound have caused this Agreement to be
written by their duly authorized representatives.

GOVARTHA HEALTHCARE PRIVATE LIMITED

KLES Dr. Prabhakar kore hospital and MRC

By: [Signature]

Name: Dr. M V Jali

Title: MD & CE KLES Dr. Prabhakar Kor Hospital and MRC

Date: 26/07/2019

[Signature]
Name: Saurin Singh
Title: Head CTO
Date: 19th July 2019

Dr. Shivakumar Patil
By: [Signature]

Name: Dr. Shivakumar Patil

Title: Associate Professor/Consultant Dermatologist

Date: 25/07/2019

ATTESTED

[Signature]
Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

PAYMENT SCHEDULE

FORM NUMBER: DCE/MSIC/2002

FORM NAME: PEARL-1

Investigator's Name: Dr. Shivakumar Patil

Centre Name: KLES Dr. Prabhakar kore hospital and MRC

Physician Name: Dr. Shivakumar Kalagouda Patil

ICR Card Number: BJJPP7382P

STUDY NA

Estimated Number of Study Subjects: 5 randomized patients


Use of Equipment provided to Institution / Principal Investigator:

- Thermo-hygrometer
- ERT Log Pads - It would be retrieved from site post database lock is achieved.
- ERT Machine - It would be retrieved from site post database lock is achieved

Payment Schedule:

Sl. No.	Screening		Double blind treatment											
	1	20	110	120	130	140	150	160	170	180	190	200	210	220
1	-4	-1	R	4	8	12	16	20	24	28	32	36	40	44
2	16800	2800	6000	5000	5000	5000	3500	3500	5000	3500	3500	3500	3500	3500
3	4000	3000	5000	3000	3000	3000	3000	3000	3000	3000	3000	3000	3000	3000
4	2000	2000	3000	2000	2000	2000	2000	2000	2000	2000	2000	2000	2000	2000
5			1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500
6	5700	1950	3750	2750	2750	2750	2375	2375	2750	2375	2375	2375	2375	2375
7	22500	9750	19250	14250	14250	14250	12375	12375	14250	12375	12375	12375	12375	12375

ATTESTED


 Dr. V.A. Kothiwale
 Registrar

KLE Academy of Higher Education and Research,
 (Deemed-to-be-University u/s 3 of the UGC Act, 1956)
 Belagavi-590 010, Karnataka

	post treatment follow up			
Visit	240/EoT/TD	310	320	1999/EOS? PSD
Week	52	56	60	64
Protocol Procedures	6200	5000	5000	5700
Investigator Fees	4000	3000	3000	4000
Coordinator Fees	2000	2000	2000	2000
Unblinded Pharmacist fee	1500	1500	1500	1500
Institutional Overhead @ 25%	3300	2750	2750	3175
TOTAL (INR)	17000	14250	14250	16375
TOTAL COST 1 PT	275375			

Payment Terms:

- The amount of payment due to the Institution/Investigator will be calculated in respect of each patient visit according to the attached budget schedule.
- For patients who are not randomized into the study based on Screening results (Screen Failures) Institution/Investigator will receive remuneration in the amount of a screening visit cost
- Any other third parties designated by the Institution/Investigator that would receive remuneration, will be managed by & paid by the Institution/Investigator.
- The work performed by the hospital laboratory in addition to budget schedule shall be paid based on actuals. It is the Investigators responsibility to liaise with the hospital laboratory.
- Sponsor shall reimburse patient's travel cost per protocol visit will be upto 1000 INR for which institution/PI shall provide original invoice along with the supporting bills.
- The Ethics committee charge will also be paid via Novartis, and this cost is not included in the budget schedule.
- Unscheduled visits covers subject visits that are not expressly set forth in the Study Schematic of the Protocol, but are otherwise required for the study. Medically necessary procedure, test performed during unscheduled visits would be paid as per actual bills. Payment for unscheduled visits will be payable to the institution within 60 days of receipt of original, itemized invoice by Novartis.

ATTESTED

- All payments are based on actual patient visits.
- All values are in INR. All budget schedule payments are subject to TDS (subject to Government of India Tax regulations) and GST as applicable. GST will be paid on providing valid tax invoice

Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

ANNEX 2: PRINCIPAL INVESTIGATOR – PERSONAL DATA DISCLOSURE FORM

Novartis wants to ask your permission to include certain elements of your personal data in a database maintained by a third party. The Grant Plan database, which is maintained and provided to pharmaceutical research sponsors by a company called TTC in the United States, is intended to assist research sponsors with transparency relating to clinical trial expenses. The database is used to support country specific forecasts for clinical trial costs and to provide benchmarking information in order to achieve transparency and fairness in setting costs for performing clinical trials.

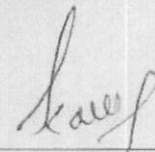
The information is entered into the database in such a way that it is not possible for anybody except the personnel of TTC to view your name or link your site to a particular clinical trial or sponsor company.

In that regard, Novartis is asking for your permission to submit your name, clinical trial site contact information, name of the clinical trial, sponsor, copy of the clinical trial agreement, and costs and fees relating to your site's retention, to a third party administrator of this database. This information will be maintained in that database for five years. If you are conducting research for Novartis in countries other than the United States, such as those in Europe, you should note that the United States does not offer the same standards of privacy protection as those offered in Europe. You are not required to give consent to this disclosure in order to proceed with this clinical study. However, by doing so, you are helping to collect information on fair costs in clinical trials.

- Yes, I hereby agree that Novartis may disclose my personal data in connection with the Grant Plan database.
- No, I do not give my permission to disclose my personal data in connection with the Grant Plan database.

Place and Date:

Belagavi/25/07/2019



Name: Dr. Shivakumar Patil

Principal Investigator

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Data Privacy and Protection

Provisions regarding any Personal Information Processed by Institution under this Agreement:

Defined Terms. For the purposes of this Section, the following terms shall have the meanings given below:

“Personal Information or Data” means any information that relates to an identified or identifiable person including without limitation electronic data and paper based files that include such information such as: (a) name or initials; (b) home or other physical address; (c) work, cell or home telephone number; (d) work or home email address or online identifier associated with the individual; (e) identification code; (f) credit card number; and (e) employment information, that is Processed directly or indirectly, by Institution on behalf of Novartis in connection with this Agreement.

“Sensitive Personal Information or Data” – constitutes a subset of Personal Information and relates to of an individual’s (a) physical, physiological or mental characteristics, (b) economic status, (c) racial or ethnic origin, (d) political, ideological, religious opinions or philosophical beliefs, (e) trade union membership, (f) health or medical information including information related to payment for health services, (g) sex life or sexual preference, (h) genetic material or information, (i) human biological samples or cells, (j) unique biometric data, (k) Personality Profiles or (ii) an individual’s name in combination with the individual’s (a) Social Security number, (b) alien registration number, (c) driver’s license number, (d) passport number, visa number or other government identifier, (e) credit card, debit card, or other financial account numbers, with or without any associated code or password that would permit access to such account, or (f) mother’s maiden name; and as applicable under local laws.

“Data Subject” – and identified or identifiable person who’s Agreement Personal Data are processed, accessed, received, transmitted, or maintained by the Supplier. An identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity.

“Processing” means any operation or set of operations which is performed upon personal information, whether or not by automatic means, such as collection, recording, organisation, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction or any other operation or set of operations otherwise defined in applicable Data Privacy Laws. This also includes the processing of personal information in structured manual files.

“Institution Third Parties” – any third party that assists Institution in performing its obligations under the Agreement, including an affiliate or direct or indirect subcontractor of Supplier.

General Obligations of Institution:


a. Compliance with Applicable Laws and Permitting Processing. Institution will, and will cause all Institution Third Parties to, hold Personal Information in confidence, use Process such data only for the benefit of Novartis and its Affiliates and Process such information in compliance with (i) all Applicable Data Protection Laws, (ii) the Agreement, (iii) any consent, authorization of a Data Subject or other authorized participant, such as subject’s legal representative, (iv) industry standards, and (v) this Data Privacy and Protection Exhibit; provided, however, that Institution (or Institution’s Third Party) may Process Personal Information only under the written instructions of an authorized signatory of Novartis.

To the extent that the Agreement involves the processing of personal information owned by or licensed to Institution prior to or separately from the Services, Institution represents and warrants that such data has been obtained in compliance with applicable laws and regulations, including Applicable Data Protection Laws and all necessary consents and authorizations, including those of any patient, if applicable. Institution further represents and warrants that Institution and/or Novartis is authorized to use such data as contemplated by this Agreement.

b. Obligations with respect to the Data Subjects participating in trials:

Institution shall take reasonable steps to ensure that each individual whose Personal Information were, or are, in its possession is able to assert his or her rights under local law, including but not limited to right of access to view and correct his or her Personal Data, right to withdraw consent and file complaint or grievance if any, with the Institution.

c. Obligations with Respect to Institution’s Third Parties.


Dr. V.A. Kothiwale
Registrar


KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

are located. In all such arrangements, Supplier will enter into agreements with Supplier Third Parties that are substantially similar to this Data Privacy Exhibit. Supplier shall provide copies of such agreements to Novartis within seven (7) business days following a written request from Novartis therefor.

Data Safeguards. The parties agree to comply with the following:

- (a) Without limitation of any provision of this Agreement, the parties agree to comply with applicable Laws governing the privacy and security of Personal Information that Institution shall create, acquire, access or receive as a result of this Agreement, to the extent that applicable Laws apply to either party.
- (b) Institution agrees to implement administrative, technical and physical security measures to protect Personal Information, from (i) unauthorised or accidental destruction, (ii) theft, forgery or loss, (iii) technical faults, (iv) forgery, theft or unlawful use (v) unauthorised alteration, copying access; or (vi) any other unauthorised processing.
- (c) Security measures implemented by Institution must take into account (i) the purpose of the data processing, (ii) nature and extent of the processing, (iii) assessment of possible risks to the data subject; and (iv) current industry best practices and state of the art technology including but not limited to encryption of information at rest and in transit. Security measures shall be reviewed on a periodic basis and updated as required.
- (d) All email communication with Novartis, especially those involving trial related information should happen via secure 'Institutional email Ids'. Exceptions (i.e. use of non-institutional email Ids), if any must be discussed with Novartis and a secure communication solution, mutually agreed and in line with Novartis' security standards, is implemented.
- (e) Institution shall not sub-contract any of its rights or obligations without the prior written notification to Novartis. In the event that any Institution Subcontractor shall have access to Personal Information, such access shall be permitted under a need-to-know basis and only to the extent required for the due performance of Institution's obligations. Institution shall enter into Agreements with its' subcontractors that contain privacy and security provisions that are equivalent to the provisions under this Agreement.
- (f) Institution shall ensure that personnel who will be undertaking the Processing of Novartis Personal Information, including that by Institution's Third Party (if any) have appropriate skills and privacy and security training to handle Sensitive Personal Information.
- (g) If Institution disposes of any paper, electronic or other record containing Agreement Personal Data, Supplier shall do so by taking all reasonable steps to destroy the information by (a) shredding; (b) permanently erasing and deleting; (c) degaussing; or (d) otherwise modifying the Agreement Personal Data in such records to make it unreadable, unreconstructable and indecipherable.
- (h) Institution shall maintain procedures to detect and respond to a Data Security Breach. Institution shall notify Novartis of any Data Security Breach within 24 hours of discovery of a data security breach. Institution shall promptly make available to Novartis details of the Data Security Breach and shall use commercially reasonable efforts to investigate and prevent the recurrence of such Data Security Breach. The parties shall reasonably cooperate to remediate a Data Security Breach and prevent any recurrence. Novartis, at its sole discretion, after consultation with Institution, shall determine whether and when to notify any individuals or persons (including Governmental Authorities) regarding any Data Security Breach affecting Novartis Personal Information. Institution, as determined in its sole discretion, shall comply with all applicable Laws to which it is subject with regard to the Data Security Breach.

ATTESTED


Dr. V.A. Kothiwale
Registrar

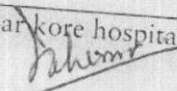
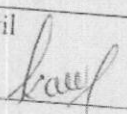
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

ANNEX 3: NOVARTIS POLICIES & STUDY DOCUMENTS

I / We, the undersigned Institution and Principal Investigator for study number CQGE031C2302 declare that I have received a copy of;

- (a) Novartis global Antibribery Policy
- (b) Professional Practices Policy

I / We, have read the policy (ies) understood its meaning and shall comply with the same.

KLES Dr. Prabhakar Kore hospital and MRC By: <u></u>	Dr. Shivakumar Patil By: <u></u>
Name: <u>Dr. M. V. Jali</u>	Name: <u>Dr. Shivkumar Patil</u>
Title: <u>MD & CEO</u>	Title: <u>Consultant Dermatologist / PI</u>
Date: <u>26/07/2019</u>	Date: <u>25/07/2019</u>

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

3
Authorized Signatory

THE DECCAN MERCHANT CO-OP BANK LTD.
DAGAR BR., KESHWA BUILDING, FIRST FLOOR
BAMBADE ROAD, DADAR (WEST)
MUMBAI - 400 028
D-5/STP(V)/C.R.1893/01/18/705-89/18

भारत 62179
144283
SPECIAL ADHESIVE
महाराष्ट्र
JUL 18 2019
10:37
R.0000200/- PB6584
INDIA STAMP DUTY MAHARASHTRA

201

CLINICAL STUDY AGREEMENT

This Clinical Agreement ("Agreement") is entered into as of 19th July 2019 ("Effective Date") between Novartis Healthcare Private Limited, a company registered under the Companies Act, 1956 and having its registered office at Sandoz House, Dr. Annie Besant Road, Worli, Mumbai - 400018 ("Novartis") which expression shall mean and include its successors and assigns of the ONE PART;

AND

KLES Dr. Prabhakar kore hospital and MRC, located at *Nehru Nagar Belagavi* ("Institution") registered under the provisions of Bombay Public Trust Act, 1950 and having its address at *Nehru Nagar, Belagavi, Karnataka, 590010* which expression shall mean and include its successors and assigns of the SECOND PART;

AND *Dr. Shivakumar Patil* as clinical practitioner in the field of *Dermatology*, acting in the role of principal investigator ("Principal Investigator") which expression shall mean and include his/her heirs, executors, administrators and assigns of the THIRD PART;

Novartis and Institution and Principal Investigator are hereinafter individually referred to as the "Party" and jointly as the "Parties".

RECITALS:

WHEREAS, Novartis is to perform a clinical trial (hereinafter the "Study") to evaluate the following drug: QGE031 (hereafter the "Study Drug") in accordance with a protocol entitled A multi-center, randomized, double-blind, active and placebo-controlled study to investigate the efficacy and safety of ligelizumab (QGE031) in the treatment of Chronic Spontaneous Urticaria (CSU) in adolescents and adults inadequately controlled with H1-antihistamines, CQGE031C2302 and its amendments (hereinafter collectively the "Protocol") attached hereto in Annex 3, and,

WHEREAS, the Institution and the Principal Investigator having each reviewed the Protocol for the Study and sufficient information regarding the Study Drug to evaluate their interest in participating in the Study, wish to conduct in the Study and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Study,

WHEREAS, the Parties wish to set forth certain the terms and conditions under which the Study shall be conducted;

NOW THEREFORE, the Parties, in consideration of the above and the mutual promises set forth below, agree as follows:

1. CONFORMANCE WITH LAW AND ACCEPTED PRACTICE

ATTESTED

The Institution and Principal Investigator shall carry out the Study in accordance with:

(a) the Protocol as amended from time to time,

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- (d) any applicable direction received from a regulatory authority (DCGI) or ethics committee with jurisdiction over the Study;
- (e) any "Applicable Law(s)" being hereinafter defined as : all regional, federal, state, and local directives, laws, including but not limited to Schedule Y of Drugs and Cosmetics Act 1940, those related to anti-bribery and promotion, rules, regulations, orders, published guidelines, operating procedures applicable to the Study and/or the Parties including but not limited to, legislation applicable to clinical Studies, the Parties, medical treatment and the processing of personal and medical data.
- (f) comply with all guidelines provided to it by Novartis from time to time individually but not limited to Code of Conduct, Novartis global Antibribery Policy and Professional Practices Policy

The Institution warrants that the Principal Investigator and the Institution's employees and collaborators involved in the Study will comply with all Applicable Laws.

PROTOCOL

- 2.1 The Parties agree that the Protocol, including any subsequent amendments and the Annexes form an integral part of this Agreement.
- 2.2 Institution and Principal Investigator agree to use their best efforts and professional expertise to perform the Study in accordance with the Protocol, all Applicable Laws, the identified timelines and the terms and conditions of this Agreement. Institution and Principal Investigator may not start the clinical trial without prior approval of the appropriate Ethics Committee and Regulatory Authority.

APPROVALS

The Study shall not commence until:

- (a) all the necessary approvals of the relevant regulatory authority hence been obtained by Novartis and the competent Ethics Committee have been obtained in writing by the Principal Investigator. Such approvals shall be forwarded to Novartis no sooner they are obtained;
- (b) the written approval of relevant authority or organisation that owns or is responsible for the administration of the facility in which the Study is to be performed has been obtained, if such authority or organisation is not the Institution.
- (c) the Informed Consent Form as defined in Section 6.4 provided by Novartis, has been approved by the Principal Investigator and/or the ethic committee.

DURATION OF THE STUDY

The Study shall commence on *1 Dec 2018*, subject to the requirements of Section 3 have been met prior to this date. The Institution shall use its best efforts to complete the Study and to perform its obligations under this Agreement by *27 July 2021* or as may be extended by a formal writing between the parties in that behalf

TERM OF THIS AGREEMENT

- 1 This Agreement shall be effective upon 9 May 2019 ('Effective Date') and shall expire upon 8 May 2022 (both days inclusive) unless extended or terminated in terms of this Agreement.
- 2 The following provisions shall survive the termination or expiry of this Agreement: Section 12 (Intellectual Property), Section 14 (Publication) and Section 15 (Confidentiality), as well as any other provisions which by their terms are understood to survive the termination or expiry of this Agreement, including compliance with Applicable Laws.

ATTESTED

- 3 In the event that the Principal Investigator decides to no longer conduct the Study both Principal Investigator and the Institution shall provide written notice to Novartis as soon as possible, and within 30 days prior to such departure. It is clarified that Principal Investigator shall

Dr. V.A.Kothiwale
Registrar

6. PERFORMANCE OF THE STUDY

Principal Investigator and the Institution shall jointly and severally be responsible for the performance of the Study, in particular for the following:

6.1 Principal Investigator may appoint individuals and investigational staff as they may deem appropriate as sub-investigator (the "Sub-Investigators") to assist in the conduct of the Study. All Sub-Investigators and investigational staff will be adequately qualified, timely appointed and an updated list will be maintained. Principal Investigator shall alone be responsible for hiring, leading, supervising and reimbursing such team of Sub-Investigators and investigational staff, who, in all respects, shall be bound by the same terms and conditions as the Principal Investigator under this Agreement. The Principal Investigator shall be responsible for the conduct of the clinical investigation in its entirety and the well-being of the study subjects ("Study Subjects") and undertake in particular to have it executed by competent resources.

6.2 Study Site

The Study shall be conducted at the premises of Institution at the *KLES Dr. Prabhakar kore hospital and MRC*, located at *Nehru Nagar, Belagavi* : (hereinafter the "Study Site").

6.3 Use of Study Drug:

Novartis shall provide QGE031 (hereinafter called "Study Drug") in sufficient quantity to conduct the Study. For purposes of this Agreement only, the Study Drug shall be supplied to Institution free of charge. In all events, the Study Drug shall remain the sole property of Novartis.

The Principal Investigator shall

- (a) at his/her risks, costs and expenses ensure the safe receipt, handling, storage, use and administration of the Study Drug and take all reasonable measures to ensure that it is kept secure;
- (b) not permit Study Drug to be used for any purpose other than the conduct of the Study in compliance with the Protocol;
- (c) shall not make the Study drug available to any third party other than as specified in the Protocol without Novartis' prior written consent;
- (d) shall fully comply with all the responsibilities set out under the law;
- (e) keep full and accurate records of who dispenses the Study Drug, the quantity dispensed, and the quantity returned which shall be available for review and /or collection by Novartis and/or designated monitor ("Novartis Monitor") at any scheduled monitoring visit; and
- (f) upon any earlier expiration or termination of this Agreement, at Novartis's expense, return any remaining quantities of the Study Drugs to Novartis.

6.4 Study Subject consent and entry into Study: Before entering a Study Subject into the Study, the Principal Investigator shall:

- (a) Exercise independent medical judgement as to the compatibility of each prospective Study Subject with the requirements of the Protocol;
- (b) advise Novartis of all instances in which, in the Principal Investigator's judgement, there is any question as to any prospective Study Subject's suitability for participation in the Study, and abide by Novartis's decision as to whether or not to enroll that Study Subject;
- (c) ensure that, before their participation in the Study, the Study Subject, and/or as the case may be, her/his legal representative, are duly informed in language understandable to them, about all aspects of the Study that are relevant to them, including (i) the purpose, duration, nature, significance, implications, potential benefits and/or risks of the Study; and (ii) the processing, auditing, and monitoring of data (including personal data) under this Agreement;

ATTESTED
Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- (d) ensure that, before his/her participation in the Study, each Study Subject and/or as the case may be her/his legal representative has given his or her Informed Consent on the basis of the information described in Clause 6.4. (c) by signing a consent form ("Informed Consent Form" or "ICF") in accordance with the Protocol and without the undue influence or coercion of any person directly involved in the Study, and in accordance with Applicable Laws. An example ICF is attached hereto as Annex 3;
- (e) ensure that a copy of the signed Informed Consent Form be provided to the Study Subject, and/or as the case may be, his/her legal representative;
- (f) acknowledge that the use of the Informed Consent Form does not release the Principal Investigator from his or her legal, regulatory and contractual obligations relating to Informed Consent, and that it remains the Principal Investigator's responsibility to ensure that those obligations are complied with;
- (g) comply with the procedures described in the Protocol in relation to that Study Subject; and,
- (h) provide details of the proposed Study Subject to Novartis.

6.5 Study Subject Recruitment

Principal Investigator has estimated that he/she can recruit the number of Study Subjects as specified in Annex 1. This target of recruitment can be increased only upon written agreement of Novartis. The Principal Investigator undertakes to comply with these limitations and conditions for further recruitment at the Study Site as required by Novartis.

Novartis will review the Study Subjects recruitment on an on-going basis to ensure that the enrollment continues at an acceptable rate. Novartis is empowered to discontinue the Study at Institution medical facilities in case of no or poor enrollment.

In a multicentre study, Novartis reserves the right, at its sole discretion, to require Institution and Principal Investigator to cease enrollment of Study Subjects prior to enrollment of the targeted number of Study Subjects. Institution and Principal Investigator undertake to cease such enrollment upon request of Novartis and further undertake not to seek any compensation therefor.

6.6 Recordkeeping, Reporting, Access and Inspections

(a) Recordkeeping, Reporting

The Institution and the Principal Investigator shall perform the following recordkeeping and reporting obligations in a timely fashion:

- (i) Preparation and maintenance of complete, accurately written and electronic records, including accounts, notes, reports, Case Reports Forms, records of Study Subject identifications, medical notes, clinical observations, laboratory tests, and the receipt and disposition of the Study Drug and all supportive documentation and data for each Study Subject of this Study (hereinafter "Records").
- (ii) Maintain a copy of all documents related to this Study for the longer of a) fifteen (15) years after the Study is completed or discontinued by Novartis) as required by applicable laws and regulations.
- (iii) Meet with a representative of Novartis to discuss the progress of the Study; and Notify Novartis immediately upon discovering any significant violations of the Protocol.
- (iv) In accordance with the procedure set out in the Protocol : Complete a Case Report Form for each Study Subject; review and sign each of the Case Report Forms to ensure and confirm their accuracy and completeness; promptly submit the Case Report Forms to Novartis following their completion,
- (v) Cooperate with Novartis in all their efforts to monitor the study and to support Novartis in all matters of data collection, verification and discrepancy resolution

ATTESTED

Dr. V.A.Kothiware
Registrar

... of compliance with Data Privacy and Protection protocols set out in this Agreement. In the event of the insolvency or bankruptcy of Institution, Institution agrees to promptly transfer all copies of such records to Novartis in accordance with Novartis' written instructions and in line with the transfer and disclosure terms set out in the ICF signed by concerned trial participants, at Novartis' expense.

- (vii) Ensure the hospital records of Study Subjects are kept safely in a known and accessible location during the period defined here-above.
- (viii) Make all Records available to Novartis or its nominee promptly upon request for monitoring and/or auditing purposes;
- (ix) Be responsible for making any necessary applications for registration under the data protection legislation in connection with data obtained under this Agreement, as provided in Article 27.

(b) **Access and Inspection**

It is agreed that the authorized representatives of Novartis, and regulatory authorities to the extent required by law, shall be entitled to:

- (i) Examine and inspect the Institution's facilities required for performance of the Study; and
- (ii) Inspect and copy all data and work products relating to the Study (including, without limitation, access to records as necessary for study monitoring or to audit the conduct of the Study in accordance with Novartis standards). Sponsor will maintain the confidentiality of any subject-identifiable medical records.
- (iii) If any governmental or regulatory authorities notifies Institution or the Principal Investigator that it will inspect Institution's records, facilities, equipment, or procedures, or otherwise take action related to the Study, Institution shall promptly notify Novartis or any designated person within 24 hours, allow Novartis to be present at the inspection/action or participate in any response to the inspection/action, and provide Novartis with copies of any reports or information issued by the authority and Institution's proposed and final response.
- (iv) Grant access to Novartis or its representative to visit periodically, as frequently as required for the proper performance and oversight of the Study, the Study Site in order to proceed with any and all monitoring activities required for the Study.
- (v) The Institution and the Principal Investigator will use their best efforts to facilitate the performance of any audit and inspection and shall give Novartis and any person designated by them access to all necessary facilities, data and documents.
- (vi) The Institution and the Principal Investigator shall take appropriate measures required by Novartis to correct without delay all observations found during the audits or inspections.
- (vii) It is expressly agreed between the Parties that Novartis will not compensate the Institution or the Principal Investigator for the audits and inspection.

The rights and obligations under this Article shall remain in effect for fifteen (15) years after the end of the Study.

6.7 **Reporting:** The Principal Investigator shall, either by himself/herself or his/her duly authorized representative, on reasonable notice

- (a) Meet with a representative of Novartis to discuss the progress of the Study; and

ATTESTED




Dr. V.A. Kothiwale
Registrar

- (b) Make the hospital notes and Case Report Forms for each Study Subject available for source data verification or auditing purposes by representatives of Novartis representatives and the officers of any competent authority.
- (c) On discovering any significant violations of the Protocol, the Principal Investigator shall notify Novartis immediately.

6.8 Reporting of Safety Information:

The Principal Investigator shall notify Novartis of each Serious Adverse Event encountered in the Clinical Trial within twenty-four (24) hours of becoming aware of it in accordance with the instructions set forth in the Protocol as well as local regulatory requirements. Each such notice shall be given by telefax or e-mail on a Novartis Serious Adverse Event Report form, whether or not notification was initially given by telephone. Section 6.6 shall apply to both the original copy of each Serious Adverse Event Report form and the telefax confirmation sheet or e-mail reflecting its transmission to Novartis.

The Principal Investigator shall also ensure that any person involved in the conduct of the study shall:

- (a) Immediately report to Novartis according to the procedure set out in the Protocol, any new safety findings on the Study Drug, including Serious Adverse Event or Serious Adverse Reaction affecting or which could have an impact on the safety of the Study Subject or which could result in a re-assessment of the risk-benefit ratio of the Study Drug. The Principal Investigator shall follow up such immediate reports and provide the additional information in a detailed, written manner to Novartis in accordance with the Protocol and local regulatory requirements;
- (b) Report to Novartis all Adverse Events (refer definition of adverse event as per ICH E6 guidelines for Good Clinical Practice and/or as mentioned in the protocol) in accordance with the study Protocol, applicable study procedures for safety data reporting;
- (c) Cooperate with and supply any further information required by Novartis and/or any relevant ethics committee or Regulatory Authority with jurisdiction over the Study.-

These reporting obligations shall survive expiration or earlier termination of the Agreement.

Novartis shall further report the adverse events to the competent Regulatory Authorities, in accordance with the current Applicable Laws. Novartis will furthermore provide the Principal Investigator with safety-related information from other investigational sites in order to inform the ethics committees IRB/IEC, as required.

After completion of the Study and evaluation of the results, Novartis will inform the Principal Investigator about relevant safety-related findings in accordance with the guidelines and Study procedures.

6.9 Items supplied by Novartis

Novartis shall provide directly or indirectly the Principal Investigator and/or the Institution with all necessary information, documents and materials, including but not limited to:

- (a) the Investigator Brochure (IB)
- (b) the Protocol,
- (c) the CRF/e-CRF
- (d) the Study Drug
- (e) the study related equipments on returnable basis listed in **ATTACHED**

6.10 The Principal Investigator, or coordinating investigator for multicentre studies, shall sign the clinical Study reports, which form part of the marketing authorization submission.

7. LIABILITY-INDEMNIFICATION

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

In the case of any injury occurring to a clinical trial subject or in the event of clinical trial related death of the subject, Novartis assumes responsibility to the extent and in the manner under the applicable laws

The Institution and Principal Investigator ("Indemnifying Party") will indemnify and hold harmless Novartis from and against any and all liabilities, claims, damages, losses, settlements, penalties, fines, costs and expenses, including attorneys' fees, (collectively, "Damages") of whatever kind or nature (but not including taxes) arising from any third party demand, investigation, claim, action or suit in the based on (i) the gross negligence, bad faith or willful or intentional misconduct of the Indemnifying Party (ii) a material breach by the Indemnifying Party of any term of this Agreement, or (iii) a violation of any relevant law, rule or regulation by the Indemnifying Party in the performance of its duties under this Agreement.

INSURANCE

The Institution warrants that it has appropriate and adequate professional indemnity insurance to cover claims or damages including those arising out of negligence of the Principal Investigator for which it shall be liable under this Agreement. The Institution shall provide evidence of its insurance upon request by Novartis.

Novartis warrants that it has insurance for the Study Subjects included in the Study in place a Study start.

9. COMPENSATION

- 9.1 In consideration for the satisfactory performance of the Study according to this Agreement and the Protocol, The Principal Investigator agrees to Payment Schedule attached hereto as Annex 1
- 9.2 Novartis reserves the right to terminate the Agreement immediately if no subjects have been recruited at the Study Site by 16 Feb 2020.
- 9.3 Subjects not completing the Study will be paid for on a prorated basis according to the number of completed visits. All payment will be made for subject visits according to the above Payment Schedule attached as Annex 1. No payment will be made for any Study Subject excluded from analysis because of Protocol violations that were within the Institution or Principal Investigator control. Reimbursement for expenses related to screening failures, patient travel, and local lab test will be made according to the Payment Schedule in Annex 1.
- 9.4 The Principal Investigator shall send the invoices to:
- Novartis Healthcare Private Limited
GDO Trial Monitoring, India
Novartis Healthcare Private Limited
Inspire BKC, 'G' Block,
6 & 7 Floor, BKC Main Road,
Bandra Kurla Complex,
Bandra (E) Mumbai 400051, India
- 9.5 Each invoice shall specify the Study Code. Novartis shall make payments into the account indicated by the Institution and Principal Investigator within 60 (sixty) days of receipt of invoice from the Institution.

10. EQUIPMENT

- 10.1 If necessary and based upon Novartis' assessment of Institution existing equipment, Novartis may provide equipment (the "Equipment") to the Institution and/or Investigator strictly on a returnable basis as detailed in Annex 1. The Equipment shall remain the sole and exclusive property of Novartis. It shall be used exclusively by the Institution and/or the Investigator. The Equipment shall only be used for the conduct of the Study in accordance with the Protocol and Novartis' instructions and until the Study is completed or discontinued.

Dr. V.A. Kothiwale

Registrar

purpose of this Study, the Institution and Investigator agree that the Equipment shall remain in the same condition during the Study, with the exception of ordinary depreciation.

- 10.3 During the term of the Study, Institution and/or Investigator shall be responsible for immediately notifying Novartis of any malfunctioning Equipment.
- 10.4 Following completion of the Study or upon discontinuation of the Study for any reason, the Institution and/or Investigator, as the case may be, shall return the Equipment to Novartis or alternatively, in the event the Equipment remains with the Institution and/or Investigator, the cost of such Equipment will be deducted from the last payment(s) to be made to either the Institution or Investigator, as the case may be.

11. TERMINATION

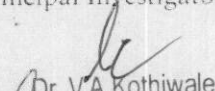
- 11.1 Either party may terminate this Agreement for any safety and/or efficacy concerns or other ethical grounds by giving written notice to the other party with immediate effect. In case of early termination the *KLES Dr. Prabbakar kore hospital and MRC/Dr. Shivkumar Patel* shall notify the relevant Ethics Committee of the early termination, and Novartis shall notify the regulatory authorities and any other competent authorities as relevant and appropriate within specified timelines
- 11.2 Novartis may terminate this Agreement for convenience by giving written notice to the Institution with immediate effect.
- 11.3 If Novartis terminates this Agreement, Novartis shall have no obligations under this Agreement except to reimburse the Institution for such reasonable costs and non-cancellable obligations which has been approved by Novartis incurred in the performance of the Study prior to receiving notice of termination.
- 11.4 The termination or expiry of this Agreement shall not affect the rights and obligations of the parties which accrue prior to the date of termination. In particular, the Institution/Principal Investigator shall provide all outstanding Case Report Forms to Novartis and return to Novartis all documents and Equipment provided by Novartis under this Agreement.

12. INTELLECTUAL PROPERTY

- 12.1 All data, information and documents provided to the Institution by or on behalf of Novartis, whether in paper, oral, electronic or other form, shall remain the sole property of Novartis.
- 12.2 All data, information, documents, inventions and discoveries, resulting from or developed in the performance of the Study or this Agreement shall be the sole property of Novartis and may be used and/or transferred by Novartis in its sole discretion with no further payment or other obligation to the Institution. The Institution shall have no rights whatsoever therein.
- 12.3 The Institution agrees to, and to cause its employees and collaborators and the Principal Investigator to, execute promptly all documents and take all such other action as may reasonably be requested by Novartis to enable Novartis to obtain the benefit of its rights under this Agreement. This includes without limitation taking all necessary steps for the transfer of ownership of all data, information, documents, inventions and discoveries to Novartis in accordance with this Agreement, and assisting Novartis in the preparation and prosecution of patent applications. Furthermore, Institution and Investigator shall execute, or procure the execution of, and enforce all documents and deeds and do, or procure the doing of, all things as Novartis including but not limited to assignment of any and all rights, title and interest in resulting intellectual property in Novartis.
- 12.4 The Institution shall ensure that the Principal Investigator and the Institution's employees and collaborators involved in the Study will comply with its obligations under this Agreement.

13. TAXES AND SOCIAL SECURITY CONTRIBUTIONS

It shall be the Institution's responsibility to comply with all obligations in respect of taxes and social security contributions, if applicable, which relate to the subject matter of this Agreement, including without limitation those which relate to the Principal Investigator, the Institution and its employees and/or collaborators.

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

PUBLICATION

- 14.1 Novartis recognizes the Institution's interest in making publications and presentations relating to the Study in journals, at meetings or otherwise, and may therefore permit such publications and presentations, provided however that the Institution shall provide to Novartis any proposed presentation at least 15 (fifteen) working days prior to being disclosed and any other proposed publication at least 45 (forty-five) working days prior to being disclosed, and provided that Novartis shall have the right to require amendments to any such proposed presentation or publication on reasonable grounds including without limitation:
- (a) to ensure the accuracy of the presentation or publication;
 - (b) to ensure that proprietary information is not inadvertently divulged;
 - (c) to enable intellectual property rights to be secured;
 - (d) to enable relevant supplementary information to be provided.
- 14.2 Authorship of any publications relating to the Study shall be determined by mutual agreement.
- 14.3 Novartis may require any proposed publication or presentation to be delayed for up to 4 (four) months to enable a patent application to be prepared and filed. The 4 (four) month period shall commence on the date of receipt of the proposed publication or presentation, or from the date when all relevant data from the Study are made available to Novartis, whichever is later.
- 14.4 If the Study is a multi-centre study, the first publication of data shall be based on consolidated data from all centres analysed according to the Protocol, unless otherwise agreed in writing by all the Principal Investigators involved in the Study and Novartis.
- 14.5 Except as otherwise required by law or regulation, neither Party shall release or distribute any materials or information containing the name of the other Party or any of its officers, agents or employees without the prior written consent by an authorised representative of the non-releasing Party.

15. CONFIDENTIALITY

- 15.1 All information and data, trade secrets, privileged records and other confidential or proprietary information (including but not limited to the Protocol, CRFs and information on password-protected Novartis websites) disclosed to or collected or developed by the Institution, the Principal Investigator and/or the Institution's employees and/or collaborators in connection with this Agreement or the Study (collectively "Information") shall be treated as confidential. The Institution and/or the Principal Investigator agree not to disclose to any third parties or to use any Information for any purpose other than the performance of the Study. The Institution and/or the Principal Investigator shall ensure that the Institution's employees and collaborators are bound by confidentiality obligations not less strict than those set out herein prior to receiving any Information.
- 15.2 Upon termination or expiry of this Agreement, the Institution and / or Principal Investigator shall safely destroy (as set in the Data Privacy and Protection annexure to this Agreement) or return to Novartis, as per Novartis' request, all documents, samples and material containing or relating to Information, except for one copy of Information which is to be retained in the confidential files of the Institution for record purposes only. If requested by Novartis, such safe destruction shall be promptly confirmed in writing by the Institution to Novartis.
- 15.3 The confidentiality obligations set out above shall not apply to:
- (a) Information which is, at the time of disclosure, in the public domain or thereafter becomes part of the public domain otherwise than by the act or omission of the Institution, the Principal Investigator, or the Institution's employees and/or collaborators;
 - (b) Information that the Institution can demonstrate by written evidence was in its possession prior to its disclosure by Novartis or that said information; its collection or creation did not occur during or in connection with the Study;

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

NOTICES

Any notice given in connection with this Agreement shall, unless otherwise provided herein, be in writing and shall be delivered personally, or sent by registered mail or facsimile to the address given in this Agreement.

Mr. K. Muruganathan

GDO Trial Monitoring,

Novartis Healthcare Private Limited

Inspire BKC, 'G' Block,

6 & 7 Floor, BKC Main Road, Bandra Kurla Complex,

Bandra (E) Mumbai 400051, India

Email: muruganathan.k@novartis.com

or to such other address as may have notified to the other party in writing.

7. ASSIGNMENT

Neither Party may assign its rights and obligations under this Agreement without the other Party's prior written consent, except that Novartis may (a) assign its rights and obligations under this Agreement or any part hereof to one or more of its Affiliates; or (b) assign this Agreement in its entirety to a successor to all or substantially all of its business or assets to which this Agreement relates. Any permitted assignee will assume all obligations of its assignor under this Agreement (or related to the assigned portion in case of a partial assignment). Any attempted assignment in contravention of the foregoing will be void. Subject to the terms of this Agreement, this Agreement will be binding upon and inure to the benefit of the Parties and their respective successors and their permitted assigns.

18. SUBCONTRACTING

The Institution and/or Principal Investigator shall not retain any subcontractor to perform any of its obligations under this Agreement without the prior written consent of Novartis. Any such consent shall not relieve the Institution and/or Principal Investigator of its obligations hereunder.

19. SEVERABILITY

The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision hereof.

20. WAIVER

No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or of any other term, provision or condition of this Agreement.

21. ENTIRE AGREEMENT

This Agreement (including the Protocol) represents the entire understanding between the parties with respect to the subject matter hereof. No amendment to this Agreement will be effective or binding unless it is in writing signed by both parties and refers to this Agreement.

22. DEBARMENT

Neither the Principal Investigator nor the Institution, nor any person employed thereby nor a collaborator who is involved in the performance of the Study has been debarred under the provisions including but not limited to provisions of the Indian Medical Council Act, 1956 as amended, Drugs and Cosmetics Act, 1940 and no debarred person will in the future be employed or engaged by the Institution in connection with any work to be performed for or on behalf of Novartis. If at any time after the execution of this Agreement, the Institution is notified by the Registrar that

Dr. V.A.Kothiwale

Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

CONFLICT OF INTEREST, FINANCIAL DISCLOSURE

The Institution and the Principal Investigator confirm that there is no conflict of interests between the Parties that would inhibit or affect their performance of the work specified in this Agreement. The Institution and the Principal Investigator further certify that they will promptly inform Novartis in the event any conflict of interests arises during the performance of this Agreement and certify that their performance hereunder does not violate any other agreement they may have with any other third party.

TRANSPARENCY/DISCLOSURE

- 4.1 In all materials relating to Services intended for an external audience, Principal Investigator shall disclose:
- (a) that Novartis has retained Principal Investigator for professional services in relation to the conduct of the Study; and
 - (b) any other relationships that Novartis has with Principal Investigator which a reasonable and ethical person would expect to be disclosed.
- 4.2 Both parties agree to make all other disclosures and/or notifications as may be required in connection with entering into, performing, or receiving compensation under this Agreement, and Principal Investigator shall follow all Applicable Laws in this respect, including those relating to Principal Investigator's professional relationships with decision-making authorities or bodies (if any), such as, for instance, recusal from any votes, discussions or recommendations regarding investigational or marketed products of Novartis, regardless of whether such are subject to the Services.
- 4.3 The Institution and Principal Investigator understand and agree that Novartis may be required to disclose certain information to governmental agencies in different jurisdictions in order to comply with local laws regulating clinical trials. The Institution and Principal Investigator consent to the disclosure of certain information that otherwise may constitute personal data in order to comply with laws regulating clinical trials, including but not limited to the Institution's and/or Principal Investigator's name, clinical trial Study Site contact information, name of the clinical trial, sponsor, copy of the Agreement, and costs and fees relating to Study Site's activities performed under the Agreement. Novartis will provide upon written request a list of any such disclosure made regarding the Institution and/or the Principal Investigator.

25. JURISDICTION AND APPLICABLE LAW

This Agreement shall be governed by and construed in accordance with the laws of India. The parties hereby submit to the exclusive jurisdiction of the competent courts of Mumbai, India without restricting any right of appeal.

26. DATA PROTECTION


A form regarding the disclosure of the Principal Investigator's personal data together with the general provisions regarding any personal information processed by the Institution under this Agreement is attached as Annex 2.

27. COUNTERPARTS

This Agreement may be executed in two or more counterparts each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

28. PRECEDENCE


To the extent that there may be any inconsistency between this Agreement and the Protocol, the Protocol shall take precedence in ONLY in relation with trial procedures while in all other instances the agreement shall prevail.

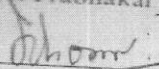
ATTESTED

Dr. V.A. Kothiwale
Registrar

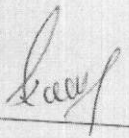
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

...with KLE, the Parties intending to be bound have caused this Agreement to be
...their duly authorized representatives.


SOVARTIS HEALTHCARE PRIVATE KLES Dr. Prabhakar kore hospital and MRC

By: 
Name: Soulin Singh
Title: Head CTO
Date: 19th July 2019

By: 
Name: Dr. M V Jali
Title: MD & CE KLES Dr. Prabhakar Kor Hospital and MRC
Date: 26/07/2019

Dr. Shivakumar Patil 
By: _____
Name: Dr. Shivakumar Patil
Title: Associate Professor/Consultant Dermatologist
Date: 25/07/2019

ATTESTED


Dr. V.A. Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

FINANCE PAYMENT SCHEDULE

PROJECT NUMBER: CUGES/12/202

PROJECT NAME: PEARL-1

Principal Investigator's Name: Dr. Shivakumar Patil

Institute Name: KLES Dr. Prabhakar Kore Hospital and MRC

Site Name: Dr. Shivakumar Kalagouda Patil

ICMR Card Number: BJPP7382P

STN: NA

Estimated Number of Study Subjects: 5 randomized patients

List of Equipment provided to Institution / Principal Investigator:

- Thermo-hygrometer
- ERT Log Pads - It would be retrieved from site post database lock is achieved.
- ERT Machine - It would be retrieved from site post database lock is achieved

Payment Schedule:

	Screening		Double blind treatment											
Sl. No.	1	20	110	120	130	140	150	160	170	180	190	200	210	220
Week	-4	-1	R	4	8	12	16	20	24	28	32	36	40	44
Total Patients	16800	2800	6000	5000	5000	5000	3500	3500	5000	3500	3500	3500	3500	3500
Investigator	4000	3000	5000	3000	3000	3000	3000	3000	3000	3000	3000	3000	3000	3000
Site/Staff	2000	2000	3000	2000	2000	2000	2000	2000	2000	2000	2000	2000	2000	2000
Medical Assistant			1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500
Normal Staff	5700	1950	3750	2750	2750	2750	2375	2375	2750	2375	2375	2375	2375	2375
	28500	9750	19250	14250	14250	14250	12375	12375	14250	12375	12375	12375	12375	12375

ATTESTED



**Dr. V.A. Kothiwale
Registrar**

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

post treatment follow up				
Visit	240/EoT/TD	310	320	1999/EOS? PSD
Week	52	56	60	64
Protocol Procedures	6200	5000	5000	5700
Investigator Fees	4000	3000	3000	4000
Coordinator Fees	2000	2000	2000	2000
Unblinded Pharmacist fee	1500	1500	1500	1500
Institutional Overhead @ 25%	3300	2750	2750	3175
TOTAL (INR)	17000	14250	14250	16375
TOTAL COST 1 PT				275375

Payment Terms:

- The amount of payment due to the Institution/Investigator will be calculated in respect of each patient visit according to the attached budget schedule.
- For patients who are not randomized into the study based on Screening results (Screen Failures) Institution/Investigator will receive remuneration in the amount of a screening visit cost
- Any other third parties designated by the Institution/Investigator that would receive remuneration, will be managed by & paid by the Institution/Investigator.
- The work performed by the hospital laboratory in addition to budget schedule shall be paid based on actuals. It is the Investigators responsibility to liaise with the hospital laboratory.
- Sponsor shall reimburse patient's travel cost per protocol visit will be upto 1000 INR for which institution/PI shall provide original invoice along with the supporting bills.
- The Ethics committee charge will also be paid via Novartis, and this cost is not included in the budget schedule.
- Unscheduled visits covers subject visits that are not expressly set forth in the Study Schematic of the Protocol, but are otherwise required for the study. Medically necessary procedure, test performed during unscheduled visits would be paid as per actual bills. Payment for unscheduled visits will be payable to the institution within 60 days of receipt of original, itemized invoice by Novartis.
- All payments are based on actual patient visits.
- All values are in INR. All budget schedule payments are subject to TDS (subject to Government of India Tax regulations) and GST as applicable. GST will be paid on providing valid tax invoice

ATTESTED

[Signature]
Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

ANNEX 2: PRINCIPAL INVESTIGATOR – PERSONAL DATA DISCLOSURE FORM

Novartis wants to ask your permission to include certain elements of your personal data in a database maintained by a third party. The Grant Plan database, which is maintained and provided to pharmaceutical research sponsors by a company called TTC in the United States, is intended to assist research sponsors with transparency relating to clinical trial expenses. The database is used to support country specific forecasts for clinical trial costs and to provide benchmarking information in order to achieve transparency and fairness in setting costs for performing clinical trials.

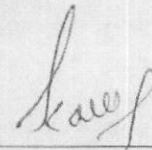
The information is entered into the database in such a way that it is not possible for anybody except the personnel of TTC to view your name or link your site to a particular clinical trial or sponsor company.

In that regard, Novartis is asking for your permission to submit your name, clinical trial site contact information, name of the clinical trial, sponsor, copy of the clinical trial agreement, and costs and fees relating to your site's retention, to a third party administrator of this database. This information will be maintained in that database for five years. If you are conducting research for Novartis in countries other than the United States, such as those in Europe, you should note that the United States does not offer the same standards of privacy protection as those offered in Europe. You are not required to give consent to this disclosure in order to proceed with this clinical study. However, by doing so, you are helping to collect information on fair costs in clinical trials.

- Yes, I hereby agree that Novartis may disclose my personal data in connection with the Grant Plan database.
- No, I do not give my permission to disclose my personal data in connection with the Grant Plan database.


Place and Date:

Belagavi/25/07/2019



Name: Dr. Shivakumar Patil
Principal Investigator

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Data Privacy and Protection

Provisions regarding any Personal Information Processed by Institution under this Agreement:

Defined Terms. For the purposes of this Section, the following terms shall have the meanings given below:

“Personal Information or Data” means any information that relates to an identified or identifiable person including without limitation electronic data and paper based files that include such information such as: (a) name or initials; (b) home or other physical address; (c) work, cell or home telephone number; (d) work or home email address or online identifier associated with the individual; (e) identification code; (f) credit card number; and (g) employment information, that is Processed directly or indirectly, by Institution on behalf of Novartis in connection with this Agreement.

“Sensitive Personal Information or Data” – constitutes a subset of Personal Information and relates to of an individual's (a) physical, physiological or mental characteristics, (b) economic status, (c) racial or ethnic origin, (d) political, ideological, religious opinions or philosophical beliefs, (e) trade union membership, (f) health or medical information including information related to payment for health services, (g) sex life or sexual preference, (h) genetic material or information, (i) human biological samples or cells, (j) unique biometric data, (k) Personality Profiles or (ii) an individual's name in combination with the individual's (a) Social Security number, (b) alien registration number, (c) driver's license number, (d) passport number, visa number or other government identifier, (e) credit card, debit card, or other financial account numbers, with or without any associated code or password that would permit access to such account, or (f) mother's maiden name; and as applicable under local laws.

“Data Subject” – and identified or identifiable person who's Agreement Personal Data are processed, accessed, received, transmitted, or maintained by the Supplier. An identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity.

“Processing” means any operation or set of operations which is performed upon personal information, whether or not by automatic means, such as collection, recording, organisation, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction or any other operation or set of operations otherwise defined in applicable Data Privacy Laws. This also includes the processing of personal information in structured manual files.

“Institution Third Parties” – any third party that assists Institution in performing its obligations under the Agreement, including an affiliate or direct or indirect subcontractor of Supplier.

General Obligations of Institution:

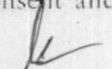
a. Compliance with Applicable Laws and Permitting Processing. Institution will, and will cause all Institution Third Parties to, hold Personal Information in confidence, use Process such data only for the benefit of Novartis and its Affiliates and Process such information in compliance with (i) all Applicable Data Protection Laws, (ii) the Agreement, (iii) any consent, authorization of a Data Subject or other authorized participant, such as subject's legal representative, (iv) industry standards, and (v) this Data Privacy and Protection Exhibit; provided, however, that Institution (or Institution's Third Party) may Process Personal Information only under the written instructions of an authorized signatory of Novartis.

To the extent that the Agreement involves the processing of personal information owned by or licensed to Institution prior to or separately from the Services, Institution represents and warrants that such data has been obtained in compliance with applicable laws and regulations, including Applicable Data Protection Laws and all necessary consents and authorizations, including those of any patient, if applicable. Institution further represents and warrants that Institution and/or Novartis is authorized to use such data as contemplated by this Agreement.

b. Obligations with respect to the Data Subjects participating in trials:

Institution shall take reasonable steps to ensure that each individual whose Personal Information were, or are, in its possession is able to assert his or her rights under local law, including but not limited to right of access to view and correct his or her Personal Data, right to withdraw consent and file complaint or grievance if any, with the Institution.

c. Obligations with Respect to Institution's Third Parties.

ATTESTED

Dr. V.A. Kothiwale
Registrar


KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

are located. In all such arrangements, Supplier will enter into agreements with Supplier Third Parties that are substantially similar to this Data Privacy Exhibit. Supplier shall provide copies of such agreements to Novartis within seven (7) business days following a written request from Novartis therefor.

Data Safeguards. The parties agree to comply with the following:

- (a) Without limitation of any provision of this Agreement, the parties agree to comply with applicable Laws governing the privacy and security of Personal Information that Institution shall create, acquire, access or receive as a result of this Agreement, to the extent that such Laws apply to either party.
- (b) Institution agrees to implement administrative, technical and physical security measures to protect Personal Information, from (i) unauthorised or accidental destruction, (ii) theft, forgery or loss, (iii) technical faults, (iv) forgery, theft or unlawful use (v) unauthorised alteration, copying access; or (vi) any other unauthorised processing.
- (c) Security measures implemented by Institution must take into account (i) the purpose of the data processing, (ii) nature and extent of the processing, (iii) assessment of possible risks to the data subject; and (iv) current industry best practices and state of the art technology, including but not limited to encryption of information at rest and in transit. Security measures shall be reviewed on a periodic basis and updated as required.
- (d) All email communication with Novartis, especially those involving trial related information, should happen via secure 'Institutional email Ids'. Exceptions (i.e. use of non-institutional email Ids), if any must be discussed with Novartis and a secure communication solution, mutually agreed and in line with Novartis' security standards, is implemented.
- (e) Institution shall not sub-contract any of its rights or obligations without the prior written notification to Novartis. In the event that any Institution Subcontractor shall have access to Personal Information, such access shall be permitted under a need-to-know basis and only to the extent required for the due performance of Institution's obligations. Institution shall enter into Agreements with its' subcontractors that contain privacy and security provisions that are equivalent to the provisions under this Agreement.
- (f) Institution shall ensure that personnel who will be undertaking the Processing of Novartis Personal Information, including that by Institution's Third Party (if any) have appropriate skills and privacy and security training to handle Sensitive Personal Information.
- (g) If Institution disposes of any paper, electronic or other record containing Agreement Personal Data, Supplier shall do so by taking all reasonable steps to destroy the information by (a) shredding; (b) permanently erasing and deleting; (c) degaussing; or (d) otherwise modifying the Agreement Personal Data in such records to make it unreadable, unreconstructable and indecipherable.
- (h) Institution shall maintain procedures to detect and respond to a Data Security Breach. Institution shall notify Novartis of any Data Security Breach within 24 hours of discovery of a data security breach. Institution shall promptly make available to Novartis details of the Data Security Breach and shall use commercially reasonable efforts to investigate and prevent the recurrence of such Data Security Breach. The parties shall reasonably cooperate to remediate a Data Security Breach and prevent any recurrence. Novartis, at its sole discretion, after consultation with Institution, shall determine whether and when to notify any individuals or persons (including Governmental Authorities) regarding any Data Security Breach affecting Novartis Personal Information. Institution, as determined in its sole discretion, shall comply with all applicable Laws to which it is subject with regard to the Data Security Breach.

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

ANNEX 3: NOVARTIS POLICIES & STUDY DOCUMENTS

I / We, the undersigned Institution and Principal Investigator for study number CQGE031C2302 declare that I have received a copy of;

- (a) Novartis global Antibribery Policy
- (b) Professional Practices Policy

I / We, have read the policy (ies) understood its meaning and shall comply with the same.

KLES Dr. Prabhakar Kore hospital <i>Shivam</i> and MRC	Dr. Shivakumar Patil
By: _____	By: _____ <i>Shivam</i>
Name: <u>Dr. M. V. Jali</u>	Name: <u>Dr. Shivkumar Patil</u>
Title: <u>MD & CEO</u>	Title: <u>Consultant Dermatologist / PI</u>
Date: <u>26/07/2019</u>	Date: <u>25/07/2019</u>

ATTESTED

[Signature]
Dr. V.A. Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

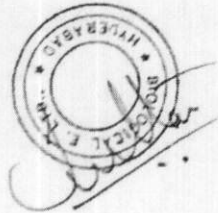


తెలంగాణ తెలంగాణ TELANGANA
S.No:4345 Date:08/07/2019 Rs.50/-
To :-MADHAVA RAO MOLABANTI
S/o :- LATE M VENKATESWARLU
FOR WHOM:-M/S.BIOLOGICAL E.LIMITED.
R/o:-HYDERABAD.

Niraj G 668219
The Advocates' Co-op Society
By: G.VIJAY KUMAR YADAV, Licensed Advocate
Lic No: 16-08-08/3017
City Local Court, Prakash, Dewa (Hid Noida)
District. Phone No. 040-24418387

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (the "Agreement") is made on 19th July, 2019 ("Effective Date") by and between **Biological E. Limited**, a company incorporated under the Companies Act, 1956 and having its registered office situated at 18/1&3, Azamabad, Hyderabad - 500020, Telangana, India ("Sponsor"), of the First Part; and **Dr. N.S. Mahantshetti**, a registered medical practitioner holding MCI registration number 22164, currently working as Professor in Department of Pediatrics, KLEs JNMC Dr Prabhakar Kore Hospital, Belgaum, Karnataka, India ("Principal Investigator") of the Second Part; and **KLEs JNMC Dr Prabhakar Kore Hospital, Belgaum, Karnataka, India** a hospital established registered under the laws of India, having its place of business at Nehru Nagar, Belgaum - 590010, Karnataka, India represented by its Medical Director ("Institution") Third Part



MH *Dr*

ATTESTED

V.A.
Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



తెలంగాణ తేలంగానా TELANGANA

S.No: 7697 DATE:08/07/2019 RS: 50/-
SOLD TO : MADHAVA RAO MOLABANTI
S/O LATE M.VENKATESWARLU
FOR WHOM :- M/S BIOLOGICAL E. LIMITED R/O HYD

B 900218
The Advocates' Co-op Society

Rep.By N Madhusudhan ,Licenced stamp Vendor,
Lic.No.16-10-10/2015, Ren.No.16-10-17/2018.
Metropolitan criminal courts, Nampally,
Telangana State Phone.No:040-23313246.

Page : 2 :

WHEREAS,

- The Sponsor is a biopharmaceutical company, which develops, manufactures and markets innovative vaccines and biologics. Biological E. Limited has developed the live attenuated Measles and Rubella vaccine developed by Biological E. and received marketing authorization by DCG(I), the present study is a phase IV Clinical Trial for obtaining additional safety data and to be conducted in twelve study centres;
- The Institution has its own premises fully equipped to conduct the Study mentioned under this Agreement;
- The Sponsor has already identified the Principal Investigator based on his experience and expertise and also furnished sufficient information regarding the Study drug and the Protocol;
- The Principal Investigator has, after careful review of the Protocol and other materials relating to the Clinical Trial conveyed his willingness to the Sponsor to conduct the proposed Study;



[Handwritten signature]

[Handwritten signature]

ATTESTED

[Handwritten signature]
Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

- E. The Sponsor shall provide technical and financial support mentioned in this Agreement to the Principal Investigator to conduct the Clinical Trial and the Principal Investigator in lieu of such support has agreed to enter into this Agreement with the Sponsor; and
- F. The Principal Investigator has obtained and shall maintain in full force and effect all permissions, sanctions and approvals from the Institution and relevant governmental and regulatory authorities to undertake and conduct the Clinical Trial;

NOW, THEREFORE, the Parties hereto, in consideration of the mutual covenants and premises contained herein, enter into this Agreement and agree as follows:

1. Definitions

- 1.1 "Study" or "Clinical Trial" shall mean study entitled:

"A multicenter single arm non-comparative Phase-IV post marketing study to Evaluate the safety and tolerability of Biological E's Live, Attenuated Measles-Rubella Vaccine (MR) in 9-12 month old Healthy Infants" and all the title amendments thereto as the Parties may from time to time agree in writing.

- 1.2 "Protocol" shall mean:

The description of the Study mentioned in the Study protocol number **BECT048/MRV-PIV/CTP-02** and all amendments thereto as the Parties may from time to time agree in writing.

- 1.3 "Study Drug" or "Investigational Drug" shall mean:

Biological E's Live, Attenuated Measles-Rubella Vaccine (MR) (Manufactured by Biological E. Ltd.).

- 1.4 "Ethics Committee" shall mean:

An independent body or an Institutional Ethics Committee, constituted and registered with the licensing authority under the provisions of Drugs and Cosmetic Act, 1945 and rules amended thereof.

2. Responsibility of the Principal Investigator and the Institution

- 2.1 The Institution agrees to provide full support to the Principal Investigator who is working in Department of Pediatrics in the Institution, to conduct the Clinical Trial in its premises and utilize reasonably the facilities available in the Institution for the Study and shall allot qualified co-investigators, Co-ordinators and other persons with prior consent of the Sponsor, for proper conduct of the Study in accordance with the terms of this Agreement and the Protocol.
- 2.2 The Principal Investigator and Institution shall be jointly and severally shall be responsible (a) to conduct and complete the Clinical Trial of the Sponsor strictly in accordance with the applicable regulatory requirements and the Protocol as approved by the Institutional Ethics Committee; (b) to comply with all applicable rules, regulations and guidelines, both national and international, including but not limited to, ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95), Good Clinical Practice Guidelines issued by CDSCO, Directorate General of Health Services,



ATTESTED

Dr. V.A. Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Govt. of India; Drugs and Cosmetics Act 1940 and Rules, gazette notifications made thereunder (as amended from time to time), ethical principles contained in the current revision of Declaration of Helsinki, Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research ("Applicable Laws & Guidelines"); (c) to fulfill all other terms and conditions stipulated herein and in the Annexures hereto, during the period of, and also after the completion of, the Clinical Trial as agreed upon by him; and (d) to provide Sponsor a copy of registration certificate issued by the licensing authority to Ethics Committee before initiation of the Clinical Trial.

- 2.3 The Principal Investigator along with any co-investigator employed/assigned in the Institution shall personally review all case report forms to assure its completeness and accuracy. A case report form is deemed complete when:
- (i) the case report form has been completed by the Principal Investigator in accordance with Study requirements;
 - (ii) it relates to a properly qualified subject who participated in and completed the Study in accordance with all Study requirements and directions from the Sponsor; and
 - (iii) it can be used in all analyses of the Study results.
- The Principal Investigator undertakes that all data shall be submitted in a timely manner to the Sponsor.
- 2.4 Principal Investigator shall at all-time exercise independent medical judgment as to the compatibility of each subject with the Study as per Protocol requirements. Principal Investigator shall notify the Sponsor, Chairman of Ethics Committee and licensing authority within twenty four (24) hours of any serious adverse events related to or unrelated to the Study Drugs and of overdoses and any other event as set forth in detail in the Protocol.
- 2.5 The Principal Investigator and Sponsor shall provide report of serious adverse events after due analysis to the Chairman of the Ethics Committee, Head of the Institution and to the licensing authority of any deviations in the Protocol or serious adverse events immediately and in any event within fourteen (14) calendar days from the date of occurrence of such deviation and/or serious adverse events, as the case may be.
- 2.6 The Principal Investigator and Sponsor shall provide report of serious adverse events after due analysis to the Chairman of Ethics Committee, licensing authority and to the Head of the Institution within fourteen (14) calendar days of occurrence of such serious adverse events.
- 2.7 In the event the Principal Investigator becomes unwilling or no longer in the employment of the Institution or unable to perform the Study, at any latter stage, the Principal Investigator/Institution shall provide notice to the Study subjects, Ethics Committee and Sponsor at least thirty (30) days before Principal Investigator intends to stop/withdraw from the Clinical Trial. The Principal Investigator and Institution shall endeavor to promptly recommend a replacement Principal Investigator, from among the consultants of the Institution. The Sponsor shall have the exclusive right to approve or reject any such replacement of Principal Investigator. The new principal investigator which is approved by the Sponsor shall be required to agree to the terms and conditions of this Agreement. In the event Sponsor does not approve such new principal investigator, the Study will be terminated immediately and no further payment shall be



[Handwritten signature]

ATTESTED

[Handwritten signature]
Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

made to Principal Investigator and the Institution. Upon such termination, Institution shall (i) ensure appropriate therapy and follow-up for enrolled Study subjects; (ii) maintain all Study related documents for such time as may be required by Sponsor and shall take measures to prevent accidental or premature destruction of these documents and (iii) undertake to complete the Study on all the enrolled subjects as per approved Protocol.

3. Conduct of Clinical Trial

- 3.1 The Sponsor shall appoint its employee to monitor the Clinical Trial and also reserves its right to nominate any other person as monitor.
- 3.2 Principal Investigator shall enroll the allotted number of subjects in a period of 60 calendar days from the date of study site initiation. It is hereby clarified that no payment shall be made to the Principal Investigator, if the Study subject is not participating in that particular visit.
- 3.3 Principal Investigator and the Institution agrees that if Principal Investigator cannot conduct and complete the Study to the satisfaction of the Sponsor within the time prescribed by the Sponsor on the agreed number of subjects as per clause 3.2 above, the Sponsor may at its sole discretion and without prejudice to its rights under this Agreement, send a notice to the Principal Investigator and the Institution to discontinue the Study. The Principal Investigator and Institution agrees to cease recruiting subjects for the Study immediately upon receiving such notice from the Sponsor to stop recruiting the subjects for the Clinical Trial.
- 3.4 Principal Investigator shall ensure that the Audio Visual recording of the informed consent form signed by or on behalf of the Study subjects have been reviewed and approved by Ethics Committee prior to initiation of the Study. Upon approval of the informed consent form by the Ethics Committee, a copy of the approval letter shall be provided to the Sponsor by the Principal Investigator, who shall further obtain audio visual informed consent form duly signed by each of the subjects/Legally acceptable representatives on behalf of the Study subjects enrolled in the Study in accordance with Applicable Laws and Guidelines. The Principal Investigator shall ensure to maintain for record an audio-visual recording of the informed consent process of individual subjects including procedure of providing information to the subjects and their understanding on such consent. However, at the request of the Sponsor, Principal Investigator shall handover a copy of such recording for regulatory compliance or any order.
- 3.5 The Study of the Sponsor is being entrusted to the Principal Investigator and Institution directly by the Sponsor as a technical assignment, based on the skill, knowledge and experience of the Principal Investigator in the specialty areas related to the Clinical Trial and Institution's experience as a qualified testing facility in the Clinical Trial. The Principal Investigator shall be personally obligated to conduct and complete the Clinical Trial in accordance with the Protocol as well as other terms and conditions specified by the Sponsor herein. All items received from the Sponsor, from time to time, (including, but not limited to, Study Drug, documents, Confidential Information, communications, instructions etc.), records and registers required to be maintained and all data generated hereunder by the Principal Investigator, shall be under the exclusive care, custody and responsibility of the Principal Investigator throughout the period of the Clinical Trial and thereafter for a period of fifteen (15) years after the Sponsor has discontinued its Study or such longer period as required by Applicable Laws &



ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Guidelines. At the end of such period mentioned above, the Institution shall obtain written approval from Sponsor before destruction of such data.

- 3.6 Principal Investigator agrees to assume all the legal obligations of the Sponsor for the Study related duties and functions under this Agreement and the Protocol.
- 3.7 Principal Investigator/Institution shall ensure that all the individuals involved in the conduct of the Study shall strictly adhere to the terms and conditions of this Agreement. Institution and Principal Investigator represents and warrants that it shall not use in any capacity, in connection with the Study, any individual who is not duly qualified or has been debarred pursuant to any Applicable Laws & Guidelines or against whom any action, suit, claim, investigation or legal or administrative proceeding is pending. Principal Investigator represents and warrants that no action, suit, claim investigation or legal or administrative proceeding is pending or threatened relating to Principal Investigator's debarment and/or debarment of the persons engaged by Principal Investigator to assist for the Study.
- 3.8 Principal Investigator represents and warrants that he has obtained and shall maintain in full force and effect all the necessary approvals, permissions and sanctions from the Institution, Ethics Committee and all the government and regulatory authorities to conduct the Clinical Trial.

4. **Study Drug**

- 4.1 The Sponsor will provide the Study Drug to the Principal Investigator/ Institution free of cost/charge and in such quantities sufficient to complete the Study, together with guidelines and descriptions for the safe and proper use, administration, storage and disposal of the Study Drug. Principal Investigator shall use Study Drug and other items provided by the Sponsor only to conduct the Study in accordance with the Protocol and Applicable Laws & Guidelines and instructions of the Sponsor and shall not chemically, physically or otherwise modify the Study Drug, unless specifically required to do so by the Sponsor in writing to the Principal Investigator. Principal Investigator and Institution jointly and severally agrees that they shall administer, handle, use, store, and or dispose the Study Drug and other items provided by the Sponsor in compliance with Sponsor's instructions and all Applicable Laws & Guidelines.
- 4.2 The Parties hereby clearly understand that the subject matter of the Agreement is to clinically evaluate the safety and tolerability of the Study Drug and that the Clinical Trial shall not constitute complete treatment to cure any disease.

5. **Visit and Inspection**

- 5.1 The Sponsor or its authorized representatives, and regulatory authorities to the extent permitted by law, shall have the absolute right to:
- i. examine and inspect the Institution's facilities whenever Principal Investigator is conducting Study;
 - ii. inspect and copy all data and work products relating to the Study, and
 - iii. audit all reports and data from Principal Investigator to ensure compliance with the terms of this Agreement and Protocol.

6. **Payment**



[Handwritten signature]

[Handwritten signature]

ATTESTED

[Handwritten signature]
Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

- 6.1 Institution hereby undertakes that in consideration of Principal Investigator's carrying out Clinical Trial at the Institution in accordance with the terms of this Agreement, Sponsor shall make the payment to the Principal Investigator as per the payment schedule as set forth in Exhibit A. All the payments shall be made directly to the Principal Investigator/designee.
- 6.2 The Parties agree that the payment of the amount set forth in Exhibit A will be paid by the Sponsor to the Principal Investigator to compensate all the expenses incurred by him in execution and conducting the Clinical Trial at the Institution so that, neither the Study subject, nor the insurance program nor the public assistance agency shall be liable for the same. The payment of the amount set forth in Exhibit A is also meant to compensate Principal Investigator for the professional and clerical allowances, laboratory examinations for all the activities as per the Protocol including but not limited to, preparation of the subject records, medication accountability records and other trial related documentation.
- 6.3 Institution and Principal Investigator shall not be entitled to any other expenses, benefits, consideration or fee of co-investigator, whether monetary or otherwise under this Agreement or elsewhere and it covers all out of pocket expenses incurred by Principal Investigator in conducting Study at the Institution including but not limited to telephone, telex, travel and office expenses.
- 6.4 Sponsor shall be entitled to deduct tax at source (if applicable) while making payment to Principal Investigator on behalf of the Institution under this Agreement.
- 6.5 In case of very slow/no recruitment, after providing stipulated time of recruitment, at any participating site the competitive recruitment strategy of study subjects would be planned to achieve the overall study timeline based upon the decision taken by the Biological. E (Sponsor). The additional supplement payment towards the additional subject's recruitment will be made by Biological E to the payee as per the same budget calculation and payment schedule.

7. Indemnification and Insurance

- 7.1 The Sponsor agrees that it shall indemnify, defend and hold harmless the Principal Investigator from and against all suits, claims, losses or damages, arising as a result of (i) either breach of any representation/warranty made by the Sponsor herein and or (ii) of personal injury to (including death of) Study subject, which injury is sustained due to serious adverse events of the Study Drug except to the extent such claims are attributable to:
- a) the failure of the Principal Investigator, any co-investigator or any other personnel involved in the performance of the Study to adhere to the terms of the Study Protocol or any written instruction relative to the administration, use, handling, storage of any drugs used in the performance of the Study, or comply with any Applicable Laws & Guidelines; or
- b) Any negligent or wrongful act or omission, or willful malfeasance/ misconduct of the Principal Investigator/ co-investigator/any other personnel (including employees, agents or independent contractors) involved in the performance of the Study.



A handwritten signature in black ink.

A handwritten signature in black ink.

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

7.2 It is a condition precedent to the Sponsor's indemnification obligations under above mentioned clause 7.1 that:

- a) whenever Principal Investigator has information from which it may reasonably conclude an incident of bodily injury or death has occurred, Principal Investigator shall immediately give notice to Sponsor of all pertinent data surrounding such incident. In addition, Principal Investigator shall comply with all of their obligations with regard to adverse event reporting procedures as set forth in this Agreement and the Protocol; and
- b) the Principal Investigator under clause 7.1 above must (i) promptly notify the Sponsor of the assertion of any such claims (ii) authorize and permit Sponsor to conduct and exercise sole control of the defense and deposition (including all decisions relative to litigation, appeal or settlement) of such claims and (iii) fully cooperate with Sponsor regarding any such claims (including access to pertinent records and documents and provision of relevant testimony) and in determining the scope of Sponsor's obligations hereunder. Subject to the foregoing, Principal Investigator may also participate with prior consent of the Sponsor in any such claims at his own cost and expense. Principal Investigator agrees to cooperate with and to authorize Sponsor to carry out sole management and defense of such claim or action. Principal Investigator shall not compromise or settle any claim or action without the prior written approval of Sponsor.

7.3 The Principal Investigator and the Institution hereby irrevocably agree that they shall indemnify and hold harmless the Sponsor, its present and future directors, officers and or employees against any and all consequences, damages, suits, actions, claims, costs and expenses including reasonable attorney's fees and any cost of medical treatment of any illness or injury sustained by a Study subject, cost of fresh studies (collectively the "Claims") arising out of or in relation to (i) any breach of any of the representations and/or warranties made/held out by the Principal Investigator and the Institution in this Agreement; or (ii) breach of any of the terms of this Agreement by the Principal Investigator, the Institution or any individual engaged by Principal Investigator to support him in the conduct of the Study; or (iii) intentional deviation or omission or negligence in conducting the Study by the Principal Investigator, the Institution or any individual engaged by Principal Investigator to support him in the conduct of the Study; or (iv) failure to follow the instructions of Sponsor by the Principal Investigator and the Institution; or (v) failure of the Principal Investigator and the Institution to conduct the Study in accordance with the Protocol, Applicable Laws & Guidelines.

7.4 Insurance

- a) The Sponsor undertakes that it will secure and maintain in full force and effect throughout the performance of the Study (and following termination or early termination of the Study and to cover any claims arising from the Study) a clinical trial liability insurance policy from an Indian insurance company for an amount appropriate to, and in accordance with, the Sponsor's activities and obligations contemplated in this Agreement.
- b) The Institution undertakes that it will secure and maintain in full force and effect throughout the performance of the Study (and following termination or early termination of the Study and to cover any claims arising from the Study) a clinical trial liability insurance coverage from an Indian insurance company for the Study for



[Handwritten signatures]

ATTESTED

[Handwritten signature]
Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

an amount appropriate to, and in accordance with, the its activities and obligations contemplated in this Agreement.

8. **Publication of Results**

It is the general policy of the Sponsor to encourage publication of results of Clinical Trial on a case to case basis. However, according to good scientific practice no interim data should be published by the Principal Investigator/ Institution unless agreed by the Parties in writing. It is further agreed that when the Principal Investigator/ Institution request for publications, the manuscript shall be based on final report of the Study and before any publication it shall be sent to the Sponsor for its perusal, comments and approval. The Sponsor may at its discretion may either refuse the publication or forward it to the Principal Investigator/ Institution along with its comments or modifications which shall be final and binding on the Principal Investigator/ Institution.

9. **Publicity and Product Promoting Activity**

It is agreed that no Party shall issue any press release or other third party communication relative to this Agreement without the prior written consent of the other Party except to the extent that the Sponsor shall have absolute right to issue any press release relating to the Study related data. Principal Investigator shall not use the name of the Sponsor and/or its employees in any advertising or sales promotional material or in any other way not required by law or regulation without the prior written consent of the Sponsor.

10. **Confidentiality**

- 10.1 The Principal Investigator and the Institution agree to keep confidential and secret all materials, documents and confidential information that the Sponsor discloses to the Principal Investigator and the Institution pursuant to this Agreement and also all materials, documents and information's gathered, generated or developed by Principal Investigator and the Institution under the Study including but without limitation to results and discoveries emanated from the Study, regardless of whether such information is marked as "Confidential," "Proprietary" or the like, which is furnished to the Principal Investigator by or on behalf of the Sponsor whether in written, electronic, oral, visual or other form ("**Confidential Information**").
- 10.2 The Principal Investigator and the Institution agree, represent and warrant that any Confidential Information that they receive shall be protected at least, with the same degree of care and protection in the strictest confidence as of its own and shall take all reasonable measures to protect it. The Principal Investigator and the Institution shall use such Confidential Information only for the purpose of fulfilling their obligations mentioned herein and shall not disclose such Confidential Information without the prior written consent of the Sponsor to any third party except as required by law provided that the Principal Investigator and the Institution shall:
- (i) first give prompt notice of such disclosure requirement to the Sponsor so as to seek any limitations on or exemptions from such disclosure requirement; and
 - (ii) reasonably co-operate the Sponsor in any such efforts of defense to be made before appropriate authority.
- 10.3 Principal Investigator and/or the Institution may disclose Confidential Information to their co-investigator, hospital authorities, Ethics Committee members and others who are required to be involved in the Study on a need-to-know basis provided that: (i) such



ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

receiving party shall always remain liable to maintain the confidentiality in terms hereof and (ii) all such receiving party shall be bound by obligations of confidentiality with respect to such Confidential Information at least as stringent as those provided herein. Principal Investigator and the Institution shall be liable for any breach of this Agreement by its representatives. The obligations of confidentiality hereunder shall continue for a period of fifteen (15) years from the date the Confidential Information is disclosed or developed. The obligation of confidentiality hereunder shall not apply to information that Principal Investigator and/or the Institution can prove and produces credible written evidence to establish that such information or material:

- (a) at the time of disclosure or after disclosure to the Principal Investigator /Institution becomes part of the public domain by publication or otherwise, except by breach of this Agreement by the Principal Investigator/ Institution or their successors or assigns;
- (b) by written records were in the Principal Investigator/ Institution's possession at the time of disclosure by the Sponsor were not acquired directly or indirectly from the Sponsor;
- (c) subsequent to disclosure hereunder, the Principal Investigator/ Institution receives from a third party legally in a position to provide with information to the Principal Investigator/ Institution, provided, however, that such was not obtained by said third party directly or indirectly from the Sponsor under an obligation of confidentiality.

- 10.4 All clinical data, including case report forms and other information and discoveries resulting from the Study ("Inventions") shall be the sole property of the Sponsor and will be treated as "Confidential Information" by the Principal Investigator and the Institution and may be used by the Sponsor in any manner. Further, Principal Investigator and the Institution shall assign to the Sponsor all of their rights, title, and interest in such Inventions.
- 10.5 All Confidential Information disclosed pursuant to this Agreement, together with all copies thereof, summaries and all information, know-how, data and materials generated by the use of the Confidential Information, shall be returned to the Sponsor by Principal Investigator and the Institution forthwith upon written request or upon termination of this Agreement, whichever is earlier.
- 10.6 Principal Investigator and the Institution agree that the Confidential Information is of a special and unique kind, the protection of which is essential to the operation of the Sponsor, and that if there is a breach (either actual or threatened) by the Principal Investigator/ Institution or co-investigator or a party in receipt of Confidential Information under this Agreement, the Sponsor would have no complete remedy at law. Therefore, in addition to any other remedies that may be available at law or equity, Principal Investigator and Institution agree that the Sponsor shall be entitled to seek from any court of competent jurisdiction, injunctive relief, specific performance or other equitable relief, for any actual or threatened violation of this Agreement (without the necessity of posting any bond or other security proving special damages) and that the Principal Investigator and Institution shall not oppose the granting of such relief. In the event of any litigation relating to this Agreement, if a court of competent jurisdiction determines that this Agreement has been breached by one Party, then that Party shall reimburse the non-breaching Party for all its costs and expenses (including, without



ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka


limitation, attorney fees and other legal expenses) incurred in connection with all such litigation.

11. Severability & Waiver and Assignment

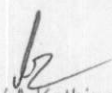
- 11.1 The invalidity or unenforceability of any term or provision of this Agreement, the remaining provisions shall stand to the fullest extent permitted by law. The failure of any Party at any time or times to require performance of any provision hereof shall in no manner affect the right of such Party at a later time to enforce such provision or any other provision of this Agreement.
- 11.2 Waiver by either Party or the failure by either Party to claim a breach of any provision of this Agreement shall not be deemed to constitute a waiver or estoppels with respect to any subsequent breach of any provision hereof.
- 11.3 This Agreement shall not be assigned as a whole or in part by Principal Investigator and/or Institution without the prior written consent of the Sponsor.

12. Validity & Termination

- 12.1 This Agreement shall become effective on the date first set forth above and shall continue for a period of 1 year thereof or until this Agreement is terminated due to:-
- a. Determination by the Sponsor that the Principal Investigator is not performing the Study as required in the Protocol and/ or is not meeting the agreed upon enrollment;
 - b. Failure of the Principal Investigator's or its associated staff or any other person engaged in the Study (excluding subjects) to be available, upon reasonable prior notice by the Sponsor, to meet at mutually convenient time with the Sponsor enabling it to monitor the course of the Study as necessary and to discuss information relevant to the Study;
 - c. Determination by the Sponsor that business or scientific considerations require termination;
 - d. Case report forms provided to the Principal Investigator by the Sponsor to be used in the Study, are not legibly completed and forwarded to the Sponsor or its designated representative;
 - e. At the request of either DCGI or Ethics Committee;
 - f. Notification to the Sponsor from central or state regulatory authorities to terminate the Study;
 - g. Failure of the Principal Investigator/ Institution to provide access by the Sponsor's representatives all original medical records necessary to verify entries on the Study case report forms;
- 12.2 The Sponsor may terminate this Agreement:
- a) At any time upon thirty (30) days written notice to the Principal Investigator/Institution.
 - b) Immediately for safety reasons relating to the use of the Study Drug.



ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

12.3 Either Party may terminate this Agreement by notice in writing to the other Party if the other Party commits a breach of this Agreement, and which, in the case of a breach capable of remedy, shall not have been remedied by the defaulting Party within thirty (30) days of receipt of notice identifying the breach and requiring its remedy.

13. Effect of Termination

13.1 Upon receipt of notice of termination, the Principal Investigator shall immediately stop enrolling subjects into the Study and to the extent medically permissible, cease administering the Study Drug and conducting Clinical Trial on subjects already entered into the Study. In case of early termination of this Agreement, due to any reason the Principal Investigator shall request all Study subjects within one month from the date of termination notice to attend a follow up visit for proper safety assessment of the subjects enrolled. The Principal Investigator shall use all reasonable efforts to complete reports for all subjects that have been entered into the Study prior to the date of termination of this Agreement.

13.2 Upon termination or completion of the Study, the Principal Investigator and Institution shall return to the Sponsor all unused Study drugs, case report forms, whether completed or not and other related materials including but not limited to materials that were furnished to the Principal Investigator/Institution by or on behalf of the Sponsor. In case, the Sponsor desires destruction of aforementioned material, the Principal Investigator/Institution shall destroy such material in front of authorized representative of the Sponsor and shall also provide the Sponsor with a certificate of destruction.

14. Miscellaneous

14.1 It is agreed by the Parties that the Principal Investigator and Institution shall act in the capacity of independent contractor hereunder and not as employees, agents or joint ventures of or with Sponsor. Neither Principal Investigator nor Institution shall have any authority to represent, or bind the Sponsor.

14.2 Principal Investigator shall comply with all the terms of the Investigator undertaking letter he has provided to the Sponsor.

14.3 This Agreement contains the entire understanding of the Parties hereto and supersedes all prior oral and written agreements and understandings of the Parties except confidentiality agreement, if any, pertaining to the subject matter hereof.

14.4 If the terms contained in the Exhibit attached hereto conflict with any provisions contained in this Agreement, the terms contained in this Agreement shall prevail. Unless otherwise provided herein, this Agreement may not be amended, supplemented or otherwise modified except by an instrument in writing signed by the Parties hereto.

14.5 The Parties undertake to notify each other of all events that influence the performance of this Agreement. Notifications shall be made to the following addresses:-

(i) **To Sponsor** : Biological E. Ltd.
18/1 & 3, Azamabad
Azamabad, Hyderabad – 500020
Telangana, India



ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

(ii) **To Principal Investigator:** Dr. NS Mahantshetti

Title: Professor
 Address: KLEs JNMC Prabhakar Kore Hospital,
 Belgaum, Nehru Nagar, Belagavi, KARNATAKA
 Telephone No.: 0674 2304400
 Mobile: +91-8312477201
 Email id: nsmahantasheeti@gmail.com

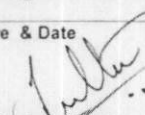


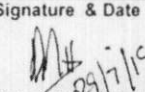
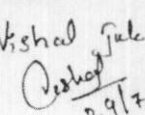
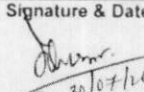
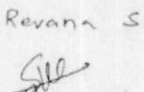
(iii) **To Institution:**

Dr. M. V. Jali
 Title: Medical Director
 Address: KLEs Dr. Prabhakar Kore Hospital &
 Medical Research Centre, Nehru Nagar,
 Belgaum 590010, Karnataka
 Telephone No.: 0831 – 2473777
 Fax No: 0831-2470732
 Email: drmvjali@gmail.com

Any dispute or difference whatsoever arising between the Parties out of or relating to the construction, meaning, scope, operation or effect of this Agreement or the validity or the breach thereof shall be exclusively settled by arbitration in Hyderabad, which shall be governed by the Arbitration and Conciliation Act, 1996 as amended from time to time. The arbitral tribunal shall comprise of sole arbitrator to be appointed by the managing director of the Sponsor. The language to be used in the arbitral proceedings shall be English. The award rendered by the arbitrator shall be final and binding upon the Parties hereto.

14.6 Parties agree that for claiming injunctive relief and for the enforcement of arbitral award courts in Hyderabad shall have exclusive jurisdiction in all matters arising out of or with this Agreement

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be duly executed as of the date first set forth above in triplicate each being legally authentic and binding.

For and on behalf of Biological E Limited	Principal Investigator	For and on behalf of Institution
<p>Signature & Date  Name: Mr. Sultan Baig Title: Vice President- Finance</p> <p>Seal: </p> <p>Witness:  N.ESWARAREDDY Sr. Vice President - Legal</p>	<p>Signature & Date  Name: Dr. N.S. Mahantshetti Title: Professor</p> <p>Dr. N. S. Mahantashetti Professor Consultant Pediatrics KMC Reg. No. 22164 KLES Dr. Prabhakar Kore Hospital & MRC, Belagavi.</p> <p>Witness:  Vishal Jalekat 29/7/19</p>	<p>Signature & Date  Name: Dr M.V. Jali Title: Medical Director</p> <p>Seal: Medical Director & Chief Executive KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, BELAGAVI.</p> <p>Witness:  Revana Sdevarini 30/07/2019</p>







ATTESTED


 Dr. V.A. Kothiwale
 Registrar

KLE Academy of Higher Education and Research,
 (Deemed-to-be-University u/s 3 of the UGC Act, 1956)
 Belagavi-590 010, Karnataka

Exhibit - A**BUDGET AND PAYMENT SCHEDULE**

The following budget will apply for the conduct of the ACTIVITY:

BECT048 – MR P-IV STUDY BUDGET	
Cost Description	Amount (INR)
Investigator, co-investigator & study team fee (INR 8,500 per Subject x 83 subjects)	7,05,500
Study coordinator fee (INR.13,500 per month x 8 months)	1,08,000
Subject travel conveyance (Rs. 500 per subject x 2 visits x 83 subjects)	83,000
Site Logistics, Setup charges (courier, Internet, AV Recording and other etc.)	50,000
Study documents archival fee (for 15 years)	50,000
Sub Total	9,96,500
Institutional Overheads (25% on Investigator fees)	1,76,375
Total	11,72,875

Total Cost (in Words): Eleven Lakhs seventy two thousand eight hundred seventy five rupees only.
(GST 18% extra as applicable by government laws, wherever applicable)

Budget Note:

- No charges will be paid for screen failure subjects
- TDS will be deducted on all payments as applicable.

The following ACTIVITY linked Payment Schedule will apply for release of total payment to the SITE:

S. No	Payment Milestone	% of Total Cost
1	On Site Initiation	25%
2	On completion of 100% Subject Recruitment	25%
3	After Last Patient/subject Last Visit/Completion of all Data Query Resolutions and Database Lock	25%
4	After Site Close out	25%

Based on the total agreed amount of Rs. 11,72,875/- for enrolling 83 subjects, the per subject cost would be Rs. 9,500/-(Investigator, co-investigator & study team fee + Subject travel conveyance)

All payments would be made based on actual number of subject's enrolled at your site, which would be paid as per the above mentioned budget proposal + GST as applicable.

All study related payments should be made in favour of:

- Payee Name: GDD Experts India Pvt. Ltd.
- Bank Name: AXIS BANK Ltd, M.G. House, Rabindranath Tagore Road, Besides Board Office, Civil Lines, Nagpur- 440001, Maharashtra, India.
- Bank Account Number: 910020034162231,
- IFSC code: UTIB0000048
- GST Registration Number: 27AADCG0363Q1ZA
- PAN of Payee: AADCG0363Q



[Handwritten signature]

ATTESTED

[Handwritten signature]
Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010, Karnataka



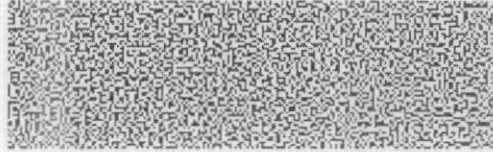
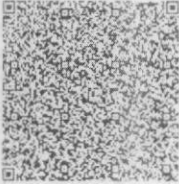
सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No. : IN-KA69900906526789R
Certificate Issued Date : 07-Aug-2019 01:41 PM
Account Reference : NONACC (FI)/ kaksfcl08/ UTTARHALLI/ KA-BA
Unique Doc. Reference : SUBIN-KAKAKSFCL0864362121573410R
Purchased by : IQVIA RDS INDIA PRIVATE LIMITED
Description of Document : Article 12 Bond
Description : CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.) : 0
(Zero)
First Party : IQVIA RDS INDIA PRIVATE LIMITED
Second Party : KLE UNIVERSITY JAWAHARLAL NEHRU MEDICAL COLLEGE
Stamp Duty Paid By : IQVIA RDS INDIA PRIVATE LIMITED
Stamp Duty Amount(Rs.) : 300
(Three Hundred only)



Please write or type below this line:

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Statutory Alert

1. The information on the e-Stamp Certificate is available on the website of the Government of Karnataka.
2. The user of the e-Stamp Certificate is not liable for the loss of the e-Stamp Certificate.
3. The user of the e-Stamp Certificate is not liable for the loss of the e-Stamp Certificate.

CLINICAL TRIAL AGREEMENT

The Clinical Trial Agreement ("**Agreement**") is made by and among

- **KLES Dr. Prabhakar Kore Hospital and Medical Research Centre**, having a place of business at, Nehru Nagar, Belagavi-590010, Karnataka, India (the "**Institution**"), and
- **Dr. Archana Uppin**, having a place of business at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi-590010, Karnataka, India. (the "**Investigator**"), and
- **Doclin Clinical Research Services** having a place of business at 445, Maruti Galli, Main Road, Hangarge, Mandoli, Belgavi-590010, Karnataka, India. (the "**Research Company**"), and
- **IQVIA RDS (India) Private Limited, (formerly Quintiles Research (India) Private Limited)**, having a place of business at III Floor, Etamin Block, Prestige Technology Park, Sarjapur - Marathahalli Outer Ring Road Bangalore – 560103, Karnataka, India ("**IQVIA** ").

Each a "Party" and together the "Parties".

Protocol Number:	201790
Protocol Title:	A 52-week, phase 3, multicentre, randomised, double blind, efficacy and safety study comparing GSK3196165 with placebo and with tofacitinib, in combination with methotrexate in participants with moderately to severely active rheumatoid arthritis who have an inadequate response to methotrexate.
Protocol Date:	22 May 2019
Sponsor:	GlaxoSmithKline Research & Development Limited
Country where Site is Conducting Study	India
Investigator:	Dr. Archana Uppin "an employee of Institution"
Key Enrollment Date:	100 Calendar Days after Site Initiation Visit (being the date by which Site must enrol at least one (1) subject as more specifically set out in section 1.7 "Key Enrollment Date" below)
IRB/IEC	Name: Institutional Ethics Committee Address: JNMC Campus, Nehru Nagar, Belagavi-590010, Karnataka, India. Ethics Committee Chairperson: Dr. Subarna Roy - +91 9449033133

The following additional definitions shall apply to this Agreement:

Protocol: the clinical protocol referenced above as it may be modified from time to time by the GSK (defined below).

Case Report Form or **CRF:** case report form (paper or electronic) to be used by Site to record all of the Protocol-required information to be reported to GSK on each Study Subject (defined below).

Study: the clinical trial that is to be performed in accordance with this Agreement and the Protocol for purposes of gathering information about the compound/medical device identified in the Protocol.

GSK Protocol Global CTA Template- KLES Dr. Prabhakar Kore Hospital and Medical Research Centre_Dr. Archana Uppin_19Sep2019
Final v. 2.0_22Jul2019
Clinical Trial Agreement – IQVIA Global template – 18 Oct 2018

Page 1 of 25

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Study Subject: an individual who participates in the Study, either as a recipient of the Investigational Product (defined below) or as a control.

Study Staff: the individuals involved in conducting the Study under the direction of the Investigator.

Investigational Product: the compound/medical device identified in the Protocol that is being tested in the Study.

Good Clinical Practices or GCPs: International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Harmonised Tripartite Guideline for Good Clinical Practice as amended from time to time and the principles set out in the Declaration of Helsinki as revised from time to time.

GSK: means the Sponsor as identified above, GSK's Affiliates or GlaxoSmithKline group of companies, as applicable. Sponsor and GSK's Affiliates are members of the GlaxoSmithKline group of companies.

MCI Regulations: Indian Medical Council (Professional Conduct, Etiquette and Ethics) (Amendment) Regulations, 2009 – Part -1, as may be amended from time to time or any replacement regulations.

Medical Records: the Study Subjects' primary medical records kept by the Institution on behalf of the Investigator, including, without limitation, treatment entries, x-rays, biopsy reports, ultrasound photographs and other diagnostic images.

Study Data: all records and reports, other than Medical Records, collected or created pursuant to or prepared in connection with the Study including, without limitation, reports (e.g., CRFs, data summaries, interim reports and the final report) required to be delivered to GSK pursuant to the Protocol and all records regarding inventories and dispositions of all Investigational Product.

Government Official: any officer or employee of a government or of any ministry, department, agency, or instrumentality of a government; any person acting in an official capacity on behalf of a government or of any ministry, department, agency, or instrumentality of a government; any officer or employee of a company or of a business owned in whole or part by a government; any officer or employee of a public international organization such as the World Bank or the United Nations; any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or any candidate for political office; any doctor, pharmacist, or other healthcare professional who works for or in any hospital, pharmacy or other healthcare facility owned or operated by a government agency, ministry or department.

Item(s) of Value: should be interpreted broadly and may include, but is not limited to, money or payments or equivalents, such as gift certificates; gifts or free goods; meals, entertainment, or hospitality; travel or payment of expenses; provision of services; purchase of property or services at inflated prices; assumption or forgiveness of indebtedness; intangible benefits, such as enhanced social or business standing (e.g., making donations to government official's favored charity); and/or benefits to third persons related to government officials (e.g., close family members).

Process(ing): (in reference to Personal Data) any operation or set of operations that is performed upon Personal Data (as defined below), including without limitation collection, recording, retention, alteration, use, disclosure, access, transfer, storage or destruction.

Security Breach: the occurrence of any event that could reasonably be expected to comprise the security of Confidential Information or the security of Personal Data in accordance with Data Protection Legislation (as defined below), or the occurrence of discovering any suspected or actual

unauthorized disclosure, loss or theft of Confidential Information (as defined below) or Personal Data in accordance with Data Protection Legislation.

RECITALS:

WHEREAS, IQVIA is providing clinical research organisation services to GSK under a separate contract between IQVIA and GSK. IQVIA's services include monitoring of the Study and contracting with clinical research sites;

WHEREAS, the Institution and Investigator (hereinafter jointly the "Site") are willing to conduct the Study and IQVIA requests the Site to undertake such Study.

NOW THEREFORE, the following is agreed:

1. CONDUCT OF THE STUDY

1.1. Compliance with Laws, Regulations, and Good Clinical Practices

Site agrees that Site and Study Staff shall perform the Study at Institution in strict accordance with this Agreement, the Protocol, any and all applicable local, national and international laws regulations and guidelines, including in particular, but without limitation, GCPs, MCI Regulations, state and local tax and finance regulations and any laws related to protection of medical confidentiality and privacy of personal data. Site and Study Staff acknowledge that IQVIA and GSK, and their respective affiliates, need to adhere to the provisions of (i) the Bribery Act 2010 of the United Kingdom (Bribery Act); (ii) the Foreign Corrupt Practices Act 1977 of the United States of America (FCPA) and (iii) any other applicable anti-corruption legislation.

1.2. Informed Consent Form

Site agrees to use an informed consent form that has been approved by GSK and is in accordance with applicable regulations and the requirements of the Institutional Review Board ("IRB") or Independent Ethics Committee ("IEC") that is responsible for reviewing the Study. Site shall obtain the prior written informed consent of each Study Subject.


1.3. Medical Records and Study Data

1.3.1. Collection, Storage and Destruction: Site shall ensure the prompt, complete, and accurate collection, recording and classification of the Medical Records and Study Data.

Site shall

- (i) maintain and store Medical Records and Study Data in a secure manner with physical and electronic access restrictions, as applicable and environmental controls appropriate to the applicable data type and in accordance with applicable laws, regulations and industry standards; and
- (ii) protect the Medical Records and Study Data from unauthorized use, access, duplication, and disclosure. If directed by GSK or IQVIA, Site will submit Study Data using the electronic system provided by GSK or IQVIA or their designated representative and in accordance with GSK's instructions for electronic data entry. Site shall prevent unauthorized access to the Study Data by maintaining physical security of the electronic system and ensuring that Study Staff maintain the confidentiality of their passwords. Investigator agrees to collect all Study Data in Medical Records prior to entering it into the CRF. Site shall ensure the prompt submission of CRFs. CRF information associated with a Subject's visit must be satisfactorily completed within seven (7) business days of the Subject's visit, after receipt of Subject's data queries, or if applicable, after receipt of the Subject's test results. Notwithstanding the foregoing, the GSK/IQVIA Study team may communicate in writing the reasonable necessity for response time to be modified (i.e. shortened) during interim analysis, urgent safety review (e.g. dose escalation timing, urgent FDA query) or study closeout periods. For dose escalation, data entry

Page 3 of 25
ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

and queries must be answered within one (1) business day. The Institution will use reasonable efforts to meet such timing requests and

- (iii) retain Medical Records and Study Data for a minimum of fifteen (15) years from the issue date of the clinical study report/summary or equivalent. GSK will inform the Investigator of the date on which the GSK-required retention period will expire. After the expiration of this period, Institution or Investigator is responsible for complying with any remaining relevant local, organizational, state, national and/or regulatory guidelines for records retention. If, at any time during the retention period, Investigator and/or Institution are unable to comply with the record retention responsibilities in this Section (e.g., Investigator retirement; Investigator is no longer employed by or associated with Institution; or, Institution site closure), Investigator or Institution shall transfer responsibility for record retention to another party at the Institution or to a third party off-site archive facility. Investigator or Institution must provide written notice to IAVIA and/or GSK prior to such transfer which specifies the name and address of the new responsible party and, if applicable, the new file location address.
- (iv) take measures to prevent accidental or premature destruction or damage of these documents during the retention period. Neither Institution nor Investigator shall destroy or permit the destruction of any Medical Records or Study Data without prior written notification to the GSK. Upon the expiration of the retention period, Site shall comply with any applicable local, organizational, state, national and/or regulatory guidelines for records retention.

If the Investigator leaves the Institution or is otherwise unable to comply with record retention responsibilities, then responsibility for maintaining Medical Records and Study Data shall be transferred to an appropriate responsible party in accordance with applicable regulations and Investigator shall provide written notice to GSK of such transfer. Institution will not in any case be relieved of its obligations under this Agreement for maintaining the Medical Records and Study Data.

1.3.2. Ownership. Institution shall retain ownership of Medical Records. The Institution and the Investigator hereby assign to GSK all of their rights, title and interest, including intellectual property rights, to all Confidential Information (as defined below) and any other Study Data.


1.3.3. Access, Use, Monitoring and Inspection. Site shall provide original or copies (as the case may be) of all Study Data to IQVIA and GSK for GSK's use. Site shall afford GSK and IQVIA and their representatives and designees reasonable access to Site's facilities and to Medical Records and Study Data so as to permit GSK and IQVIA and their representatives and designees to monitor the Study.

Site shall afford regulatory authorities reasonable access to Site's facilities and to Medical Records and Study Data, and the right to copy Medical Records and Study Data.

The Site agrees to cooperate with the representatives of IQVIA and GSK, and the Site agrees to ensure that the employees, agents and representatives of the Site do not harass, or otherwise create a hostile working environment for such representatives.

The Site shall immediately notify IQVIA of, and provide IQVIA copies of, any inquiries, correspondence or communications to or from any governmental or regulatory authority relating to the Study, including, but not limited to, requests for inspection of the Site's facilities, and the Site shall permit IQVIA and GSK to attend any such inspections. The Site will make reasonable efforts to separate, and not disclose, all Confidential Information that is not required to be disclosed during such inspections.

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

1.3.4. License. GSK hereby grants to Institution a perpetual, non-exclusive, nontransferable, paid-up license, without right to sublicense, to use Study Data (i) subject to the obligations set forth in section 3 "Confidentiality", for internal, non-commercial research and for educational purposes, and (ii) for preparation of publications in accordance with Section 5 "Publication Rights".

1.3.5. Survival. This section 1.3 "Medical Records and Study Data" shall survive termination or expiration of this Agreement.

1.4. Duties of Investigator

Investigator is responsible for the conduct of the Study at Institution and for supervising any individual or party to whom the Investigator delegates Study-related duties and functions. In particular, but without limitation, it is the Investigator's duty to review and understand the information in the Investigator's Brochure or device labeling instructions, to ensure that all informed consent requirements are met, to ensure that all required reviews and approvals by applicable regulatory authorities and IRBs or IECs are obtained, and to review all CRFs to ensure their accuracy and completeness. Investigator agrees to answer queries related to CRFs submitted within seven (7) business days of the request, except for dose escalation. Investigator must respond to dose escalation queries within one (1) business day.

If the Investigator and Institution retain the services of any individual or party to perform Study-related duties and functions, the Institution and Investigator shall ensure this individual or party is qualified to perform those Study-related duties and functions and shall implement procedures to ensure the integrity of the trial-related duties and functions performed and any data generated.

Investigator agrees to provide a written declaration revealing Investigator's possible economic or other interests, if any, in connection with the conduct of the Study or the Investigational Product.

Investigator agrees to provide a written declaration revealing Investigator's disclosure obligations, if any, with the Institution in connection with the conduct of the Study and the Investigational Product.

Site agrees to provide prompt advance notice to GSK and IQVIA if Investigator will be leaving the Institution or is otherwise no longer able to perform the Study. The appointment of a new Investigator must have the prior approval of GSK and IQVIA.

1.5. Adverse Events

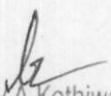
The Site shall report adverse events and serious adverse events as directed in the Protocol and by applicable laws and regulations. The Site shall cooperate with GSK in its efforts to follow-up on any adverse events. The Site shall comply with its IRB/IEC reporting obligations.

GSK will promptly report to the Site, the Site's IRB/IEC, and IQVIA, any finding that could affect the safety of participants or their willingness to continue participation in the Study, influence the conduct of the Study, or alter the Site's IRB/IEC approval to continue the Study.

1.6. Use and Return of Investigational Product and Equipment

GSK or a duly authorized agent of GSK, shall supply Institution or Investigator with sufficient amount of Investigational Product as described in the Protocol.

The Site shall use the Investigational Product and any comparator products provided in connection with the Study, solely for the purpose of properly completing the Study and shall maintain the Investigational Product as specified by GSK and according to applicable laws and regulations, including storage in a locked, secured area at all times.


Dr. V.A. Kothiwale
Registrar

Upon completion or termination of the Study, the Site shall return or destroy, at GSK's option, the Investigational Product, comparator products, and materials and all Confidential Information (as defined below) at GSK's sole expense.

Institution and Investigator shall comply with all laws and regulations governing the disposition or destruction of Investigational Product and any instructions from IQVIA that are not inconsistent with such laws and regulations.

1.7. Enrollment of Study Subjects

Site shall not be permitted to screen potential Study Subjects, randomize Study Subjects, receive Investigational Product or receive any payment until the Effective Date of this Agreement is reached.

1.8. Key Enrollment Date

The Site understands and agrees that if Site has not enrolled at least one (1) Study Subject by the Key Enrollment Date then IQVIA may terminate this Agreement in accordance with Section 15 "Term & Termination" GSK/IQVIA has the right to limit enrollment at any time.

1.9. Attendance at Start Up Meeting

If Sponsor or IQVIA requests Site's attendance at a Study startup meeting or other meeting necessary to provide information regarding the Study or Investigational Product, Site will be reimbursed for reasonable and necessary travel and lodging expenses (including meals) incurred to attend such meetings. Reimbursement will be as set forth in Attachment A.

1.10. Human Biological Samples

If the Study includes the collection by Site of human biological materials from Study Subjects for research use, Site will comply with all applicable laws, rules, regulations and codes of practice and guidance relating to the collection, storage, use, shipping, and disposal of human biological materials in the conduct of the Study and with respect to any such human biological materials from the Study retained in Site's possession. Site agrees to appropriate informed consent (including, as appropriate, for any genetic analyses) for the Study and for research use of any human biological materials, with ethics approval. Site agrees that any human biological materials collected as part of the Study that are transferred to GSK or a GSK's contractor, or held by Institution for GSK, will be under the custodianship and control of GSK.


1.11. Human Rights

Respectful of its employees right to freedom of association, Institution represents and warrants, to the best of its knowledge, that in connection with this Agreement, it respects the human rights of its staff and does not employ child labour, forced labour, unsafe working conditions, discrimination of protected characteristic or cruel or abusive disciplinary practices in the workplace; and that it pays each employee at least the minimum wage, provides each employee with all legally mandated benefits, and complies with the applicable laws on working hours and employment rights in the countries in which it operates. Institution shall be respectful of its employee's right to freedom of association' and Institution shall encourage compliance with these standards by any supplier of goods or services that it uses in performing its obligations under this Agreement.

2 PAYMENT

In consideration for the proper performance of the Study by Site in compliance with the terms and conditions of this Agreement, payments shall be made in accordance with the provisions set forth in Attachment A, with the last payment being made after the Site completes all its obligations hereunder, and IQVIA has received all properly completed CRFs, all data required by the Protocol, including adverse events, and, if IQVIA requests, all other Confidential Information (as defined below).

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Institution and Investigator agree that GSK may make public the amount of funding provided to Institution by IQVIA for the conduct of the Study and may identify Institution and Investigator as part of this disclosure.

3 CONFIDENTIALITY

3.1 Definition

"Confidential Information" means the confidential and proprietary information of GSK and includes (i) all information disclosed by or on behalf of GSK to Institution, Investigator or other Institution personnel, including without limitation, the Investigational Product, technical information relating to the Investigational Product, all Pre-Existing Intellectual Property (as defined in Section 4) of GSK, and the Protocol; and (ii) Study enrollment information, information pertaining to the status of the Study, communications to and from regulatory authorities, information relating to the regulatory status of the Investigational Product, and Study Data and Inventions (as defined in Section 4).

Confidential Information shall not include information that:

- (i) can be shown by documentation to have been public knowledge prior to or after disclosure by GSK, other than through wrongful acts or omissions attributable to Investigator, Institution or any of its personnel;
- (ii) can be shown by documentation to have been in the possession of Investigator, Institution or any of its personnel prior to disclosure by GSK, from sources other than GSK that did not have an obligation of confidentiality to GSK;
- (iii) can be shown by documentation to have been independently developed by Investigator, Institution or any of its personnel; or
- (iv) is permitted to be disclosed by written authorization from GSK.

3.2 Obligations

Site and Site's personnel, including Study Staff shall not

- (i) use Confidential Information for any purpose other than the performance of the Study or
- (ii) disclose Confidential Information to any third party, except as permitted by this Section 3 or by Section 5 "Publication Rights", or as required by law or by a regulatory authority or as authorized in writing by the disclosing party.

To protect Confidential Information, Site agrees to:

- (i) limit dissemination of Confidential Information to only those Study Staff having a need to know for purposes of performing the Study;
- (ii) advise all Study Staff who receive Confidential Information of the confidential nature of such information; and
- (iii) use reasonable measures to protect Confidential Information from disclosure.

Nothing herein shall limit the right of Site to disclose Study Data as permitted by Section 5 "Publication Rights."


3.3 Compelled Disclosure

In the event that Institution or Investigator receives notice from a third party seeking to compel disclosure of any Confidential Information, the notice recipient shall provide GSK with prompt notice so that GSK may seek a protective order or other appropriate remedy. In the event that such protective order or other remedy is not obtained, the notice recipient shall furnish only that portion of the Confidential Information which is legally required to be disclosed and shall request confidential treatment for the Confidential Information.

3.4 Return or Destruction

Upon termination of this Agreement or upon any earlier written request by GSK at any time, Site shall return to GSK, or destroy, at GSK's option, all Confidential Information other than Study Data.

ATTESTED


Dr. V.A. Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

3.5 Survival

This Section 3 "Confidentiality" shall survive termination or expiration of this Agreement for ten (10) years.

4 INTELLECTUAL PROPERTY

4.1 Pre-existing Intellectual Property

Ownership of inventions, discoveries, works of authorship and other developments existing as of the Effective Date and all patents, copyrights, trade secret rights and other intellectual property rights therein (collectively, "**Pre-existing Intellectual Property**"), is not affected by this Agreement, and no Party or GSK shall have any claims to or rights in any Pre-existing Intellectual Property of another, except as may be otherwise expressly provided in any other written agreement between them.

4.2 Inventions

For purposes hereof, the term "**Inventions**" means all inventions, discoveries and developments conceived, first reduced to practice or otherwise discovered or developed by a Party or GSK or any of such entity's personnel in performance of the Study. GSK shall own all Inventions, that are conceived, first reduced to practice or otherwise discovered or developed by the Institution, the Investigator or any of their personnel in performance of the Study.

4.3 Assignment of Inventions

Site shall, and shall cause its personnel to, disclose all Inventions promptly and fully to GSK in writing, and Site, on behalf of itself and its personnel, hereby assigns to GSK all of its rights, title and interest in and to Inventions, including all patents, copyrights and other intellectual property rights therein and all rights of action and claims for damages and benefits arising due to past and present infringement of said rights. Site shall cooperate and assist GSK by executing, and causing its personnel to execute, all documents reasonably necessary for GSK to secure and maintain GSK's ownership rights in Inventions.

4.4 License

GSK hereby grants to Institution a perpetual, non-exclusive, non-transferable, paid-up license, without right to sublicense, to use Inventions, subject to the obligations set forth in Section 3 "Confidentiality," for internal, non-commercial research and for educational purposes.

4.5 Patent Prosecution

Site shall cooperate, at GSK's request and expense, with GSK's preparation, filing, prosecution, and maintenance of all patent applications and patents for Inventions.

4.6 Survival

This Section 4 "Intellectual Property" shall survive termination or expiration of this Agreement.


5 PUBLICATION RIGHTS

5.1 Study Transparency and Publication

Before commencement of the Study, GSK will register the Study with a public clinical trials registry. GSK will make public a summary of the Protocol and a summary of the Study results from all Study sites in one or more publicly accessible worldwide registers at any time after the commencement of the Study. GSK will also post the full Study Protocol and statistical analysis plan at the time of results summary posting. Institution and Investigator agree that GSK may make public the names of the Investigator and Institution as part of a list of investigators and institutions conducting the Study when making either protocol or results summary register postings.

Institution and Investigator shall have the right to publish or present the results of Institution's and Investigator's activities conducted under this Agreement, including Study Data, only in accordance with the requirements of this Section. Institution and Investigator agree to submit

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka


any proposed publication or presentation to GSK for review at least thirty (30) days prior to submitting any such proposed publication to a publisher or proceeding with such proposed presentation. Within thirty (30) days of its receipt, GSK shall advise Institution and/or Investigator, as the case may be, in writing of any information contained therein which is Confidential Information (other than Study Data) or which may impair the availability of patent protection for Inventions. GSK shall have the right to require Institution and/or Investigator, as applicable, to remove specifically identified Confidential Information (other than Study Data) and/or to delay the proposed publication or presentation for an additional sixty (60) days to enable GSK to seek patent protection for Inventions. The Institution's publication will reference the GSK Publication (as defined below). Institution agrees that GSK's financial support of the Study will be disclosed in any Institution publication. Institution shall ensure that Investigator complies with the obligations identified in this Section 5.

5.2 Multi-Center Publications

GSK will seek to publish the Study results in searchable, peer reviewed scientific literature. The first publication and all subsequent publications of the Study results from all Study sites ("GSK Publication (s)") or disclosure(s) of the Study results, shall be coordinated by GSK. Once the Study is published in a scientific journal, GSK may list the Study on an external website for patient-level data sharing for further research and may also make available the full Study report on the GSK register. If the Study is a multi-center study, Institution and Investigator agree that they shall not, without the GSK's prior written consent, independently publish, present or otherwise disclose any results of or information pertaining to Institution's and Investigator's activities conducted under this Agreement until GSK's Publication is published; provided, however, that if a GSK Publication is not published within eighteen (18) months after completion of the Study and lock of the database at all research sites or any earlier termination or abandonment of the Study, Institution and Investigator shall have the right to publish and present the results of Institution's and Investigator's activities conducted under this Agreement, including Study Data, solely in accordance with the provisions of Section 5.3 "Confidentiality of Unpublished Data." Study Subjects' personal information, such as name or initials, shall not be publicly disclosed at any time.

Any participation of Investigator or other representatives of Institution as a named author of this GSK Publication will be determined in accordance with the International Committee of Medical Journal Editors ("ICMJE") Uniform Requirements for Manuscripts, and Institution and Investigator acknowledge that the enrollment of Study Subjects alone is not a qualification for authorship. If the Investigator or other representative of Institution is a named author of the GSK Publication, as an author, he/she (1) will enter into a written author agreement prior to beginning work on the GSK Publication; (2) will have access to the Study data from all Study sites as necessary to fully participate in the development of the GSK Publication; and, (3) will disclose as part of the GSK Publication that GSK financially supported the Study and the GSK Publication, and will disclose any personal financial relationship with GSK. GSK will not compensate authors for authorship activities.

If considered appropriate by GSK, the Investigator or other Institution personnel involved with the Study may participate in the Publication Steering Committee ("PSC") or core writing team(s) for the Study or in public presentations of the Study results. Persons participating as a member of a PSC, in core writing team(s) activities or in public presentation of the Study results will not receive any payment, honorarium or other fee for participation in such activities nor ownership to nor other title or interest in work product arising out of such activities. However, GSK will reimburse such persons or the Institution (as the case may be and as advised by such persons) for their reasonable travelling and lodging expenses while travelling at GSK's request, provided that travel and lodging expenses have been authorized by GSK in writing in advance and that GSK receives proper original receipts.


Dr. V.A. Kothiwale
Registrar

the date of the assignment, and the Site hereby consents to such an assignment. Site will be given prompt notice of such assignment by the assignee.

18.4 Third Party Beneficiary

The Parties agree that GSK shall have the right to enforce any of the provisions of this Agreement as a third-party beneficiary.

Each Party to this Agreement acknowledges that except for the GSK, there are no third-party beneficiaries with any rights to enforce any of the provisions of this Agreement.

18.5 Applicable Law

This Agreement shall be interpreted under the laws of the state or province and country in which Site conducts the Study.

18.6 Survival


The terms of this Agreement that contain obligations or rights that extend beyond the completion of the Study shall survive termination or completion of this Agreement, even if not expressly stated herein.

18.7 Binding Authority

IQVIA represents that GSK has granted IQVIA written authority to bind GSK to the GSK obligations expressly included in this Agreement

THIS SECTION IS INTENTIONALLY LEFT BLANK; SIGNATURE PAGE IMMEDIATELY FOLLOWS

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

ACKNOWLEDGED AND AGREED BY IQVIA RDS (India) Private Limited:
(formerly Quintiles Research (India) Private Limited)

Name : Tanuka Ganguly

Title : Director, Site and Patient Networks

Signature: Tanuka Ganguly

Date : 26/sep/2019

ACKNOWLEDGED AND AGREED BY THE INVESTIGATOR:

Name : Dr. Archana Uppin

Title: Principal Investigator

Signature : [Signature]

Date : 30/9/19.

ACKNOWLEDGED AND AGREED BY KLES DR. PRABHAKAR KORE HOSPITAL AND
MEDICAL RESEARCH CENTRE:

By : Dr. Mallikarjun Vamadevappa Jali

Title: Medical Director and Chief Executive

Signature : [Signature]

Date : 4/10/19

Doclin Clinical Research Services Research Company agrees to abide by all obligations placed on Institution in the provisions of this Agreement concerning Confidentiality (Section 3); Intellectual Property (Section 4); Publication Rights (Section 5); Debarment (Section 10); Anti-Kickback and Anti-Fraud (Section 12); and Anti-Bribery (Section 13)

ACKNOWLEDGED AND AGREED BY DOCLIN CLINICAL RESEARCH SERVICES

Name : Maruti Patil

Title (must be authorized to sign on Research Company's behalf): Managing Director

Signature: [Signature]

Date : 30 sep 2019

GSK Protocol Global CTA Template- KLES Dr. Prabhakar Kore Hospital and Medical Research Centre_Dr. Archana Uppin_19Sep2019
Final v. 2.0_22Jul2019
Clinical Trial Agreement - IQVIA Global template - 18 Oct 2018

ATTESTED of 25

[Signature]
Dr. V.A. Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

**ATTACHMENT A
BUDGET & PAYMENT SCHEDULE**

A. PAYEE DETAILS

The Parties agree that the payee designated below is the proper payee for this Agreement, and that payments under this Agreement will be made only to the following payee ("Payee"):

Payee Name	Doclin Clinical Research Services
Payee Address	Doclin Clinical Research Services, 445, Maruti Galli, Main Road, Hangarge, Mandoli, Belgavi-590010, Karnataka, India.
Payee Remittance Email Address	maruti.patil171@gmail.com
Bank Name	Axis Bank
IFSC Code	UTIB0001690
Bank Account Number	919020049795418
GST Number	29AZXPP8818R1ZP
PAN Number	AZXPP8818R
Mode of Payment	Electronic Fund Transfer

The Payee's Tax Identification Number will be required before any payments can be made under this Agreement.

In case of changes in the Payee's address, Site is obliged to inform IQVIA in writing. The parties agree that in case of changes in address which do not involve a change of Payee, tax numbers, or tax- exempt status, no further amendments are required.

The Parties acknowledge that the designated Payee is authorized to receive all of the payments for the services performed under this Agreement.

If the Investigator is not the Payee, then the Payee's obligation to reimburse the Investigator, if any, is determined by a separate agreement between Investigator and Payee, which may involve different payment amounts and different payment intervals than the payments made by IQVIA to the Payee.

Investigator acknowledges that if Investigator is not the Payee, IQVIA will not pay Investigator even if the Payee fails to reimburse Investigator.

B. PAYMENT DISPUTE

Site will have thirty (30) days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

C. PAYMENT TERM

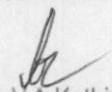
IQVIA will pay the Quarterly (January, April, July, October), on a completed visit per subject basis in accordance with the attached budget. Ninety percent (90%) of each payment due, including any Screening Failure that may be payable under the terms of this Agreement, will be made based upon prior 3 months' enrollment data confirmed by subject CRFs received from the Site supporting subject visitation.

The balance of monies earned, up to ten percent (10%), will be pro-rated upon verification of actual subject visits, and will be paid by IQVIA to the Payee upon final acceptance by GSK of all CRFs pages, all data clarifications issued, the receipt and approval of any outstanding regulatory documents as required by IQVIA and/or GSK, the return of all unused supplies to IQVIA, and upon satisfaction of all other applicable conditions set forth in the Agreement.

GSK Protocol Global CTA Template- KLES Dr. Prabhakar Kore Hospital and Medical Research Centre_Dr. Archana Uppin_19Sep2019
Final v. 2.0_22Jul2019
Clinical Trial Agreement – IQVIA Global template – 18 Oct 2018

Page 20 of 25

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Major, disqualifying Protocol violations are not payable under this Agreement

Any expense or cost incurred by Site in performing this Agreement that is not specifically designated as reimbursable by IQVIA or GSK under the Agreement (including this Budget and Payment Schedule) is Site's sole responsibility.

Site represents that the services it provides under this Agreement are taxable services under the laws governing Goods and Services Tax ("GST") in India, and that it is required to charge GST for the services rendered to IQVIA at the prevailing rate. Site represents that it is entitled to require such payment of the GST under the laws of India. Site undertakes to provide IQVIA with an invoice, to be sent to IQVIA at the address mentioned in Section G of this Attachment A, in respect of such taxable services and such invoice shall be in accordance with the applicable legislation as may be amended from time to time or any successor legislation.

All amounts specified in this Agreement are in **Indian Rupees (INR)** and are exclusive of GST. IQVIA will pay to the Payee any amount of GST that the Payee is required to pay in addition to the amounts set out in this Attachment A and in accordance with GST legislation.

D. SCREENING FAILURE

Reimbursement for screen failures will be at the amount indicated on the screening visit of the attached budget, not to exceed one (1) screen failure(s) paid per three (3) subjects randomized.

To be eligible for reimbursement of a screening visit, completed screening CRF pages must be submitted to IQVIA along with any additional information, which may be requested by IQVIA to appropriately document the subject screening procedures.

E. DISCONTINUED OR EARLY TERMINATION

Reimbursement for discontinued or early termination subjects will be prorated based on the number of confirmed completed visits.

F. UNSCHEDULED VISITS

Payment for unscheduled visits will be reimbursed in the amount up to **Eleven Thousand Six Hundred and Seventy Eight Indian Rupees (11678 INR)** [which includes overhead], as denoted in the Budget Table. To be eligible for reimbursement for unscheduled visits, completed CRF pages must be submitted to IQVIA along with any additional information which may be requested by IQVIA to appropriately document the unscheduled visit.

G. INVOICES

Invoices pertaining to this Study for the following items must be submitted to IQVIA for reimbursement at the following address:

IQVIA RDS (India) Private Limited
(formerly **Quintiles Research (India) Private Limited**)
Attn: QBAN Finance Department
Address: III Floor, Etamin Block,
Prestige Technology Park,
Sarjapur- Marathahalli, Outer Ring Road,
Bangalore- 560103, India

Phone: +91 -080 71315909

Please note that invoices will not be processed unless they reference the GSK name, Protocol number and Investigator name and site number. After receipt and verification, reimbursement for invoices will be included with the next regularly scheduled payment for subject activity.

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- **Institutional Review Boards ("IRBs") or Independent Ethics Committees ("IECs") Payments**

IRB/IEC costs will be reimbursed on a pass-through basis upon receipt of invoice and are not included in the attached Budget. Any subsequent re-submissions or renewals, upon approval by IQVIA and GSK, will be reimbursed upon receipt of invoice.


- **Record Storage Fee/Archiving Fee** – a record retention payment of **Ninety Thousand Indian Rupees (90,000INR)** will be paid upon receipt of invoice and are not included in the attached Budget. In accordance with Sponsor's Protocol requirements, Institution shall maintain at Site Study records in a safe and secure location to allow easy and timely retrieval, when needed.

H. BUDGET TABLE

VISIT	TOTAL AMOUNT (OVERHEAD INCLUDED)
SC	36986.4
BL W0	25148.4
W1	17270.4
W2	22060.8
W3	5948.4
W4	19183.2
W5	5948.4
W6	5948.4
W7	5948.4
W8	19183.2
W9	5948.4
W10	5948.4
W11	5948.4
W12	31566
W13	22882.8
W14	5948.4
W15	3475.2
W16	22602
W17	3475.2
W18	5948.4
W19	3475.2
W20	6489.6
W21	3475.2
W22	5948.4
W23	3475.2
W24	28497.6
W25	3475.2
W26	5948.4
W27	3475.2
W28	6489.6
W29	3475.2
W30	5948.4
W31	3475.2
W32	6489.6
W33	3475.2
W34	5948.4
W35	3475.2
W36	22602
W37	3475.2

GSK Protocol Global CTA Template- KLES Dr. Prabhakar Kore Hospital and Medical Research Centre_Dr. Archana Uppin_19Sep2019
 Final v. 2.0_22Jul2019
 Clinical Trial Agreement – IQVIA Global template – 18 Oct 2018

ATTESTED Page 22 of 25


 Dr. V.A. Kothiwale
 Registrar

KLE Academy of Higher Education and Research,
 (Deemed-to-be-University u/s 3 of the UGC Act,1956)
 Belagavi-590 010,Karnataka

W38	3475.2
W39	3475.2
W40	6489.6
W41	3475.2
W42	3475.2
W43	3475.2
W44	6489.6
W45	3475.2
W46	3475.2
W47	3475.2
W48	13503.6
W49	3475.2
W50	3475.2
W51	9288
EoT W52	29572.8
TOTAL COST PER SUBJECT (INCLUDING OVERHEAD)	506578.8

OTHER VISITS	TOTAL AMOUNT (OVERHEAD INCLUDED)
Safety Follow Up Visit (SFU)	17901
Re-Screening Visit (Re-SC)	29628
Unscheduled Visit (UV)	11678

PD and Biomarkers Sub- study

VISIT	TOTAL AMOUNT (OVERHEAD INCLUDED)
BL W0	1032
W1	1032
W2	1032
W4	1032
W12	1032
W24	1032
Total Additional Cost Per Patient under PD and Biomarker sub study (including Overhead)	6192

I. CONDITIONAL PROCEDURES (WITH INVOICE)

The following conditional procedure costs will be reimbursed on a pass-through basis upon receipt of an original invoice in the amount indicated in the table below (which includes overhead). Subject number and visit dates must be included on the invoice for payment to be issued.

Procedure	Total (OVERHEAD INCLUDED)
Re-consent, Informed consent performed again with the same patient	1,404
Partner pregnancy Informed consent	859
Genomics consent; DNA consent; Genetics	859
Urine pregnancy, gonadotropin chorionic (hCG) (BetahCG); qualitative	360
High Resolution Computed Tomography (HRCT), thorax, chest, lung for interpretation and report use R1255; (CT Scan)	31,225
Interpretation and Report; High Resolution Computed Tomography	9,163
Telephone assessment and management service provided by a qualified nonphysician health care professional to an	1,104

ATTESTED

[Signature]
 Dr. V.A. Kothiwale
 Registrar


KLE Academy of Higher Education and Research,
 (Deemed-to-be-University u/s 3 of the UGC Act, 1956)
 Belagavi-590 010, Karnataka

established patient, parent, or guardian not originating from a related assessment and management service provided within the previous 7 days nor leading to an assessment and management service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion	
Copies of Diagnostic Films, Complex (e.g. high technology, video recordings, compact discs, CDs) - Per Copy	1,560
Physician: Pulmonary Medicine - Per Hour	4,652
Serious adverse events (SAE)	2,828
Patient Reimbursement, Expenses, Patient Travel - Per Visit	913
Meal Reimbursement- Per Visit	795

J. MINIMUM ENROLMENT GOAL

Site acknowledges that Site's minimum enrollment goal is 75 subjects and that Site will use best efforts to reach the enrollment goal within a reasonable time after commencement of the Study at Site. If Site fails to adhere to this principle IQVIA may reconsider Site's suitability to continue participation in the Study.

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

ATTACHMENT B

The Site will be supplied with a Lenovo Tablet; the model number is YB1-X90L. The cost of the tablet is USD 439 (Four Hundred and Thirty Nine US dollars).

All materials and equipment provided ("Equipment") by the GSK or IQVIA/vendors contracted by the GSK shall remain the sole property of the GSK/IQVIA/vendor, as the case may be.

Therefore, it is hereby agreed that such Equipment shall:

a) be subject to removal at any time upon the GSK's or, IQVIA' demand provided that such removal does not prevent the Site from conducting the Study and carrying out their obligations under this Agreement;

b) be used only for the purposes of the Study;

c) be used in accordance with any manuals or instructions while in possession of the Site;

d) shall remain in the same condition, ordinary wear and tear excepted. As long as the Equipment are in the possession of the Site, it is liable for maintenance or any risk of loss in connection with the Equipment during the conduct of the Study;

e) be clearly identified as the sole property of the GSK/IQVIA/vendor, as applicable, by clearly stating "BELONGS TO "Name of legal owner" in order to notify any third parties, including creditors, that the legal owner retains title thereto; and

f) upon completion or termination of the Study, IQVIA or GSK, together with Site assistance, shall arrange the return of all equipment provided for the Study within one (1) month of request to return, or if requested by the GSK or IQVIA in writing, arrange for the disposal of the Equipment as soon as reasonably practicable

NO OTHER ADDITIONAL FUNDING REQUESTS WILL BE CONSIDERED UNLESS APPROVED BY IQVIA AND GSK

Except for GST, these amounts include all applicable taxes.

ATTESTED

Page 25 of 25


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



महाराष्ट्र MAHARASHTRA

© 2019 ©

VP 609520

प्रधान मुद्रांक कार्यालय, मुंबई
प.स. क्र. १००००९५

1 6 AUG 2019

सक्षम अधिकारी

श्री. दि. क. गवई

PRODUCT CODE:

SSR29263

STUDY CODE:

LPS14914

STUDY NAME:

KIDDIE

INVESTIGATOR/INSTITUTION CONTRACT

Site Name: KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Belgavi

Study Code / Name: LPS14914/KIDDIE

Effective date: 16th October 2019

Initials SPONSOR

Initials INSTITUTION

Initials INVESTIGATOR

Initials SMO

ATTESTED

Page No: 1

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

This Contract (hereinafter "the Contract") is made on this 7th day of November 2019, by and among:

DOCTOR MAHANTESH V. PATIL having his address at KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belguam-590010, Karnataka, India

Hereinafter the "INVESTIGATOR",

AND

KLEs DR. PRABHAKAR KORE HOSPITAL & MEDICAL RESERCH CENTRE having its address Nehru Nagar, Belguam-590010, Karnataka, India represented for the purposes hereof by Dr. M. V Jali, Medical Director

Hereinafter the "INSTITUTION"

AND

GDD EXPERTS INDIA PRIVATE LIMITED having its address at Ground floor, Gulmohar Apartment, Opp. Hislop College, Civil Lines, Nagpur – 440001, Maharashtra, India represented for the purposes hereof by Mr. Vinod Gyanchandani, Head Clinical Operations

Hereinafter the "SMO",

AND

SANOFI-SYNTHELABO (INDIA) PRIVATE LIMITED, a company having its registered office at Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai – 400072, represented for the purposes hereof by Dr. Chirag Trivedi, CSU Cluster Head, India-South East Asia

Hereinafter the "SPONSOR"

The INVESTIGATOR, the INSTITUTION, the SMO and the SPONSOR are hereinafter individually referred to as a "Party" or collectively referred to as the "Parties".

WITNESSETH:

WHEREAS, the SPONSOR is to perform a ~~clinical~~ **A randomized, double-blind, placebo-controlled, parallel group, multicenter, comparative study to assess the efficacy and safety of spores of Enterogermina in combination with oral rehydration therapy (ORT) and Zinc versus placebo in combination with ORT and Zinc administered for 5 days in the treatment of acute diarrhea in children** (hereinafter the « Study ») to evaluate Sanofi drug **Enterogermina® /Bacillus clausii /SSR29263** (hereafter the «Investigational Medicinal Product») in accordance with a protocol entitled KIDDIE/LPS14914 and its amendments (hereinafter collectively the « Protocol»), and

WHEREAS, the INSTITUTION is a Hospital known for its medical excellence, having the highest caliber faculty, high class education, research and patient care;

WHEREAS the INVESTIGATOR is a doctor attached to the INSTITUTION and is specialized in the field of Pediatrics, and

WHEREAS, the SMO is a site management organization which specializes in providing the services of clinical research coordinators, management of funds of the INSTITUTION at the clinical studies/trials sites and has accordingly provided the SPONSOR a certificate, a copy of which is attached hereto as "Annexure 1", and

WHEREAS, the SPONSOR shall have no liability whatsoever arising out of selection and appointment of SMO and payments made to the SMO, including but not limited to any claims, demands, actions, causes of action, judgments, damages, expenses and costs, including attorney's fees, which arise out of, result from, occur during or are connected in any

ATTESTED

Dr. V.A.Kothiwale .
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

manner with the Study or any related activities or Investigator meetings, irrespective of whether or not they are sponsored, supervised or controlled by the SPONSOR, except such liability arising directly and solely from gross negligence on the part of the SPONSOR, and

WHEREAS, the INSTITUTION, the INVESTIGATOR and the SMO having each reviewed the Protocol for the Study, the Clinical Investigator Brochure and sufficient information regarding the Investigational Medicinal Product to evaluate their interest in participating in the Study, wish to participate in the Study and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Study, and

WHEREAS the INVESTIGATOR is responsible for ensuring that the Ethics Committee is registered before starting the Study;

WHEREAS, the "Subject" means an individual who is selected in accordance with the terms of the Protocol to participate in the Study.

In consideration of the undertakings and commitments set forth herein, the Parties agree to enter into the Contract, which provisions shall apply in compliance with those of the Protocol.

ARTICLE 1. PROTOCOL.

INVESTIGATOR/INSTITUTION/SMO shall perform the Study in strict compliance with the Protocol and a copy of the same has been provided and signed by the INVESTIGATOR and is submitted to the relevant Independent Ethic Committee («IEC/IRB»)/ Regulatory Authority («RA»)/Competent Authority («CA») for favorable opinion/approval and as the Protocol may be amended from time to time thereafter.

Any amendment to the Protocol shall be notified to the relevant IEC/IRB/RA/CA according to local regulations. All of the terms of the Protocol and any further amendments to the Protocol are incorporated hereunder and are part of the Contract.

To the extent that there may be any inconsistency between this Contract and the Protocol, this Contract shall control, except with respect to medical or clinical matters, for which the provisions of the Protocol shall take precedence.

ARTICLE 2. STUDY SITE.

The Study shall be performed at the INSTITUTION KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belguam-590010, Karnataka, India. (hereafter the «Study Site»). The INVESTIGATOR and the SMO shall be responsible for obtaining any authorization from the representatives of the Study Site where the Study is performed.

For the avoidance of doubt, the sums paid under Exhibit 1 of the Contract to the INVESTIGATOR and/or the INSTITUTION and/or the SMO include global compensation for the performance of the Study carried out at the Study Site.

The INVESTIGATOR hereby represents, warrants and covenants that he/she has and shall maintain all necessary authorizations from the Study Site representatives to perform the Study and that he/she shall take responsibility for the payment of any cost incurred by the Study Site in connection with the Study, the amount and terms of which shall be directly and exclusively handled by the INVESTIGATOR and the Study Site.

For the purpose of the Contract, the term «Collaborators» shall mean any person involved in the Study including but not limited to associates, sub-investigators, biologists, assistants and nurses.

The INVESTIGATOR shall bind the Collaborators with obligations at least as stringent as those provided for in the Contract. Therefore, the INVESTIGATOR shall be held liable should any of the Collaborators fail to comply with any of the obligations provided for in this Contract.

It is agreed among the Parties that the INVESTIGATOR shall attend the mandatory training session(s) organized in relation with the Study. The Parties further agree to inform each other of the Study performance and discuss Study results and therefore agree to organize and to participate in meetings to be held at places and locations to be determined by SPONSOR as well as

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

participating in face to face meetings and teleconferences organized by the SPONSOR at its own expense in relation to the Study. Any and all travel arrangement, meeting arrangement, accommodation etc. for such meetings shall be done by the SPONSOR.

ARTICLE 3. COMPLIANCE.

3.1 The Study shall be performed in accordance with (i) the Protocol (ii) all applicable Central, State and Local laws, rules and regulations in India including the Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research and the Indian GCP Guidelines (iii) the Guideline for Good Clinical Practice of the International Conference on Harmonization (hereinafter the «ICH – GCP»), (iv) the principles laid down by the 18th World Medical Assembly (Helsinki, 1964) and all applicable amendments laid down by the World Medical Assemblies, and (v) the specific procedures provided by the SPONSOR applicable for conducting the Study.

3.2 The INVESTIGATOR, the INSTITUTION and the SMO shall ensure that all procedures defined in the Protocol are complied with, so that all data coming from the Study Site are reliable and have been processed correctly (especially the randomization lists, and the blind character of the Study as the case may be) and will ensure that the content of the case report form (CRF) / electronic case report form (e-CRF) will accurately reflect source documents.

3.3 The INVESTIGATOR and the INSTITUTION shall submit CRF/eCRFs to the SPONSOR.

The INVESTIGATOR and any Collaborator (as such term is defined at Article 5.2) will be trained by the SPONSOR with respect to the use of eCRFs.

3.4 The INVESTIGATOR, the INSTITUTION and the SMO shall submit CRF/eCRFs to the SPONSOR. If needed, the SPONSOR will provide the INVESTIGATOR and/or the INSTITUTION with a computer and/or internet connection in order to submit eCRFs for the Study. The INVESTIGATOR and any Collaborator (as such term is defined at Article 2) will be trained by the SPONSOR with respect to the use of eCRFs. Before the training process, the INVESTIGATOR, each Collaborator and the representative of the INSTITUTION/the SMO shall acknowledge statements of understanding and acceptance of their obligations regarding the eCRF process.

ARTICLE 4. TERM.

This Contract is being entered into force from **16th October 2019** (“the Effective Date”) and shall expire upon receipt by the SPONSOR of all data generated by the INVESTIGATOR and after completion of the close-out visit for the Study Site.

The Parties estimate that the whole Study will take 13 (thirteen) months from the first visit of the first Subject to the last visit of the last Subject.

ARTICLE 5. ITEMS SUPPLIED BY THE SPONSOR.

5.1 The SPONSOR shall provide directly or indirectly the INVESTIGATOR, the INSTITUTION and the SMO with all necessary information, documents and materials, including but not limited to :

- the Investigator Brochure (IB) / SmPC data
- the Protocol,
- the Informed Consent Form
- the CRF/e-CRF
- the Investigational Medicinal Product manufactured in accordance with the applicable regulations and/or the Good Manufacturing Practice (GMP), suitably packaged and labeled and in sufficient quantity to conduct the Study.

5.2 The INVESTIGATOR, the Collaborators, the SMO and the INSTITUTION shall use the information, documents and Investigational Medicinal Product provided by the SPONSOR, solely for the purpose of the Study as per Protocol requirements, or to fulfill their own regulatory obligations, to the exclusion of any use for their own or for a third party's account.

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

5.3 The INVESTIGATOR shall bind the Collaborators with obligations at least as stringent as those provided for in the Contract. Therefore, the INVESTIGATOR shall be held liable should any of the Collaborators fail to comply with any of the obligations provided for in this Contract.

5.4 Unless otherwise instructed by the SPONSOR or required by applicable laws and regulations, the information, documents and Investigational Medicinal Product shall be returned or made available to the SPONSOR upon completion of the Study.

The Investigational Medicinal Product will not be made available to the investigator until the SPONSOR has received a copy of the written and dated approval/opinion of the IEC/IRB/RA/CA.

5.5 Should the Study require the use of a specific material, the SPONSOR (or its designee) may provide such material to the INVESTIGATOR and/or the INSTITUTION and/or the SMO under conditions (reference of the material, quantities, conditions of restitution, etc.) detailed in a separate agreement.

5.6 The INVESTIGATOR, the INSTITUTION and the SMO or its designee shall ensure that an accurate record of the quantity of Investigational Medicinal Product received and dispensed to each Subject is maintained. The INVESTIGATOR/INSTITUTION/SMO shall ensure that the Investigational Medicinal Product is stored and dispensed in accordance with the SPONSOR's specifications and applicable laws and regulations.

5.7 The INVESTIGATOR/INSTITUTION and the SMO agree to take responsibility for the safeguarding of such materials and to notify the SPONSOR promptly in case of any loss damage, or failure of these materials.

5.8 Upon termination or completion of the Study, all unused Study Drug, compounds, drugs devices, case report forms, whether or not completed, and other related materials that were furnished to the INVESTIGATOR/INSTITUTION and the SMO by or on behalf of the SPONSOR shall be returned to the SPONSOR.

ARTICLE 6. SUBJECTS RECRUITMENT.

6.1 The INVESTIGATOR has estimated that he/she can recruit a maximum of **85 (Eighty Five)** Subjects, within **12 (Twelve)** months. This target of recruitment can be increased only upon written agreement of the SPONSOR. In addition, the SPONSOR may establish a threshold number of Subjects and rate of accrual of Subjects to allow for appropriate monitoring of the Study and will communicate this information to the INVESTIGATOR. The INVESTIGATOR undertakes to comply with these limitations and conditions for further recruitment at the Study Site as required by the SPONSOR.

6.2 A minimum of one (1) Subject must be enrolled within two (2) months of initiating the Study at the Study Site. Subsequently, if no Subjects are enrolled over a period of three (3) months, or if the INVESTIGATOR cannot begin the Study at the Study Site, the SPONSOR may decide at its discretion to discontinue the Study at the Study Site.

6.3 Especially in case of multicenter studies, the SPONSOR reserves the right to request the INVESTIGATOR to limit the recruitment of further Subjects or cease the recruitment, notably in case the global recruitment target for the Study has been reached. In such case, the SPONSOR shall inform the INVESTIGATOR to stop the recruitment of any subject who has not yet signed the Informed Consent. The INVESTIGATOR shall upon receipt of the notice stop immediately further recruitment of Subjects. Payments shall only be made according to the number of Subjects recruited up to the date of receipt of the notice. The SPONSOR will not take any responsibility and make any payment for the Subjects recruited after this date.

ARTICLE 7. CONSENT OF THE SUBJECTS.

7.1 Before any Subject's participation in the Study, the INVESTIGATOR shall fully inform any Subject and/or, as the case may be, her/his legal representative, in language understandable to them, of all pertinent aspects of the Study in accordance with the requirements stipulated under Indian laws/regulations (Article 3.1). The Privacy Rules of each country shall be followed in order to obtain consent from Subjects as required throughout the Study.

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

7.2 The INVESTIGATOR shall ensure that all Subjects participating in the Study and /or their legal representative (i) have received a copy of the Subject information leaflet, and (ii) have expressed their prior consent by signing the Informed Consent Form, in such format as approved by DCGI or Other Authority, without the undue influence or coercion of any person directly involved in the Study, and only after having been duly informed.

ARTICLE 8. MONITORING OF THE STUDY.

8.1 The SPONSOR shall appoint monitor(s), bound by a professional confidentiality obligation, who will work with the INVESTIGATOR, the INSTITUTION and the SMO to ensure proper conduct of the Study (hereinafter the «Monitor(s)»). The INVESTIGATOR, the INSTITUTION and the SMO agree to fully cooperate with the SPONSOR's monitoring procedures and maintain all necessary patient information.

8.2 The Monitor shall be entitled to visit the Study Site and be regularly informed about the performance of the Study and shall collect all the documents and information about the Study in accordance with the Protocol and the ICH-GCP. He/she shall have access to all records on the Subjects and all information pertaining to the Study, as well as, copies thereof, if needed.

ARTICLE 9. DUTY OF INFORMATION.

The INVESTIGATOR, the INSTITUTION and/or the SMO shall immediately inform the SPONSOR of any Serious Adverse Event («SAE») or other events as defined in the Protocol.

ARTICLE 10. FINANCIAL TERMS AND CONDITIONS.

10.1 As consideration for the proper performance by the INVESTIGATOR, the INSTITUTION and the SMO of their obligations under the Contract, the SPONSOR shall pay the PAYEE as directed by the INVESTIGATOR and/or the INSTITUTION and/or the SMO in compliance with the payment terms defined in Exhibit 1. Payment terms may be modified only upon prior written consent of the Parties. Likewise, non-emergency additional tests or services (tests or services non-required by the Protocol or performed in excess of Protocol requirement) shall not be reimbursed hereunder without the prior written consent of the SPONSOR.

10.2 Out of pocket expenses authorized in advance by the SPONSOR that have been provided for in Exhibit 1 shall be reimbursed to the PAYEE as directed by the INVESTIGATOR and/or the INSTITUTION (without any mark-up) within 30 (thirty) days on receipt by the SPONSOR of an itemized invoice on the Letter Head of the PAYEE.

10.3 The PAYEE will bear the responsibility for the declaration of these sums and for the payment of all taxes and social contributions on the fees it will receive hereunder.

10.4 Fees/reimbursement of costs to the INVESTIGATOR and/or the INSTITUTION by the PAYEE will be an internal arrangement among themselves and the SPONSOR will not be liable to pay/reimburse any amount to the INVESTIGATOR and/or the INSTITUTION.

ARTICLE 11. CONFIDENTIALITY AND RESTRICTED USE.

11.1 All information disclosed or provided by the SPONSOR or produced during the Study, including but not limited to the Protocol, the Investigator's Brochure and CRF/e-CRF, the results obtained during the course of the Study, the financial terms of the Contract (hereafter the «Confidential Information »), is confidential. The INVESTIGATOR, the INSTITUTION and the SMO agree to keep confidential and not to disclose the Confidential Information to any third party without the prior written approval of the SPONSOR. The INVESTIGATOR, the INSTITUTION and the SMO shall use the Confidential Information solely for the purposes of the Study.

Furthermore, the Parties agree to adhere to the principles of personal data confidentiality in relation to the Subjects, the INVESTIGATOR, the INSTITUTION, the SMO and Collaborators involved in the Study. Each Collaborator shall be subject to these obligations of confidentiality and restricted use.

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

The INVESTIGATOR shall inform the Collaborators of the confidential nature of the Study and will only provide them with the information that is strictly necessary for the accomplishment of their acts.

11.2 Confidential Information shall not include information that: (1) is at the time of disclosure, or thereafter becomes, publicly available through no fault of the INVESTIGATOR/ INSTITUTION/SMO; (2) is disclosed to the INVESTIGATOR/INSTITUTION/SMO by a third party entitled to disclose such information in a non-confidential manner; (3) is known to the INVESTIGATOR/INSTITUTION/SMO prior to disclosure under this Contract, as shown by the INVESTIGATOR'/INSTITUTION's/SMO's prior written records; (4) can be documented to have been independently developed by Study Site's personnel without reliance on Confidential Information; or (5) is required by applicable law to be disclosed, provided that the INVESTIGATOR/INSTITUTION/SMO gives the SPONSOR prompt notice of such fact so that it may obtain a protective order or other appropriate remedy concerning any such disclosure, cooperate fully with the SPONSOR in connection with its efforts to obtain any such order or other remedy, and disclose, where disclosure is necessary, only the information legally required to be disclosed.

11.3 The obligations of confidentiality and restricted use contained herein are applicable during the term of the Contract and shall survive for 10 (ten) years from its date of termination, whether by expiration or by early termination.

ARTICLE 12. RECORD RETENTION.

The INVESTIGATOR and the INSTITUTION through the Study Site shall retain and preserve one (1) copy file containing the essential documents related to the Study and records generated during the Study ("**Study File**") for the longest of the two following periods (**the «Retention Period»**):

- Twenty-five (25) years after the signature of the final Study report or,
- Such longer period as required by applicable regulatory requirements.

The SPONSOR must be informed in writing of any change of address or relocation of the Study files and of the INVESTIGATOR /the INSTITUTION/the SMO during this period.

If during the Retention Period, the INSTITUTION/the SMO is no longer able to retain the Study File due to exceptional circumstances (such as bankruptcy), the INSTITUTION/the SMO shall contact the SPONSOR to organize the transfer of the Study File to the SPONSOR at the SPONSOR's expense.

Following the Retention Period, as instructed by the SPONSOR, the INVESTIGATOR and/or the INSTITUTION and/or the SMO will either forward such records to the SPONSOR at the SPONSOR's expense, retain such records for a reasonable additional charge to be negotiated, or destroy the records, and send to the SPONSOR proof of such destruction. Subject files should be retained as per GCP requirements as defined in the Protocol and in compliance with local regulations.

ARTICLE 13. PERSONAL DATA PROTECTION.

13.1 The Subject data and specific data regarding the INVESTIGATOR, the INSTITUTION, the SMO and Collaborators which may be collected by the SPONSOR and included in the SPONSOR's databases, shall be treated by both Parties in compliance with all applicable laws and regulations. These data may be transferred by the SPONSOR or its representative to Regulatory Authorities or to the SPONSOR's representative located in a country where there is no personal data protection law, or where the level of protection imposed by local law is less stringent than requirements of the European Union under which Sanofi is governed.

13.2 As data controller, when processing or archiving data pertaining to the INVESTIGATOR, the INSTITUTION, the SMO, the Collaborators and/or the Subjects, the SPONSOR shall take all appropriate measures to safeguard and prevent access to this data by unauthorized third party.

13.3 The INVESTIGATOR, the INSTITUTION, the SMO, the Collaborators and/or the Subjects have the right to access and, where appropriate, to request the rectification and/or deletion of their personal data by sending a written notice to the address of the SPONSOR, to the attention of the Data Privacy/Compliance officer Dr. Chirag Trivedi (e-mail: chirag.trivedi@sanofi.com). Deletion of data is possible only for justifiable reason and if it is not required by law to keep it. **ATTESTED**

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

ARTICLE 14. PUBLICATIONS AND COMMUNICATIONS.

14.1 The INVESTIGATOR, the INSTITUTION and the SMO undertake not to make any publication or release pertaining to the Study and/or results of the Study without the SPONSOR's prior written consent, being understood that the SPONSOR will not unreasonably withhold its approval.

As the Study is being conducted at multiple sites, the SPONSOR agrees that, consistent with scientific standards, first presentation or publication of the results of the Study shall be made only as part of a publication of the results obtained by all sites performing the Study.

However, if no multicenter publication has occurred within twelve (12) months following the completion of the Study at all sites, the INVESTIGATOR shall have the right to publish or present independently the results of the Study subject to the review procedure set forth herein.

The INVESTIGATOR shall provide the SPONSOR with a copy of any such presentation or publication derived from the Study for review and comment at least thirty (30) days in advance of any presentation or submission for publication. In addition, if requested by the SPONSOR, any presentation or submission for publication shall be delayed for a limited time, not to exceed ninety (90) days, to allow for filing of a patent application or such other measures as the SPONSOR deems appropriate to establish and preserve its proprietary rights.

14.2 The INVESTIGATOR, the INSTITUTION and the SMO shall not use the name(s) of the SPONSOR and/or of its employees in advertising or promotional material or publication without the prior written consent of the SPONSOR. The SPONSOR shall not use the name(s) of the INVESTIGATOR, the INSTITUTION, the SMO, and/or the Collaborators in advertising or promotional material or publication without having received their prior written consent(s).

14.3 The SPONSOR has the right at any time to publish the results of the Study.

ARTICLE 15. PROPERTY RIGHTS.

15.1 All information, documents, materials (hereinafter collectively «Information») and Investigational Medicinal Product provided by the SPONSOR are and shall remain the sole and exclusive property of the SPONSOR or its designee.

15.2 The INVESTIGATOR, the INSTITUTION and the SMO shall not themselves and/or shall not permit any of its Collaborators to mention any Information or the Investigational Medicinal Product in any application for a patent or any other intellectual property rights whatsoever.

15.3 All the results, data, documents, discoveries and inventions which arise directly or indirectly from the Study in any form, shall be the immediate and exclusive property of the SPONSOR or its designee. For this purpose, the INVESTIGATOR, the Collaborators and the INSTITUTION presently assign to the SPONSOR (or its designee) all intellectual property rights (including all patents, copyrights, databases and any application or right to apply for registration of any of those rights) which may arise directly or indirectly from the Study and all existing or future materials created in relation to the Study.

15.4 The SPONSOR may use or exploit all the results at its own discretion, without any limitation to its property right (territory, field, continuance...), and without any additional payment. The SPONSOR shall be under no obligation to patent, develop, market or otherwise use the results of the Study, issued under this Contract.

15.5 As the case may be, the INVESTIGATOR, the INSTITUTION, the SMO and/or the Collaborators shall provide all assistance required by the SPONSOR, at the SPONSOR's expense, for obtaining and defending any patent, including signature of all legal documents.

ARTICLE 16. LIABILITY – INDEMNIFICATION – INSURANCE.

16.1 In accordance with Rule 122-DAB of the Drugs & Cosmetics Rules, 1945 in the event of injury to or death of a Subject during the Study, the following shall apply:

- (1) In the case of an injury occurring to the Subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010 Karnataka

(2) In case the injury occurring to the Subject is related to the Study, such Subject shall also be entitled for financial compensation as determined by the Licensing Authority under the said Rules over and above the expenses incurred on the medical management of the Subject;

In case, there is no permanent injury, the quantum of compensation shall be commensurate with the nature of the non-permanent injury and loss of wages of the subject;

(3) In the case of Study related death of the Subject, his/her nominee(s) would be entitled for financial compensation as per the order of the Licensing Authority and the financial compensation will be over and above any expenses incurred on the medical management of the Subject;

(4) The expenses on medical management and financial compensation in the case of Study related injury or death of the Subject shall be borne by the SPONSOR;

(5) Any injury or death of the Subject occurring in the Study due to the following reasons shall be considered as Study related injury or death and the Subject or his/her nominee(s), as the case may be will be entitled for financial compensation for such injury or death :

- (a) adverse effect of the Investigational Medicinal Product;
- (b) violation of the Protocol, scientific misconduct or negligence by the SPONSOR or the INVESTIGATOR, Provided that if such violation of the Protocol, scientific misconduct or negligence is by the INVESTIGATOR, then the INVESTIGATOR will be liable to reimburse to the SPONSOR the expenses on such medical management and financial compensation that the SPONSOR shall have paid to the Subject or his/her nominee(s), as the case may be;
- (c) failure of the Investigational Medicinal Product to provide intended therapeutic effect; where the standard care, though available, was not provided to the subject as per the clinical trial protocol;
- (d) use of placebo in a placebo-controlled trial; where the standard care, though available, was not provided to the subject as per the clinical trial protocol;
- (e) adverse effects due to concomitant medication excluding standard care, necessitated as part of the Protocol;
- (f) for injury to a child in-utero because of the participation of parent in the Study;
- (g) any clinical trial procedures involved in the Study.

16.2 The SPONSOR certifies it has subscribed a liability insurance policy to cover its liability as required by applicable law. The SPONSOR will provide the INVESTIGATOR and/or the INSTITUTION with a certificate of insurance in the countries where this document is required.

16.3 The insurance subscribed by the SPONSOR does not release either the INVESTIGATOR or the INSTITUTION from their obligation to maintain their own liability insurance policy.

16.4 The SPONSOR agrees to indemnify, hold harmless and defend the INVESTIGATOR, the INSTITUTION, and Collaborators (« Indemnities ») from and against any and all claims and suits, including reasonable attorneys' fees incurred in the defence thereof, arising out of an injury to a Subject (including death) caused by the administration of the Investigational Medicinal Product or the performance of any procedure required under the Protocol, except to the extent such claim or suit is attributable to:

- (1) a failure to adhere to the terms of this Contract, the Protocol or any written instructions from the SPONSOR regarding the administration of the Investigational Medicinal Product or the performance of any required procedure; or
- (2) a failure to comply with any applicable laws, regulations and government requirements (including, without limitation, obtaining informed consents); or
- (3) the negligence or willful malfeasance of the Indemnities.

The SPONSOR shall have no obligation under this Article, however, unless: (i) the SPONSOR is promptly notified of any such claim or suit; (ii) the Indemnities cooperate fully in the handling thereof; and (iii) the SPONSOR has sole control over the disposition of such claim or suit, including

ATTESTED


Dr. V.A. Kothiwale
Registrar

the selection of counsel and any settlement thereof, provided, however, that no settlement shall include an admission of liability on the part of the Indemnities without their prior written consent, which consent shall not be unreasonably withheld.

ARTICLE 17. AUDITS AND INSPECTIONS.

17.1 For the purpose of ensuring compliance with the Protocol, Good Clinical Practice ("GCP") and applicable regulatory requirements, the INVESTIGATOR and/or the INSTITUTION / the SMO/ PAYEE shall permit inspections, investigations and audits by or on behalf of the SPONSOR subject to the provisions below, and inspections by any health or regulatory authority, including, but not limited to, European Medicines Agency and U.S. Food and Drug Administration ("Regulatory Authorities"). The INVESTIGATOR and the INSTITUTION/ the SMO/PAYEE shall prepare for the abovementioned investigations, audits and inspections in cases where they are informed in advance, and shall make their best efforts to facilitate their conduct.

17.2 The INVESTIGATOR agrees to allow the auditors and/or inspectors to have direct access to his/her Study records and to Subjects files for review, being understood that this personnel is bound by professional secrecy, and as such will not disclose any personal identity or personal medical information.

17.3 The INVESTIGATOR, the INSTITUTION and the SMO shall devote their best efforts to facilitate the performance of any audit, investigations and inspection and shall give to the SPONSOR or to any person designated by the SPONSOR access to all necessary facilities, data and documents.

17.4 As soon as the INVESTIGATOR, the INSTITUTION and/or the SMO is notified of an inspection by any Authorities which is related to the Study or may affect its conduct, they shall, to the extent permitted by applicable regulations or the relevant Regulatory Authorities (i) promptly inform the SPONSOR of the inspection (ii) prepare for such inspections in collaboration with the SPONSOR (iii) provide in advance the SPONSOR, for review and comment, with any draft of written answer to a question of an Authority, (iv) authorize the SPONSOR to participate to the aforementioned inspections, (v) provide the SPONSOR with a copy of any and all documents given to, sent or collected by the Authorities in the framework of said inspections, and (vi) provide the SPONSOR with any reports, result or analyses issued by the Regulatory Authorities in the framework of said inspections.

17.5 The INVESTIGATOR, the INSTITUTION and the SMO shall take appropriate measures required by the SPONSOR to take corrective actions without delay in order to solve all problems found during the audits, investigations or inspections.

17.6 It is expressly agreed between the Parties that the SPONSOR will not compensate the INVESTIGATOR/INSTITUTION/SMO for the audits, investigations and inspections and that the assistance and availability of the INVESTIGATOR/INSTITUTION/SMO for the audits, investigations and inspections is included in the amount mentioned in Exhibit 1.

17.7 The rights and obligations under this Article shall remain in effect for **25 (Twenty Five)** years after the end of the Study.

ARTICLE 18. TERMINATION OF THE CONTRACT.

18.1 This Contract may be terminated: (1) by a joint decision of the INVESTIGATOR/the INSTITUTION and the SMO upon thirty (30) days prior written notice if the Study Site or the INVESTIGATOR for any reason becomes unable to perform or complete this Study; or (2) by the SPONSOR upon thirty (30) days prior written notice.

18.2 In the event this Contract is terminated, the SPONSOR will be responsible for compensating the INVESTIGATOR and/or the INSTITUTION and/or the SMO for actual activities performed hereunder in accordance with the terms of this Contract and reasonable non-cancellable expenses incurred prior to notice of termination if such expenses were required under the Protocol and contemplated within Exhibit 1. Any funds paid in advance will be prorated and any excess funds will be returned to the SPONSOR. The INVESTIGATOR shall provide the SPONSOR with all documentation required by the Protocol and applicable laws and regulations and any equipment

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

provided by the SPONSOR in connection with the Study no later than ninety (90) days after the completion or early termination of the Contract.

18.3 The terms and conditions of Articles 3; 11; 12; 13; 14; 15; 16; 17; 19; 20, 21 and 22 shall survive the expiration or earlier termination of this Contract.

ARTICLE 19. DEBARMENT AND SENTENCING FOR MALPRACTICE.

19.1 The INVESTIGATOR, the INSTITUTION and the SMO represent and warrant that neither the INVESTIGATOR/INSTITUTION/SMO nor any Collaborators involved in conducting the Study or any member of the staff of the INSTITUTION/SMO has been debarred, excluded, disqualified or restricted in their ability to practice medicine, participate in a clinical trial/studies, or perform services in connection with the evaluation of a pharmaceutical product under any laws, regulations or professional code of conduct including without limitation United States 21 U.S.C. §335a and 21 CFR §312.70.

19.2 The INVESTIGATOR and/or the INSTITUTION and/or the SMO shall immediately notify the SPONSOR should he/she/it or any Collaborators involved in conducting the Study, be so debarred, excluded, disqualified or restricted, or should a procedure or action be initiated against any of them that could result in their being so debarred, excluded, disqualified or restricted, at any time during the term of this Contract and during the twelve (12) months following the expiration or termination of the Contract.

ARTICLE 20. FINANCIAL DISCLOSURE – TRANSPARENCY – CONFLICT OF INTEREST.

20.1 The INVESTIGATOR, the INSTITUTION/ the PAYEE and the Collaborators involved in this Study at the INVESTIGATOR's Study Site, shall ensure that they provide the SPONSOR with the appropriate financial disclosures required for compliance with 21 CFR Part 54, on such forms as the SPONSOR may supply or approve.

During the term of this Contract and for one (1) year following termination or completion of the Study, the INVESTIGATOR, the INSTITUTION and the SMO shall promptly notify the SPONSOR of any material change in the information disclosed on a previous form.

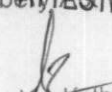
20.2 In the interest of transparency relating to the SPONSOR's financial relationships with the INVESTIGATOR/INSTITUTION/SMO, the SPONSOR may collect, publicly disclose, and communicate to relevant authorities/institutions, the funding, including payments made to the INVESTIGATOR/INSTITUTION/SMO and payments made to individuals, and/or any direct or indirect advantages and/or or any related information or document associated with this Contract, if required by applicable law.

20.3 The INVESTIGATOR represents and warrants to the SPONSOR that he/she:

- (a) is not bound, at the date of signature of this Contract, by any obligation or commitment to a third party, including any legal entity of which he/she is an employee or to which he/she refers, that could conflict with the terms of this Contract and
- (b) will not knowingly enter into any agreement with a third party that would in any way prevent him/her from participating as an investigator in the Study or could conflict with the terms of this Contract.

ARTICLE 21. ANTI-BRIBERY.

21.1 The INVESTIGATOR, the INSTITUTION and the SMO represent and warrant that they have not accepted nor been offered any payment of money or other assets, or anything of value, for the purpose of influencing their decisions or actions to help the SPONSOR obtain or maintain business or obtain a business advantage where such payment or advantage would constitute violation of any applicable anti-bribery legislation, regulations and/or codes, both national and foreign, including but not limited to, the US Foreign Corrupt Practices Act and the UK Bribery Act (hereinafter and above designated by "Anti-Bribery Provisions").

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

21.2 The INVESTIGATOR, the INSTITUTION and the SMO further represent and warrant that they have not made and agree that they shall not make any payment or any offer or promise for payment, either directly or indirectly, of money or other assets, or transfer anything of value, to government or political party officials, officials of international organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing for the purpose of influencing decisions or actions or where such payment or advantage would constitute violation of any applicable Anti-Bribery Provisions.

ARTICLE 22. MISCELLANEOUS.

22.1 The Protocol, the Contract and all others documents exchanged between the Parties constitutes the whole undertaking of the Parties. All appendices attached hereto shall be deemed to be incorporated herein.

22.2 Any work performed by the INVESTIGATOR, the Collaborators and/or the INSTITUTION and/or the SMO under this Contract shall be considered to be performed by them as independent contractors and not as employees, partners or agents of the SPONSOR. No Party shall have the authority, either express, implied or apparent, to bind the other Party, except to the extent that same may be consistent with the performance of that Party's obligations in accordance with the terms of this Contract.

22.3 Except as otherwise expressly mentioned hereinabove, any notification shall be made by mail or fax.

22.4 If either Party is prevented from fulfilling its obligations in accordance with the terms of this Contract due to force majeure (as defined by applicable law and/or competent court), this Party shall be released from performance to the extent that it is so prevented from doing so for the duration of the intervening circumstances. The Party wishing to claim relief on the grounds of the said circumstances shall notify the other Party in writing without delay on the intervention or cessation thereof. The Party so prevented from fulfilling its obligation shall devote its best endeavors to remove or avoid the impediment as soon as possible. If the Party is prevented from fulfilling its obligations under this Contract due to force majeure for a period exceeding two (2) running months, each Party shall have the right to terminate this Contract by registered mail with acknowledgment of receipt. The termination will become effective forthwith.

22.5 No indulgence granted by either Party to the other in relation to any term hereof shall be deemed a waiver of such term or prejudice the later enforcement of that or any other term hereof.

22.6 Should a provision of this Contract in any manner whatsoever contravene any applicable laws and regulations, such provision shall be deemed to be severable and shall not affect any other provision of this Contract, nor affect the enforceability of those remaining provisions which are not in contravention of any law and regulation.

22.7 The Contract is concluded by the SPONSOR *intuitu personae*. Hence, the INVESTIGATOR, the INSTITUTION and the SMO shall not be allowed to transfer totally or partially the obligations the SPONSOR charged them with, nor to subcontract them without the prior written consent of the SPONSOR. The INVESTIGATOR, the INSTITUTION and the SMO shall, where applicable, transmit to the Collaborators the Contract and shall cause them to abide by its terms and conditions. The SPONSOR may transfer this Contract to an affiliate company or to a successor in interest to its business by reason of any merger, acquisition, partnership, license agreement or otherwise, provided that the assignee is subject to the terms and obligations provided in this Contract. For use herein, affiliated company shall mean Sanofi (B 395 030 844 R.C.S. PARIS, hereinafter "SANOFI") and any legal entity which controls SANOFI, is controlled by SANOFI or is under common control with SANOFI. "Control" means the ownership directly or indirectly of at least fifty percent (50%) of the capital stocks or the voting rights of such entity.

22.8 This Contract constitutes the entire agreement between the Parties relative to the subject matter hereof and supersedes all representations, warranties, agreements or undertakings previously made relative to such subject matter, and no such representations, warranties, agreements or undertakings shall be in any force and effect unless contained herein. No variation of any terms and conditions of this Contract will be binding upon the Parties unless committed in writing and signed by them respectively.

ATTESTED

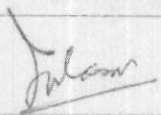
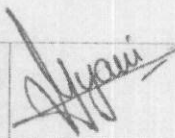


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

22.9 This Contract shall be governed by the law of India. Prior to taking any legal action, the Parties shall endeavor to settle by amicable arrangement any disputes arising between them regarding this Contract. Should the Parties fail to reach an amicable settlement, the Parties agree to submit to the exclusive jurisdiction of the courts of Mumbai and the Parties waive any other forum to which they may be entitled by reason of their present or future address or for any other reason.

IN WITNESS WHEREOF, the Parties hereto have caused this Contract to be duly executed on their behalf in four counterparts, each of which shall be deemed to be an original, as of the Effective Date.

SANOFI-SYNTHELABO (INDIA) PRIVATE LIMITED (SPONSOR)		INVESTIGATOR	
[Signature]		[Signature]	
[Name]	Dr. Chirag Trivedi	[Name]	Dr. Mahantesh V. Patil
[Title]	CSU Cluster Head, India-South East Asia	[Title]	Principal Investigator
In presence of		In presence of	
[Signature]		[Signature]	
[Name]	S. S. Parab	[Name]	Shrutika H

KLEs DR. PRABHAKAR KORE HOSPITAL & MEDICAL RESEARCH CENTRE (INSTITUTION)		GDD EXPERTS INDIA PRIVATE LIMITED (SMO)	
[Signature]		[Signature]	
[Name]	Dr. M. V Jali	[Name]	Dr. Vinod Gyanchandani
[Title]	Medical Director	[Title]	Head Clinical Operations
In presence of		In presence of	
[Signature]		[Signature]	
[Name]	Revana Soevaniti	[Name]	Rajani Asundi

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

EXHIBIT 1

CONDITIONS OF PAYMENT

Agreement Effective Date: - 16th October 2019

- 1) The SPONSOR will pay INR.1,00,000/- (Rupees One Lakh only) per Subject included in accordance with the Protocol and who has completed the Study. The said amount is inclusive of audits and inspections compensation as referred to under Article 17.5.

Such amount is divided as follows:


Visits	Visit no.	Per visit cost (INR) (A)	Hospitalization (5 days) (INR) (B)	Patient reimbursement (INR)	Total (INR)
V1/ Screening/ Baseline visit Day 1	V 1	19,000	1,000	1000	21,000
Day 2	V 2	13,000	1,000		14,000
Day 3	V 3	13,000	1,000		14,000
Day 4	V 4	13,000	1,000		14,000
EOT/ Day 5	V 5	15,000	1,000	1000	17,000
EOS/ Day 6	V 6	19,000	-	1000	20,000
		92,000	5,000	3,000	100,000

*In case, the Study Coordinator is to be provided by the SPONSOR, the study coordinator Fees will not be payable to the INSTITUTION/INVESTIGATOR and the same shall not be applicable.

**Unscheduled Visit- This cost does not apply to unscheduled phone calls made to the patients. Also, the unscheduled visit cost will be INR 1,000/- per visit as the maximum payable amount when all tests/procedures are done during unscheduled visit. In case all tests/procedures are not done, the payment will be commensurate to the actual work done by the site during patient's unscheduled visit.

- 2) Cost of local lab tests, if any, shall be paid based on actuals and shall be payable on receipt by the SPONSOR of an itemized invoice. Additional investigations apart from protocol specified investigations will be reimbursed based on proper rationale provided by the INVESTIGATOR and based on verification provided by the SPONSOR.

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Local lab cost workings:

Parameters	Price (INR)
Hemoglobin	1190
Hematocrit	
Red blood cell [RBC] count	
Morphology [if RBC count is abnormal]	
White blood cell [WBC]	
WBC differential	
Neutrophils	
Lymphocytes	
Monocytes	
Eosinophils	
Basophils	
Platelet count	950
Absolute neutrophil count [ANC]	
Blood Chemistry	
Sodium	
Potassium	
Chloride	
Bicarbonate	
Blood urea nitrogen (BUN)	
Creatinine	
Creatinine clearance	
Calcium	
Phosphate	
Total protein	
Albumin	
C-reactive protein	2200

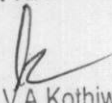
- 3) For screen failure, the SPONSOR will pay INR 2,000/- (Rupees Two Thousand only) per screen failed subject (this is as per the expectation that the screen failure rate is in line with the country screen failure rate).
- 4) Ethics committee's fees, if any, shall be paid on actuals to payee, upon receipt of a valid invoice issued on letterhead of payee and receipt by Sponsor.
- 5) 25% Institutional overheads on aforesaid Point 1 (except Subject reimbursement)
- 6) Monthly admin charges of INR 2,000/- (Rupees Two thousand only) per month will be paid towards stationary, internet, fax, courier and telephone charges from SIV till Study site close out visit.
- 7) A onetime start-up fee of INR. 75,000/- (Rupees Seventy Five thousand only) shall be paid for the time spent for Health Authority documentation, undertaking study specific training, patient identification, Ethics Committee submission, approval activities and shall cover the cost of any study related infrastructure if required. The payment shall be made on the receipt of Ethics Committee approval unless discontinued due to regulatory obligations.
- 8) Sponsor will pay INR 165 (Rupees One Hundred and Sixty Five only) per box per month after the Study Closure to PAYEE for archival and document storage for a period of 25 years from the date of site closure

ATTESTED

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- 9) Concomitant medications that are standard of care for the underlying diseases are not reimbursable.
- 10) Taxes, as applicable, will be paid on generation of valid invoice showing the amount of tax to be charged before any payment is made under this Contract.
- 11) Each payment made shall be inclusive of all applicable taxes and duties except for Goods and Service Tax ("GST") which shall be reimbursed by the SPONSOR to the PAYEE against presentation by the PAYEE of all relevant documentation.

The party who makes a taxable service under or in connection with this Contract shall be entitled to recover such taxes that it is required by law to collect from the other party to whom the services are made by issuing a valid tax invoice in the format prescribed under the relevant law. Notwithstanding anything contrary stated herein in this Contract, the other party to whom the services are made shall not be under any obligation to make any payment until the receipt of the tax invoice. In addition, if the PAYEE fails to upload its return on GSTN portal and is unable to pay GST within prescribed time period, the PAYEE shall indemnify the SPONSOR such GST amount along with applicable interest.

A Subject is considered as having completed the Study when he/she has completed the specified Study period, and is evaluated as per the Protocol.

In case of Subjects recruited but not having completed the Study, the amount to be paid will be calculated according to the fees of the visits actually performed by these Subjects. No payment will be made for an ineligible Subject incorrectly randomized into the Study or in case the Subject did not complete the Study due to negligence, malpractice, breach of Protocol, willfully wrong act or omission on the part of the INVESTIGATOR/INSTITUTION.

The payment for recruited Subjects will be made to the PAYEE on *Quarterly* basis upon presentation of the invoices in Indian Rupees by a bank wire transfer within 30 days (from the receipt of correct Invoice) on the following PAYEE account:

Bank Name & Branch:	AXIS BANK Ltd, M.G. House, Rabindranath Tagore Road, Besides Board Office, Civil Lines, Nagpur- 440001, Maharashtra, India.
Bank IFSC	UTIB0000048
Account No.:	910020034162231
PAYEE:	GDD EXPERTS (INDIA) PVT.LTD.
PAN No.:	AADCG0363Q
GST No.:	27AADCG0363Q1ZA

The final payment will occur only after:

- the delivery and review of the final data of the Study, provided that they shall be ready for statistical analysis;
- the completion of all CRF/e-CRF, including resolution of all Discrepancy Resolution Form/ electronic-Discrepancy Resolution Form "DRF/e-DRF" and after the positive opinion on the part of the SPONSOR regarding their filling;
- receipt of all responses to the DRF from the INVESTIGATOR/INSTITUTION;
- the INVESTIGATOR has returned all remaining Investigational Medicinal Product and applicable study material, if any, in compliance with Article 5).

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

<SMO letterhead>

Annexure 1

TO WHOMSOEVER IT MAY CONCERN

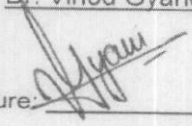
THIS IS TO CERTIFY that GDD Experts India Private Limited is responsible for Clinical Trial Operations/Clinical Studies/Clinical activities / coordination and financial management of Acharya Vinoba Bhave Rural Hospital, Jawaharlal Nehru Medical College, Datta Meghe Institute of Medical Sciences, Sawangi (Meghe), Wardha- 442004, Maharashtra, India. All clinical responsibilities towards patient care has been accordingly subcontracted to GDD Experts India Private Limited who is responsible for such activities on a non-profit basis.

All Clinical Trial Operations/Clinical Studies/Clinical activities / coordination and financial management related money shall be credited to "GDD Experts India Private Limited" as per following details:

Bank Name & Branch:	AXIS BANK Ltd, M.G. House, Rabindranath Tagore Road, Besides Board Office, Civil Lines, Nagpur- 440001, Maharashtra, India.
Bank IFSC	UTIB0000048
Account No.:	910020034162231
PAYEE:	GDD EXPERTS (INDIA) PVT.LTD.
PAN No.:	AADCG0363Q
GST No.:	27AADCG0363Q1ZA

ACKNOWLEDGED AND AGREED BY GDD EXPERTS:

Name: Dr. Vinod Gyanchandani

Signature: 

Date: 19/Nov/2019

Place of Issue: Nagpur

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

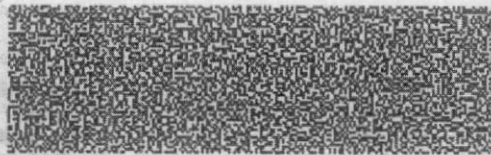
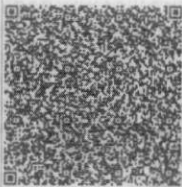
Rs. 100

e-Stamp

Certificate No. : IN-KA34506370229744R
 Certificate Issued Date : 07-Nov-2019 11:54 AM
 Account Reference : NONACC (FI)/ kacrsf108/ BELGAUM30/ KA-BL
 Unique Doc. Reference : SUBIN-KAKACRSFL0887327659172204R
 Purchased by : DR MAHESH KALLOLI
 Description of Document : Article 5(J) Agreement (In any other cases)
 Property Description : AGREEMENT
 Consideration Price (Rs.) : 0
 (Zero)
 First Party : KLES Dr PRABHAKAR KORE HOSPITAL AND MRC BELAGAVI
 Second Party : DR MAHESH KALLOLI
 Stamp Duty Paid By : DR MAHESH KALLOLI
 Stamp Duty Amount(Rs.) : 100
 (One Hundred only)

सत्यमेव जयते

Issued by
 The Judicial Employees
 Co-operative Credit Society Ltd.
 Dist. Court Compound, Belagavi
Pooja
 Authorised Signatory



Please write or type below this line

TO,
 THE MD & CE,
 KLE'S DR.PRABHAKAR KORE HOSPITAL & MRC,
 NEHRU NAGAR, BELAGAVI-590010

**SUBJECT: UNDERTAKING REGARDING HANDLING OF FINANCES FROM THE
 CLINICAL TRIALS AND RESEARCH PROJECT BY DR. MAHESH KALLOLI**

Statutory Alert:

1. The authenticity of this Stamp Certificate should be verified at "www.shclrestamp.com". Any discrepancy in the details of the certificate and as available on the website renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

ATTESTED

k
 Dr. V.A.Kothiwale
 Registrar

KLE Academy of Higher Education and Research,
 (Deemed-to-be-University u/s 3 of the UGC Act.1956)
 Belagavi-590 010,Karnataka

- 1 The Sponsor would like to test the biosimilar namely Trastuzumab Emtansine (TDM1) which will be used in patients with metastatic breast cancer aged 18 to 65 years at the time of enrollment in the study. The Sponsor hereby declares that all the necessary permissions and licenses required under the provisions of relevant Acts and Rules namely Drugs & Cosmetics Act, 1940 and Drug & Cosmetic Rules 1945 and their subsequent amendments (including Schedule Y) will be obtained before the start of the study.
- 2 The Sponsors have approached the Investigator as they desire to perform the study in regards to the said drug in accordance with the Declaration of Helsinki, the Indian Guidelines on Good Clinical Practices and Local Regulations and have accordingly finalized the Clinical Trial Protocol.
- 3 The Principal Investigator hereby confirms that he has read and understood the clinical trial protocol entitled "A Prospective, Randomized, Multicenter, Comparative, Open-label, Parallel study to evaluate the Efficacy, Safety and Pharmacokinetics of Test-Trastuzumab Emtansine (ZRC-3256; Cadila Healthcare Ltd) and Reference-Trastuzumab Emtansine (Kadcyla®, a product of Roche) in HER2- Positive Metastatic Breast Cancer Patients" (Project No. _TDM1.17.001)". All amendments and appendices have also been read and understood. The investigator agrees to the protocol and will perform the study in accordance with the Declaration of Helsinki, the Indian Guidelines on Good Clinical Practices, and applicable laws, rules and regulations.

THE PARTIES AGREE AS FOLLOWS:

4 **Investigators and Research Staff**

- 4.1 **Principal Investigator:** The Study will be conducted by Dr. Maheshkumar Veeranna Kalloli, KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre Nehru Nagar, Belgavi- 590010, India, with registration number **71566**; the Principal Investigator. The Principal Investigator hereby confirms that he is a competent person to sign this agreement on behalf of his sub-investigators and research staff. The terms "Investigator" or "Investigators" as used in this Agreement refers, as applicable, to the Principal Investigator and his sub-investigators and research staff and the Institution.
- 4.2 **Sub-investigators and Research Staff:** Investigator will ensure that only individuals, who are appropriately trained and qualified, assist in the conduct of the Study as sub-investigators or research staff.
- 4.3 **Obligations:** Principal Investigator will ensure that all personnel, who assist in the conduct of the Study, are informed of and agree to abide by all terms of this Agreement applicable to the activities they perform. Principal Investigator is responsible to the Sponsor for compliance by Investigators, with the terms of this Agreement.
- 4.4 **No Substitution:** The Principal Investigator shall not reassign the conduct of the Study to a different Principal Investigator without prior written authorization from the Sponsor.

Page 2 of 12

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- 4.5 **Delegation of Duties by Principal Investigator:** The Principal Investigator may delegate duties and responsibilities to sub-investigators or research staff only to the extent permitted by the relevant laws and regulations governing the conduct of clinical trials in India.
- 4.6 **Compliance with Institutional Policies:** The Principal Investigator will comply with the policies and procedures of the organization/institute with which Principal Investigator is affiliated, including any applicable financial policies. Principal Investigator will notify the Sponsor promptly of any conflict between the terms of this Agreement and any such policy or procedure, and the parties will attempt to reach an appropriate accommodation
- 4.7 **Audit:** The Principal Investigator will make necessary arrangement for inspection of documents etc. by Sponsor's monitor, official of regulatory agency.
- 5 **Funding:** The conduct of the study will not impose any financial burden on the Principal Investigator or the Institution. The Sponsor declares to bear all the expenses pertaining to the conduct of the study.
- 5.1 **Financial Support for Clinical Trial:** The details of the financial support to investigators and the budget sheet are attached in Annexure A hereunder:
- 6 **Protocol:** Investigator will conduct the Study in accordance with the Protocol, Indian GCP guidelines and applicable rules and regulations in India.
- 6.1 **Amendments:** The Protocol may be modified only by a written Amendment, signed by both the Sponsor and the Principal Investigator.
- 6.2 **Emergency Amendments:** If it is necessary to change the Protocol on an emergency basis for the safety of the subjects, Investigator will notify the Sponsor and the responsible Independent Ethics Committee or Institutional Review Board (as applicable) as soon as practicable but, in any event, not later than five working days after the change is implemented. Any emergency change to the Protocol must be followed by execution of a written Amendment within 30 days.
- 6.3 **No Additional Research:** No additional research may be conducted on Study subjects during the conduct of the Study unless it is approved and documented as a sub-study protocol or an Amendment to the original Protocol. Such prohibited research activities include, but are not limited to, analyses of biological samples from Study subjects for any non-therapeutic purpose.
- 7 **Subject Enrolment:** Investigator has agreed agrees to enrol the subjects in the study as may be defined and decided by the Sponsor from time to time. A qualified subject is one who meets all Protocol criteria such as inclusion & exclusion criteria and agrees to participate in the study through informed consent in writing.
- 7.1 **Excess Enrolment:** If Investigator enrolls the maximum number of qualified subjects, the Sponsor may or may not invite Investigator to enroll additional subjects. However, the Principal Investigator shall not enroll more than maximum number without prior approval by the Sponsor.

ATTESTED

Dr. V.A.Kothiwale
Registrar

- 7.2 **Failure to Enroll:** If Investigator fails to enroll subjects at a rate adequate to meet the enrollment requirement, the SPONSOR shall be free to terminate the Study early (see Section 23, Termination).
- 8 **Study Conduct:** Investigator will conduct Study in accordance with the Protocol, the Sponsor's written instructions, Indian Good Clinical Practices (Indian GCP) guidelines and all applicable governmental laws, rules, and regulations.
- 8.1 **No Charge for Investigational Drug or Reimbursed Services:** Investigator will not charge a Study subject or third-party payer for Investigational Drug (see Section 13, Investigational Drug) or for any services reimbursed by the Sponsor under this Agreement.
- 9 **Independent Ethics Committee/Institutional Review Board:** Before the Study is initiated, Investigator will ensure that both the Study and the informed consent form are approved by an Independent Ethics Committee or Institutional Review Board (as applicable) (both referred to as a 'IRB') that complies with all applicable laws and regulations. Investigator will further ensure that the Study is subject to continuing oversight by the IRB throughout its conduct.
- 10 **Study Disapproval:** If, through no fault of Investigator, the Study is disapproved by the IRB, this Agreement will immediately terminate with no penalty to the Investigator, as provided in Section 23.1.a, Disapproval by IRB, below.
- 11 **Data Protection:** Data collected in Study may include personal data and sensitive information which is subject to specific legislation relating to the processing, storage, transfer and use of such data or information. The Investigator will comply with all relevant laws relating to the protection and use of personal data and data privacy in its conduct and reporting of the Study. The Investigator shall take all technical and organizational measures to prevent unauthorized or unlawful processing or accidental loss or destruction of, or damage to, or disclosure of such data. THE SPONSOR will take appropriate measures to protect the confidentiality and security of all personal data that it receives from Investigator in connection with the Study. Personal data relating to the Investigator shall be processed and used for the purposes of administration of this agreement and in connection with the Study and will be held on one or more databases for the purposes of determining the Investigator's involvement in future research and in order to comply with any regulatory requirements. Such data may be disclosed or transferred to other members of Cadila Healthcare Limited group of companies, to representatives and contractors working on behalf of the Sponsor group and to regulatory authorities across the world. The Investigator shall ensure that all necessary consents are in place to comply with the provisions of this clause 11. The Principal Investigator shall be responsible for obtaining Sponsor's permission before publication or conference presentation of any Sponsors' data.
- 12 **Informed Consent and Authorization to Use and Disclose Health Information**
- 12.1 **Informed Consent:** Investigator will obtain a written informed consent from each Study subject and will maintain a signed original of that consent in the subject's record. Investigator will allow the Sponsor to inspect signed informed consent forms or photocopies thereof during monitoring visits or audits (see Monitoring and Audits, Section 16).

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

13. **Adverse Events:** Investigator will report adverse events experienced by Study subjects in accordance with instructions in the Protocol and applicable regulations. This includes, where required, prompt reporting by telephone, e-mail or facsimile. The Investigator shall, so far as is lawful, have full responsibility for the reporting of all serious and unexpected adverse events and/ or deaths to local regulatory authorities as per prevailing regulations. The Sponsor has and will maintain during the Study, an insurance policy adequate to cover adverse events or injury to Study Subject(s) as a direct result of participation in the Study. . **Investigational Drug:** The Sponsor will provide Investigator with sufficient quantities of the investigational drug(s) needed to conduct the Study.
- 13.1 **Custody and Dispensing:** The Principal Investigator will maintain appropriate control of supplies of Investigational Drug and will not provide it to anyone else except sub-investigators or research staff. The Principal Investigator shall maintain the records of inventory of the Investigational drug.
- 13.2 **Use:** Investigator will use Investigational Drug only as specified in the Protocol. Any other use of Investigational Drug constitutes a material breach of this Agreement.
- 13.3 **Ownership of Investigational drug:** Investigational drug remains the property of the Sponsor except for, and limited to, the use specified in the Protocol, the Sponsor grants Investigator no express or implied intellectual property rights in Investigational drug or in any methods of making or using the Sponsor's DRUG.
14. **Confidential Information:** During the course of the Study, Investigator may receive or generate information that is confidential to the Sponsor. Any information marked by the sponsor as confidential and provided to the investigator 1 year before the execution of this agreement will also be treated as confidential information.
- 14.1 **Definition:** Except as specified in Section 14.2, Exclusions, below, "Confidential Information" includes
- the Protocol,
 - the Investigator Brochure,
 - Study Data (as defined in Section 15, Study Data, Biological Samples, and Study Records, below), subject to Investigator's right to publish the results of the Study (as described in Section 18, Publications, below),
 - Biological Sample Analysis Data (as defined in Section 15, Study Data, Biological Samples, and Study Records, below), and
 - Any other information related to the Study, the Sponsor's DRUG, or The Sponsor technology, research, or business plans that THE SPONSOR provides to Investigator in writing or other tangible form and marks as CONFIDENTIAL and then summarizes and confirms in writing as CONFIDENTIAL within 90 days after the date of oral disclosure.
- 14.2 **Exclusions:** Confidential Information does not include information that
- is known or open to the public or otherwise in the public domain at the time of disclosure,
 - becomes part of the public domain during the term of this confidentiality obligation by any means other than breach of this Agreement by Investigator,
 - is already known to Investigator at the time of disclosure and is free of any obligations of confidentiality, or

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- d. Is obtained by Investigator, free of any obligations of confidentiality, from a third party that has a lawful right to disclose it.
- 14.3 **Obligations of Confidentiality:** Unless the Sponsor provides prior written consent, Investigator may not use Confidential Information for any purpose other than that authorized in this Agreement, nor may Investigator disclose Confidential Information to any third party except as authorized in this Agreement or as required by law.
- Required disclosure of Confidential Information to the IRB or to regulatory representatives is specifically authorized.
 - Publication of the results of the Study based on Study Data collected or generated by Investigator is specifically authorized, subject to the provisions of Section 18, Publications, of this Agreement.
- 14.4 **Disclosure Required by Law:** If disclosure of Confidential Information to any party other than the IRB relevant regulatory authority is required by law, that disclosure does not constitute a breach of this Agreement so long as Investigator
- Notifies the Sponsor in writing in 15 working days advance of the disclosure so as to allow the Sponsor to take legal action to protect its Confidential Information,
 - Discloses only that Confidential Information required to comply with the legal requirement, and
 - Continues to maintain the confidentiality of this Confidential Information with respect to all other third parties.
- 14.5 **Individually Identifiable Health Information:** If, in connection with this Study or performance of this Agreement, the Sponsor comes into contact with individuality identifiable health information relating to subjects who are not Study subjects, the Sponsor agrees to maintain the confidentiality of such information and not to use it for any purpose.
- 14.6 **Survival of Obligations:** These obligations of confidentiality survive termination of this Agreement and continue for a period of five years after completion of the study and marketing of the drug.
- 14.7 **Return of Confidential Information:** If requested by the Sponsor in writing, Investigator will return all Confidential Information except that required to be retained at the Study site by law. However, Investigator may retain a single archival copy of the Confidential Information for the sole purpose of determining the scope of obligations incurred under this Agreement.
15. **Study Data, Biological Samples and Study Records:**
- 15.1 **Study Data:** During the course of the Study, Investigator will collect and submit certain data to the Sponsor or its agent, as specified in the Protocol. This may include case report forms or their equivalent ("Case Report Forms"), or other types of medical images, ECG, or other types of tracings or printouts, data summaries, or any combination of these (collectively, "Study Data"). Investigator will ensure accurate and timely collection, recording, and submission of Study Data. Investigator will deliver Study Data to the Sponsor or its agent within the reasonable time period.
- Ownership of Study Data:** Subject to Investigator's right to publish the results of the Study (see Section 18, Publications), the Sponsor is the exclusive owner of all Study Data.

ATTESTED

Dr. V.A. Kothiwale
Registrar

- b. **Non-exclusive License:** The Sponsor grants Investigator no right to use study data for any purpose including internal research and/or education purpose.
- c. **Data Management and statistical Analysis:** The Sponsor or its representative shall carry out the data management and statistical analysis. The Sponsor may consult and / or provide the Principal Investigator for interpretation during report writing.
- d. **THE SPONSOR** is the exclusive owner of study data.
- 15.2 **Biological Samples:** If so specified in the Protocol, Investigator may collect and provide to the Sponsor or its designee biological samples (e.g., blood, urine, tissue, saliva, etc.) obtained from Study subjects for testing that is directly related to subject care or safety monitoring, including pharmacokinetic, pharmacogenomic, or biomarker testing ("Biological Samples").
- a. **Use:** Investigator will not use Biological Samples collected under the Protocol in any manner or for any purpose other than that described in the Protocol.
- b. **Analysis samples:** The Sponsor or its designees will test Biological Samples as described in the Protocol. Unless otherwise specified in the Protocol, the Sponsor will provide the results of these tests ("Biological Sample Analysis Data") to the Investigator or Study subject.
- c. **Ownership:** The Sponsor is the exclusive owner of all Biological Samples and Biological Sample Analysis Data.
- 15.3 **Study Records:** Investigator will ensure that subject's Study records, which include the Investigator's copies of all Study Data as well as relevant source documents (collectively, "Study Records"), are kept up to date and maintained in accordance with applicable regulations and institutional guidelines.
- a. **Retention:** Investigator will retain Study Records, under storage conditions conducive to their stability and protection, for a period of 5 years after termination of the Study unless the Sponsor authorizes, in writing, earlier destruction. Investigator agrees to notify the Sponsor before destroying any Study Records after the required retention period. Investigator further agrees to permit the Sponsor to ensure that the records are retained for a longer period if necessary, at the Sponsor expense, under an arrangement that protects the confidentiality of the records (e.g., secure off-site storage).
16. **Monitoring, Inspections and Audits**
- 16.1 **Monitoring:** The Sponsor shall be entitled at its absolute discretion (and in such form as the Sponsor sees fit) to monitor and audit the conduct of the Study. Upon reasonable notice, Investigator will permit the Sponsor representatives access to the premises, facilities, procedures and records relating to the Study, investigators, and research staff as required to accomplish this. The Investigator agrees to co-operate and provide all reasonable assistance with any monitoring and/or auditing activity. No such monitoring and/or auditing by the Sponsor will relieve the Investigator of any of its obligations hereunder.
- 16.2 **Inspections and Audits:** The Study is subject to inspection by regulatory agencies worldwide. Regulatory inspections may occur after completion of the Study and may include auditing of Study Records. Auditing involves comparison of Case Report Forms or Data Records with the source documentation on which they are based. The Sponsor may also choose to audit Study Records as part of its monitoring of Study conduct.

ATTESTED 7 of 12

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- a. **Notification:** Investigator will notify the Sponsor as soon as reasonably possible if the site is inspected or scheduled to be inspected by a regulatory agency.
- b. **Cooperation:** Investigator will cooperate with regulatory agency or the Sponsor representatives in the conduct of inspections and audits and will ensure that Study Records are maintained in a way that facilitates such activities.
- c. **Resolution of Discrepancies:** Investigator will promptly resolve any discrepancies that are identified between the Study Case Report Forms and the subject's medical records.
- d. **Inspection Findings and Responses:** Investigator will promptly forward to the Sponsor copies of any inspection findings that Investigator receives from a regulatory, agency. Whenever feasible, Investigator will also provide. The Sponsor with an opportunity to prospectively review and comment on any Investigator responses to regulatory agency inspections.
- e. **Data Clarification Form:** The Sponsor may raise data clarification forms (queries) during or after the monitoring and/or auditing and/or statistical review of the study, which the Principal Investigator or his nominee shall clarify within 7 working days.
- f. **Study Conduct Evaluations:** The Sponsor or its external service providers may document and evaluate the performance of Investigator in the conduct of the Study. The Sponsor will use these evaluations solely for internal purposes.

17. Inventions:

- 17.1 **Notification:** If the conduct of Study results in any invention or discovery whether patentable or not ("Invention"), Investigator will promptly inform the SPONSOR
- 17.2 **Assignment:** Investigator will assign all interest in any such Invention to the Sponsor, free of any obligation or consideration beyond that provided for in this Agreement.
- 17.3 **Assistance:** Investigator will provide reasonable assistance to the SPONSOR in filing and prosecuting any patent applications relating to Invention, at the Sponsor's expense.

18. Publications:

- 18.1 **Prepublication Review:** The Sponsor has no objection to publication by Investigator of any information collected or generated by Investigator, whether or not the results are favourable to the Investigational Drug. However, to ensure against inadvertent disclosure of Confidential Information or unprotected Inventions, Investigator will provide the Sponsor, an opportunity to review any proposed publication or other type of disclosure before it is submitted or otherwise disclosed. The timing of such publication shall be mutually agreed upon.
 - a. **Submission to the Sponsor:** Investigator will provide manuscripts, abstracts, or the full text of any other intended disclosure (poster presentation, invited speaker or guest lecturer presentation, etc.) to the Sponsor at least 90 days before they are submitted for publication or otherwise disclosed. If any patent action is required to protect intellectual property rights, Investigator agrees to delay the disclosure for a period not to exceed an additional 360 days.
 - b. **Redaction of Confidential Information:** Investigator will, on request, remove any previously undisclosed Confidential Information (other than the Study results themselves) before disclosure.

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

19. **Debarment and Exclusion:** The Principal Investigator and Investigator each certify that it/s/he / she is not debarred and that it/s/he/she is not and will not use in any capacity the services of any person debarred under such law with respect to services to be performed under this Agreement. During the term of this Agreement and for three years after its termination, Investigator and Principal Investigator will notify the SPONSOR promptly if either of these certifications needs to be amended in light of new information.
20. **Use of Name:** Neither party will use the name of the other party or any of its employees for promotional or advertising purposes without written permission from the other party. However, the Sponsor reserves the right to identify the Principal Investigator and Investigator in association with a listing of the Protocol in publicly available listings of ongoing clinical trials, or other subject recruitment services or mechanisms.
21. **Assignment and Delegation**
- 21.1 The Principal Investigator may not assign its rights or delegate or subcontract any duties under this Agreement without written permission from the Sponsor. Any attempt to so assign, delegate, or subcontract is invalid. If the Sponsor authorizes delegation or subcontracting, Institution remains responsible to the Sponsor for the performance of all delegated duties.
- 21.2 The Sponsor may not assign its rights or delegate its duties under this Agreement without written permission from the Principal Investigator. Any attempt to so assign or delegate is invalid. However, the SPONSOR may freely subcontract Study-related duties to an external provider upon advance notice to the Principal Investigator, and also may freely assign its rights or delegate its duties to any of the Sponsor affiliate. If the SPONSOR delegates or subcontracts any duties, the Sponsor remains responsible to the Principal Investigator for the performance of those duties.\
- 21.3 **Affiliates:** As used in this Agreement, the term "affiliate" means any entity that directly or indirectly controls, is controlled by, or is under common control with the Sponsor
- 21.4 **Successors and Assigns:** This Agreement will bind and inure to the benefit of the successors and permitted assigns of each party.
22. **Conflict with Attachments:** If there is any conflict between this Agreement and any Attachments to it, or between this Agreement and the Protocol, the terms of this Agreement control.
23. **Indemnity:** Each Party upon receipt of prompt notice and opportunity to defend, shall indemnify and hold the other party harmless, and hereby forever releases and discharges the other Party from and against claims, demands, liabilities, damages and expenses including attorney fees arising out of the negligence of the indemnifying Party in connection with the work performed under this Agreement, provided, however, each party shall not be obligated to indemnify, defend or hold harmless the indemnified party to the extent the claim is caused by gross negligence or willful misconduct of that party.
24. **Term and Termination:**

ATTESTED

Page 9 of 12



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- 24.1 **Termination Conditions:** This Agreement terminates upon the earlier of any of, the following events:
- Disapproval by IRB:** If, through no fault of Investigator, the Study is never initiated because of IRB disapproval, this Agreement will terminate immediately.
 - Study Completion:** For purposes of this Agreement, the Study is considered complete after conclusion of all Protocol-required activities for all enrolled subjects; receipt by the Sponsor of all Protocol-required data and Biological Samples; and receipt of all payments due to either party.
 - Termination Upon Notice:** The SPONSOR reserves the right to terminate the Study for any reason upon 30 days written notice to Investigator.
 - Immediate Termination by the Sponsor:** The Sponsor further reserves the right to terminate the Study immediately upon written notification to Investigator for causes that include, but are not limited to, failure to enroll subjects at a rate sufficient to achieve Study performance goals; material unauthorized deviations from the Protocol or reporting requirements; circumstances that in the Sponsor 's opinion pose risks to the health or well-being of Study subjects; or regulatory agency actions relating to the Study or the Investigational Drug.
 - Termination Upon Notice by Investigator:** The Principal Investigator may terminate the study, if the Sponsor does not comply with the agreement related to finance, supply of medication for the study and supply of related material. Written notice of any such termination by principal investigator including the reasons therefore shall be provided by registered mail to the SPONSOR fifteen days prior to termination and the Sponsor shall have fifteen days to cure its default.\
 - Immediate Termination by Investigator:** Investigator reserves the right to terminate the Study immediately upon notification to the SPONSOR if requested to do so by the responsible IRB or if such termination is required to protect the health of Study subjects.
- 24.2 **Payment upon Termination:** If the Study is terminated early in accordance with Section 23.1 Termination Conditions, above, the Sponsor will provide a termination payment equal to the amount owed for work already performed, less' payments already made. If the Study was never initiated because of disapproval by the IRB (see Section 23.1.a, Disapproval by IRB, above), the Sponsor will reimburse Investigator for IRB fees and for any other expenses that were prospectively approved, in writing, by the Sponsor
- 24.3 **Return of Materials:** Unless the Sponsor instructs otherwise in writing, Investigator will promptly return all materials supplied by the Sponsor for Study conduct, including unused Investigational Drug, unused Case Report Forms, other study related material and any the Sponsor - supplied Equipment.
- 24.3.1 **Electronics Items:** On completion of the clinical study, the Investigator will return all the electronic items & their accessories in the working condition (if any) as provided by the Sponsor during the study.
- 24.4 **Treatment Code (Blinded Studies Only):** Upon request, the Sponsor will provide Investigator with a treatment assignment list that identifies, by subject number, the treatment that each Study subject received. Unless otherwise specified in the Protocol, the Sponsor will provide such treatment assignment information only after the Study is completed (or has been terminated and all data submitted) at all participating sites.




ATTESTED Page 10 of 12


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- 24.5 **Survival of Obligations:** Obligations relating to Funding, Confidential Information, Study Records, Inventions, Publications, and Debarment and Exclusion survive termination of this Agreement as does any other provision in this Agreement or its Attachments that by its nature and intent remains valid after the term of the Agreement.
25. **Modification:** Any alteration, modification or amendment to this Agreement must be in writing and signed by each of the parties.
26. **Entire Agreement:** This Agreement and any Exhibits and Attachments and the Indemnity at Exhibit represent the entire understanding between the parties relating to the conduct of this Study. This Agreement supersedes all previous agreements between the parties (oral and written) relating to this Study, except for any obligations that, by their terms, survive termination.
27. This agreement shall be interpreted and enforced under the laws of India and the Courts of Ahmedabad shall have exclusive jurisdiction to resolve any dispute under this Agreement.

ATTESTED Page 11 of 12


Dr. V.A. Kothiwale
Registrar


KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Annexure A:

Budget Sheet and other expenses:

Investigational drug	Trastuzumab emtansine	Clinical trial phase	III		
Investigators & Center	Dr. Mahesh Kalloli, KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre				
Protocol title/number(s)	A Prospective, Randomized, Multicenter, Comparative, Open-label, Parallel study to evaluate the Efficacy, Safety and Pharmacokinetics of Test-Trastuzumab Emtansine (ZRC-3256; Cadila Healthcare Ltd) and Reference-Trastuzumab Emtansine (Kadcyla®, a product of Roche) in HER2- Positive Metastatic Breast Cancer Patients: TDM1.17.001				
Budget:	Rate per patients	No. of patients	No. of visit	Total cost	Maximum payable amount
Investigators' Professional Fees:					
Screening	13000	1	1	13000	103000
Enrollment visit without PK	10000	1	1	10000	
Follow up visits (cycle 2-8 and End of study visit)	10000	1	8	80000	
Patients reimbursement:					
Screening	1000	1	1	1000	10000
Enrollment visit	1000	1	1	1000	
Follow up visits (cycle 2-5 and End of study visit)	1000	1	8	8000	
Study co-ordinator:					
Screening	4000	1	1	4000	26500
Enrollment visit without PK	2500	1	1	2500	
Follow up visits (cycle 2-5 and End of study visit)	2500	1	8	20000	
Phlebotomist:					
Screening	500	1	1	500	5000
Enrollment visit without PK	500	1	1	500	
Follow up visits (cycle 2-5 and End of study visit)	500	1	8	4000	
Radio Diagnostic Tests					
Screening (contrast CT_Chest, abdomen with pelvis)	14000	1	1	14000	47000
*Enrolled (CT scan-Contrast-Chest and Abdomen with Pelvis)	14000	1	2	28000	
Bone scan	5000	1	1	5000	

Page 1 of 2

ATTESTED


 Dr. V.A. Kothiwale
 Registrar

 KLE Academy of Higher Education and Research,
 (Deemed-to-be-University u/s 3 of the UGC Act, 1956)
 Belagavi-590 010, Karnataka

Special Clinical Examination (2D ECHO)						
Screening	2000	1	1	2000	2000	
Special Clinical Examination (Chest X-Ray)						
Screening	450	1	1	450	450	
Special Clinical Examination (ECG)						
Screening	300	1	1	300	2700	
*Enrolled	300	1	8	2400		
Hospitalization charges:						
Enrolled	3500	1	8	28000	28000	
Administration costs:						
Phone/fax calls					2000	
Couriers/Xerox						
Drug Storage						
Institutional Overhead (25%)- only PI and CRC						32375
Total				226650	259025	
Note	(1) Maximum amount paid per completed patient without PK will Rs.				259025	
	(2) First installment is for ethics committee fees(As per actual).					
	(3) Reimbursement of all expenses against monthly invoices with supporting vouchers (if required).					
	(4) Final payments made will be only on the basis of subjects completed in the trial. Cost of screen failures is adjusted in the payments for the enrolled subjects as per the above projections.					
	(5) Payments will not be done for wrongly enrolled subjects.					
	(6) Of the total eligible payment,70% will be paid while the study is on-going at regular intervals, 20% will be paid after completion of data management and remaining 10 % on signing of the clinical study report.					
	(7) Upto 10% of the drop-outs in the study will be reimbursed as per the actual expenses. Drop-out above 10 % will not be reimbursed.					
	(8) Tax deduction at source (TDS)/GST as per the applicable regulations. GST as per applicable rules.					
	(9) Archival charges of INR 42,000 will be paid extra to archive study documents for 15 years.					
	(10) No monthly payments will be processed if no patients are enrolled within two months from date of study was conducted at site					
	(11) Local pathology/pharmacy/any other investigations charges as per actuals.					
	(13) Payee details: Payee name: MG CLINICAL RESEARCH Payee address: sector no 12, Plot no 17, M M Nagar, Jain bhasti, Karnataka-590018, Belgaum Bank name: HDFC BANK Bank account name: MG CLINICAL RESEARCH Bank account number: 50200044101301 IFSC code: HDFC0000253					

ATTESTED

Page 2 of 2

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010, Karnataka

Clinical Trial Agreement

Lambda Therapeutic Research Ltd.
Plot No. 38, Survey no 388, Near Silver Oak Club,
S G Highway, Gota, Ahmedabad 382481, Gujarat, India.
(Hereinafter referred to as "LAMBDA" or "CRO")

Engaged by:

Intas Pharmaceuticals Ltd.,
Plot No: 423/P/A,
Sarkhej-Bavla Highway,
Moraiya, Sanand,
Ahmedabad,
Gujarat, India 382213.
(Hereinafter referred to as the "Sponsor")

AND

KLES Dr. Prabhakar Kore Hospital and MRC
Second Floor, SMO, Nehru Nagar,
Belagavi – 590010, Karnataka, India
(Hereinafter referred to as the "Institution" or "Site")

AND

Dr. Maheshkumar Kalloli
KLES Dr. Prabhakar Kore Hospital and MRC
Second Floor, SMO, Nehru Nagar,
Belagavi – 590010, Karnataka, India
(Hereinafter referred to as the "Investigator")

THIS AGREEMENT shall come into effect on the date of signature of all the parties.

BETWEEN

Lambda Therapeutic Research Ltd.
Plot No. 38, Survey no 388, Near Silver Oak Club,
S G Highway, Gota, Ahmedabad 382481, Gujarat, India.
(Hereinafter referred to as "LAMBDA")

Intas Pharmaceuticals Ltd.,
Plot No: 423/P/A,
Sarkhej-Bavla Highway,
Moraiya, Sanand,
Ahmedabad,
Gujarat, India 382213.
(Hereinafter referred to as the "Sponsor")

AND

Dr. Maheshkumar Kalloli, Belagavi



NUTAN NAAGRIK SAHKARI BANK LTD. AHMEDABAD
 GU/SOS/AUTH/AV/ZZ/005
 00000 SPECIAL ADDRESS
 00005000
 363080 GUJRAT
 INDIA
 11/11/2019

ATTESTED

Page 1 of 20

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

“Ethics Committee”	The relevant properly constituted ethics committee as organized by the Hospital Authority or independent, which has reviewed or will review the application for conducting the Clinical Trial.
“ICH GCP”	ICH Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) as may be amended from time to time.
“Site Investigator File”	The file maintained by the Investigator containing the documentation specified in section 8 of ICH GCP.
“Payment Agreement”	The payment agreement set out in Schedule “B”.
“Protocol”	The protocol together with its amendments as agreed between the parties from time to time (Schedule “A”).
“SAE”	Serious Adverse Event as defined by ICH GCP.
“Site”	The site at which the Clinical Trial is conducted.
“Study”	The study to be undertaken by the Investigator and the Institution in accordance with the Protocol, ICH-GCP and applicable regulatory requirements.

2 Investigator/Institution responsibilities

- 2.1 The Investigator in his personal capacity and as an authorized representative of the Institution and the Institution undertakes to adhere to the Protocol and general acceptable clinical practices for the conduct of the Clinical Trial.
- 2.2 The Investigator and the Institution will adhere to ICH GCP, Declaration of Helsinki, New Drugs and Clinical Trials Rules, 2019, and all applicable laws and regulations for the conduct of the Clinical Trial.
- 2.3 The Investigator and Institute is also responsible for supporting Sponsor and Lambda in resolving any technical issues encountered during the performance of the Clinical Trial and queries from national / international authorities in close coordination with Lambda in a timely manner. The provisions of this article shall remain in force for a period of 10 years even after expiry or termination of this agreement.
- 2.4 The Investigator is responsible for submitting to the Ethics Committee; the conduct of the Clinical Trial in accordance with the terms of the Protocol and for obtaining written approval from the Ethics Committee prior to the commencement of the Clinical Trial. The Investigator will deliver a copy of such approval to LAMBDA. Trial supplies to the Investigator or the Institution will not be delivered until LAMBDA has received a copy of such approval. The said approval must indicate the date of approval and contain the name and signature of the Chairperson/member secretary of the Ethics Committee.
- 2.5 The Investigator is responsible for training and supervision of sub-investigators and other site study team members on the procedures specified in the Protocol to ensure scientific, technical and ethical conduct of the Clinical Trial. In case of any personnel changes, the Investigator is responsible for notifying LAMBDA of such change in a timely manner.

Dr. Maheshkumar Kalloli, Belagavi



ATTESTED

Page 3 of 20

[Signature]
Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

this Agreement to the contrary, the Investigator and the Institution shall have the right to disclose findings that could adversely affect the safety of Clinical Trial subjects to the Ethics Committees of participating sites, and appropriate regulatory authorities if they deemed necessary to protect the health of study participants, provided that Sponsor is copied on such reports.

2.9 The Investigator and the Institution shall indemnify, defend and hold harmless Lambda and the Sponsor against any and all claims arising out of or in connection with the performance of this agreement, allegedly arising from Investigator's and / or his team's negligence or reckless or intentional misconduct, breach or failure to perform its obligations and responsibilities under this agreement. Lambda undertakes to provide timely written notice after such claim is served upon Lambda / Sponsor. The Investigator shall have the right to defend the same at his own expenses including selection of counsel, control of the proceedings and settlement of the claim. Lambda shall fully cooperate and aid in such defense. In the event that a claim or suit is or may be asserted, Lambda shall have the right to select and to obtain representation by separate counsel, at its own expense. Investigator may not settle or compromise a claim or suit without the express prior written approval of Lambda.

2.10 The Investigator is responsible for supporting LAMBDA in development of the Clinical Trial Report.

3 CRO responsibilities

3.1 LAMBDA will adhere to and confirms the Sponsor will adhere to ICH GCP, the Declaration of Helsinki, requirements of DCGI and all applicable guidelines, laws and regulations for the conduct of the Clinical Trial.

3.2 LAMBDA confirms that the Sponsor has committed to provide Lambda with the Compound and with guidelines and descriptions for the safe and proper handling regarding the use, storage and disposal of the Compound. Lambda will be responsible for shipment of drug supplies and investigational products to the PI or Site. The Compound is the property of Sponsor and is being provided only for the purposes of the performance of the Clinical Trial by the PI or by individuals working under his direct supervision at the Institution. The Compound shall not be used for any other research or study activities other than outlined in this Agreement.

3.3 LAMBDA and/or Sponsor is responsible for obtaining and maintaining all applicable government or regulatory approvals for the Clinical Trial in India, and warrants that these will be obtained before the Clinical Trial begins at the Institution. Development and improvement of the Protocol is the responsibility of LAMBDA and Sponsor.

3.4 LAMBDA on behalf of the Sponsor will provide the study-specific documents, e.g. Investigator Site File, Electronic Case Report Form, etc. to the Investigator before commencement of the Clinical Trial.

3.5 LAMBDA on behalf of the Sponsor will provide the Investigator with documentation, which describes the Compound being tested in the Clinical Trial and its known effects and safety information (e.g. Prescribing Information / Summary of Product Characteristics, an Investigator Brochure equivalent document). LAMBDA on behalf of Sponsor will, to the best of its knowledge; answer any questions the Investigator or the Institution may have regarding the Protocol or the Compound being tested, whether such questions are asked before the commencement of the Clinical Trial or during its conduct. Sponsor is responsible for reporting of relevant new information regarding the investigational Compound.

Dr. Maheshkumar Kalloli, Belagavi



Page 5 of 20

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

6.1 This Agreement shall be effective as of the date executed by all the parties and shall continue in full force and effect until the site is closed, Clinical Trial and Clinical Trial Report are completed unless otherwise extended, renewed, or amended by mutual written consent or unless terminated earlier in accordance with Section 14 of this Agreement. In any event, the terms of this Agreement shall not be longer than fifteen (15) years from the date of commencement.

- 6.2 However following matters shall survive even after expiry/termination of the agreement:
- Archival of study documents including source data as referred to in para 2.7 (i) and Section III/k on page # 24.
 - Reasonable access by monitors, auditors and regulatory authority to original study documents and source data and providing appropriate working conditions for monitors, auditors and regulatory authority to perform study-related monitoring, audit and inspection;
 - Confidentiality as per para 11

7 Data ownership / Intellectual property rights

7.1 LAMBDA, the Institution and the Investigator undertake to be bound by applicable laws and regulations on the protection of personal data.

7.2 The Investigator undertakes to transfer data to Sponsor, LAMBDA, Ethics Committee, and the regulatory authority. In the event of an audit/inspection, LAMBDA, the Sponsor, Ethics Committee, and regulatory authority may obtain information that includes patient identification.

7.3 All data and results derived from the Study and any inventions or discoveries made as a result of the Clinical Trial will be the property of Sponsor. Disclosure to LAMBDA, Ethics Committee, or regulatory authority does not transfer the ownership thereof.

7.4 All intellectual property rights owned by, or licensed to, the Investigator / Institute prior to and after the date of this Agreement, other than intellectual property rights arising from the Clinical Trial is and shall remain the property of the Investigator / Institution.

7.5 All intellectual property rights owned by, or licensed to, Sponsor prior to and after the date of this Agreement, other than intellectual property rights arising from the Clinical Trial is and shall remain the property of Sponsor.

7.6 All intellectual property rights in the data and results derived from the Clinical Trial shall be the property of Sponsor and shall be assigned to Sponsor.

7.7 The Investigator/Institute is obliged to report any inventions or discoveries promptly to Sponsor and/or LAMBDA.

7.8 Investigator and Institute agree that Sponsor may utilize the data at its own discretion in compliance with the applicable data protection rules, including but not be limited to, submission to government regulatory authorities.

7.9 The Investigator and the Institution shall assist Sponsor in making any patent applications and shall execute, complete, deliver and perform any and all instruments necessary to make all such applications.

ATTESTED

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

11 Confidentiality

- 11.1 For a period of 10 (ten) years from the effective date of this Agreement, Recipient shall not disclose the Discloser's Confidential Information to any third party. Recipient shall use the Confidential Information solely for purpose of the terms of the agreement, unless otherwise mutually agreed in writing. Upon request, Recipient shall return or destroy, at the Discloser's option, all Confidential Information, including any copies and extracts thereof, will immediately cease using such Confidential Information and shall deliver to the disclosing party all such Confidential Information including all copies, reproduction, facsimiles and any other tangible records of such information.
- 11.2 Notwithstanding the performance, or the discharge for whatever reason including breach of this Agreement, the provisions of this article shall remain in force for a period of 10 years from the date of execution of this Agreement but shall, thereafter, cease to apply provided that the expiry of such period shall not entitle Investigator or Institution to sell or otherwise dispose of, or otherwise turn to use for its own or another's advantage, any confidential information received during the conduct of projects covered by this Agreement.
- 11.3 The Investigator may only to the extent is, as far as necessary for the performance of its obligations under this Agreement, but not further or otherwise, disclose confidential information to study staff or to any relevant committee, that need to know the same to undertake and/or participate in this study. Investigator shall ensure that all persons shall be made aware of the relevant terms and conditions of this Agreement and shall agree to be bound by them.
- 11.4 The Investigator/institution shall not disclose or use any confidential information, which is provided by Sponsor or LAMBDA or generated by Investigator as a result of the Study, for any purpose other than the conduct of the Clinical Trial as outlined in the Protocol and this Agreement.
- 11.5 Confidential information shall remain the confidential and proprietary property of Sponsor, and shall only be disclosed to those who have a need to know the same. Where it is necessary to disclose any confidential information to any third party for the performance of this Agreement, a confidentiality agreement with the same terms and conditions as this Agreement shall be entered into with such third party.
- 11.6 Each party will keep an updated list of all individuals who have received the other parties' confidential information, together with their contact information and job title, and will provide the list if it is legally requested. All confidential information must be identified as confidential at the time of disclosure, preferably provided in writing. If the disclosure is verbally, visually, or otherwise (e.g. an X-ray, a visit to a site or lab), then the information must be summarized in writing within thirty (30) days after the disclosure and provided to the receiving party.
- 11.7 Confidential information shall not include any information which:
- is already in the public domain at the time of disclosure
 - becomes part of the public domain after receipt of the information through no fault of the Institution or the Investigator
 - was previously known to the Institution or the Investigator as evidenced by written documents

Dr. Maheshkumar Kalloli, Belagavi

ATTESTED
Page 9 of 20Dr. V.A. Kothiwale
RegistrarKLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

14 Termination

LAMBDA on behalf of Sponsor retains the right to terminate this Agreement on Institution or Investigator's involvement in the Study for any reason with or without cause including but not limited to the following:

1. Investigator or Institution fails to recruit patients within **60** days of site initiation visit.
2. The incidence and/or severity of adverse drug reactions in this or other studies with the Compound indicate a potential health hazard.
3. Adherence to the Protocol is poor or data recording is inaccurate or seriously incomplete.
4. LAMBDA, the Principal Investigator and/or the Institution agree to terminate this Agreement.
5. The total number of patients required to be randomised is reached before the end of the recruitment period.
6. The Sponsor of the Study mandates the termination of the Study for any reason, with or without cause.
7. The appropriate Regulatory Agency mandates the termination of the Study.

In case of termination of the agreement without any default on the part of Investigator or Institution, except in the event of non-recruitment of patients by the Institution or Principal Investigator, LAMBDA shall reimburse the Institution or Principal Investigator on a pro rata basis of the number of visits completed by patients. Should the Institution or the Principal Investigator have already received payments in excess of the actual pro rated amounts due then that overpayment will be promptly remitted to LAMBDA by the Institution or Principal Investigator. Payments should be payable to LAMBDA.


15 Record retention

- 15.1 The Investigator and/or the Institution shall provide Sponsor through LAMBDA any and all records and data in relation to the Clinical Trial in time and in full according to requirements of ICH GCP, New Drugs and Clinical Trials Rules, 2019 and the Declaration of Helsinki, and all applicable guideline, laws and regulations.
- 15.2 The Investigator and/or the Institution, LAMBDA/CRO and Sponsor shall comply with all regulatory requirements relating to the retention of records and shall maintain all such records, and make them available for inspection, and shall allow Sponsor and all applicable authorities in charge of the Clinical Trial to inspect such records. The Investigator and /or the Institution shall inform Sponsor in the event of relocation or transfer of archiving responsibilities.
- 15.3 The Site Investigator File containing the essential documents, case report forms, informed consent forms and any other source data/document (like patient medical records) must be archived for at least 15 (Fifteen) years following completion of the study at the Site or such other facilities as agreed between Sponsor and the Investigator. Sponsor shall also keep all clinical trial data and documents according to the relevant regulatory requirements.

Dr. Maheshkumar Kalloli, Belagavi



ATTESTED 11 of 20


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Telephone : +918312470400
Fax : +918312493099

18.2 Either party should inform the other party of any change of the said addresses in writing within forty-eight (48) hours of the change.

18.3 Any notice shall be deemed to be given: a) If sent by courier - on the day when the recipient signs for the notice; b) If sent by registered letter - at 9:00 am on the five (5) working day of dispatch; or c) If sent by telefacsimile - at 9:00 am on the second day of delivery.

18.4 Any notice one party delivered to other parties, which concerns important issues such as claims or amendments under this Agreement should be signed by the legal representative or the authorized representative of the delivering party.

19 Miscellaneous

19.1 Any unsettled issues of this Agreement shall be negotiated and agreed upon in separate supplementary agreement signed by all parties. The supplementary agreement and Schedules of this Agreement which form an integral part of this Agreement and have the same legal effect as this Agreement.

19.2 No party shall assign to any third party its rights and obligations hereunder without the prior written consent of the other parties except when Sponsor takes over some of the activities from Lambda. The Investigator and the Institution acknowledge that Lambda is acting as the agent of the Sponsor and hence in such case Sponsor will get into the shoes of Lambda for all rights and obligations contemplated under this agreement as between Lambda on one side and Investigator and the Institution on the other side.


19.3 This Agreement shall constitute the entire agreement among the parties and shall supersede all previous negotiations, discussions, understandings or agreements among the parties.

19.4 No amendment or modification to this Agreement shall be effective unless made in writing and signed by all the parties or their duly authorized representatives.

19.5 All infrastructures provided by Lambda on behalf of sponsor for the conduct of this clinical trial to the Institute/Investigator will be retrieved from the Institute/Investigator upon completion of the trial.

19.6 "All the Invoices raised to Lambda (CRO) should be GST compliant, according to the GST Invoice rules. Absence of necessary detail will result in delay /non-payment of Invoices till the time of rectification made."

Principal Investigator:

Sign: 

Date: 05/NOV/2019

Dr. Maheshkumar Kalloli
Principal Investigator
KLES Dr. Prabhakar Kore Hospital and MRC
Second Floor, SMO, Nehru Nagar,
Belagavi – 590010, Karnataka, India

Witness:

Sign: 

Date: 05 Nov 2019

Witness Name Dr Deepak
Witness Address : KLES Dr Prabhakar Kore
Hospital & MRC

Schedule B: Budget and Payment Agreement (I) Budget

Protocol Number: 0566-18		INVESTIGATOR GRANT (For Three Weekly Regimen)									
Visit No.	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Total	
Cycle No.	NA	1	2	3	4	5	6	NA	NA		
Weeks	Wk -2 to 0	0	3	6	9	12	15	18	24		
1	Investigator Grant	8500	8000	8000	9000	8000	9000	8000	10500	11000	80000
2	Co-ordinator Grant	3000	1500	1500	2000	1500	2000	1500	1500	3000	17500
3	Day Care Charges		3000	3000	3000	3000	3000	3000			18000
4.1	ECG (12 Lead)	400	400	400	400	400	400	400	400	400	3600
4.2	ECHO	2000					2000			2000	6000
4.3	CT/MRI scan (Whole Body) - Contrast / Bone Scan ⁵ (if applicable)	17000			17000		17000		17000		68000
4.4	Hepatitis (HCV and HepB) and HIV Screen	LTR Central Lab									0
4.5	Serum Pregnancy Test (For Female Subjects)	LTR Central Lab						450	LTR Central Lab		450
4.6	Urine Pregnancy Test (For Female Subjects)		200	200	200	200	200	200			1200
4.7	Biochemistry and Urinalysis ^{1,6}	LTR Central Lab			4000		4000			LTR Central Lab	8000
4.8	Hematology ¹ - at Local Lab	500	500	500	500	500	500	500	500	500	4500
4.9	Biochemistry ² - at Local Lab		800	800		800		800			4000
	Total	31400	14400	14400	36100	14400	38100	14400	31150	16900	211250
5	Institutional Overhead (25%) - Applicable on Investigator Grant and Coordinator Grant	2875	2375	2375	2750	2375	2750	2375	3000	3500	24375
	Total (with Institutional Overhead at 25%)	34275	16775	16775	38850	16775	40850	16775	34150	20400	235625
6	Patient Compensation (on actuals)	500	500	500	500	500	500	500	500	500	4500
	Total Grant/patient										240125

Note:

Hematology: Hemoglobin, hematocrit, WBC count with differential (as percentage for white blood cells and absolute for neutrophils & eosinophils only) RBC count and platelet count.

1 BioChemistry: Total protein, albumin, alkaline phosphatase, GGT, AST, ALT, total bilirubin, triglycerides, cholesterol, glucose, calcium, phosphorous, potassium, sodium, urea, creatinine, eGFR and uric acid.
Urinalysis: Specific gravity, pH, semi-quantitative evaluation of glucose, protein, bilirubin, ketones, leukocytes, blood. A microscopic examination including RBC, WBC, and casts

2 BioChemistry: ALT, AST, ALP, Total Bilirubin & Serum Creatinine

3 Patient compensation will be provided based on actual bills only (provided is upper limit)

4 Archival would happen at Lambda Clinical Services facility.

5 If Bone Scan will be performed as per PI discretion, only INR 5000/- per bone scan will be paid.

6 Biochemistry and Urinalysis at visit 4 and visit 6 will be performed at Local Lab

Dr. Maheshkumar Kalloli, Belagavi



ATTESTED

Page 17 of 20

Dr. V.A. Kothiwale
RegistrarKLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

LAMBDA will release payment within 30 days from the receipt of invoice.

k) Archival would happen at Lambda Clinical Services facility.

Should the trial terminate prematurely, any payments made by LAMBDA exceeding the amount actually earned will be promptly refunded to LAMBDA (minus Ethics Committee fees, and patient conveyance/compensation).

Method of payment

LAMBDA, on behalf of the Sponsor, shall pay the relevant cost and fee as set out in this Payment Agreement to following payee through A/c Payee Cheque as agreed by the Institution & PI. Details of Payee are:

Payment through Cheque:	
Name of Payee:	MG CLINICAL RESEARCH
Address of Payee:	sector no 12, Plot no 17, M M Nagar, Jain bhasti, Belgaum, Karnataka,590018
PAN / TAN Number:	ABFPG5340M
Payment through wire transfer:	
Name of Beneficiary Account:	MG CLINICAL RESEARCH
Beneficiary's Account Number:	50200044101301
Bank Name:	HDFC BANK
Bank Address:	4830 / 28A, DrAmbedkar Rd, Belgaum, Karnataka,590002
IFSC:	HDFC0000253
GST Number:	29ABFPG5340M1ZG

Note: All the payments made to the payee are subject to Tax Deducted at Source (TDS) as per the applicable existing tax laws in the country. LAMBDA will deduct the tax at the time of making payments unless a valid Certificate from tax authority is made available.

(III) Per Patient Fee, Payment Schedule and Terms

- As consideration for performance under the terms of this Agreement, the Sponsor will provide financial support for the Trial that will be transferred by the LAMBDA on behalf of the Sponsor to the Investigator / Institute at the rate specified above per patient grant, for each Subject completing all Protocol specified treatments.

The "Per patient grant" is a fixed fee per patient which includes all costs and honoraria, including, but not limited to:

- all study related activities such as conduct of visits and eCRF completion
- time and effort of investigators and other site staff
- study coordinator salary
- electricity expenses for use of equipment for study conduct
- procurement of any study related material
- all diagnostic tests and other investigations (like Hb level measurement etc.)
- housing/hospital stay (if applicable) and meals during housing for patient and patient's relative
- Phlebotomy expenses for safety samples
- usage of internet while filling of eCRF
- Patient conveyance/compensation which will be on a pro rata basis
- miscellaneous (telephone, fax, courier, etc.)

ATTESTED

[Signature]
Dr. V.A. Kothiwale
Registrar

- All overhead costs.

Not included are (which are separate and in addition to per patient payment):

- EC submission fee
2. In the event that the LAMBDA requests that additional Subjects be enrolled in the Trial, the Trial Cost will be equal to the Per patient grant multiplied by the number of complete and evaluable Subjects.
 3. All payments to be made by the LAMBDA under this Agreement will be done within 30 days following receipt of the corresponding invoice from the Investigator to LAMBDA, it being understood that such payment will only take place after the CRO (LAMBDA) has received the necessary funds for that purpose from the Sponsor. All such payments will be Any made by A/C Payee Cheques to the Institution/Investigator.
 4. Payment mentioned under "safety follow up" will be released at the time of site close out. The Final Payment will be made by LAMBDA in accordance with the following paragraphs.
 5. As regards tasks that are not specifically itemized in this Agreement, payments will not be made without prior written approval of the LAMBDA. These additional tasks will be submitted to LAMBDA in writing, with estimated completion dates and costs, if any. Any expenses not specified in this Agreement or any changes to the amounts mentioned in this agreement, will be communicated to LAMBDA and are subject to prior written approval by LAMBDA, which, in its turn, must obtain prior written approval from Sponsor.
 6. In the event that a randomized Subject is determined to be ineligible for the Trial, LAMBDA will decide, together with the Sponsor, if required, whether or not to pay to the Institution/Investigator the Per Subject Fee for such Trial Subjects. In the event that a Trial Subject withdraws voluntarily or is withdrawn from the Trial (a) by LAMBDA or (b) by the Investigator for any reason other than the Trial Subject failing to meet eligibility requirements for the Trial, then LAMBDA will pay the Institution/Investigator a prorated amount of the per patient grant through the date of such withdrawal. Further, if, at the completion of the Trial, LAMBDA has advanced sums under the terms of this Agreement that exceed the adjusted Trial Cost, the Investigator/Institute will reimburse to LAMBDA any amount by which amounts advanced by the CRO exceed the adjusted Trial Cost.
 7. The CRO may withhold all or part of any amounts in the event of:
 - (1) failure of the Investigator/Institute to complete the services according to the Protocol;
 - (2) failure to provide LAMBDA with requested documentation;
 - (3) Failure of the Investigator/Institute to comply with the terms of this Agreement.
 8. Sponsor reserve right to verify study related payment records (e.g. invoices , patient reimbursement receipts) at SITE or at LAMBDA as applicable ; as a compliance measure .
 9. **Screen Failures:** All screen failure patients payments will be made post LPLV. Reimbursement for screen failures will be at the amount indicated on the screening visit of the schedule-B budget, not to exceed One (1) screen failure(s) paid to four (4) Subject(s) randomized. Reimbursement for discontinued or early termination Subjects will be prorated based on the number of confirmed completed visits.
 10. For any disputed payments from the invoices, site will communicate through proper channel of LAMBDA.

ATTESTED


Dr. V.A. Kothiwale
Registrar

LAMBDA will pay a sum **Rs. 2, 40, 125/- (Two Lakh Forty Thousand One Hundred Twenty Five Rupees Only) for Three Weekly regimen** for every complete and evaluable Subject as defined in the payment schedule.

The above budget also includes the

- a. Investigator (s), other team members fees
- b. The cost which would be incurred for stationary, cupboard, courier, telephone, fax, internet and electricity bills etc.
- c. Patient recruitment
- d. e-Case Report Form completion
- e. Data Clarification Form Resolution
- f. Consultation charges

(I) Payment Schedule

The parties hereto agree as follow on the basis of the Clinical Trial Agreement:

- a) A complete and evaluable patient is defined as follows:
 - all procedures must be performed according to the protocol
 - a patient will only be included according to the inclusion/exclusion criteria
 - all data are documented completely and accurately
- b) All payments will be on a *pro rata* basis as mentioned in budget above. For patients who do not complete (early termination, drop-out, etc.), the budget will be evaluated according to the number of days completed as per protocol. If any investigation is not performed during a visit then an equivalent amount mentioned in the above budget will be deducted.
- c) Invoice will be generated/requested for payment on monthly basis according to the actual work performed (after source data verification and e-CRF review for completed visits). Invoice will be generated / requested according to days completed by patient as specified above.
- d) Any other parties designated by you (including Radiology, Local Laboratory, Cardiology, etc.) will be managed and paid by you.
- e) The **Ethics Committee fees** will be paid by LAMBDA on behalf of the Sponsor, and it is separate from per patient grant as mentioned in budget.
- f) For Screen failure patients, the payment will be paid **ONLY** if the patient is screen failure based on results or reports of laboratory investigations, ECG, SAE, radiological investigation or in case patient withdrew consent. Payment for patients withdrawn before randomization will be paid for screening day.
- g) If patient was randomized in the study deviating from protocol inclusion and exclusion criteria (without waiver, if applicable) then payment will not be made for such wrong randomization and subsequent visits, however screening visit can be paid, if performed according to protocol.
- h) Patient conveyance/compensation will be paid by LAMBDA on behalf of the Sponsor, and is included in budget as mentioned. "TDS would not be deducted on Reimbursement only if original supporting are provided for full amount." GST applicable as per union budget rules.
- i) The investigator grant includes payment of meals provided to patient and patient's relative (if applicable) during the study.
- j) Payment mentioned under "Final Payment" will be released at the time of site close out.

Dr. Maheshkumar Kalloli, Belagavi



Page 18 of 20

ATTESTED

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

Schedule A

Study Protocol

Protocol No: 0566-18

“A MULTICENTRIC, OPEN LABEL, SINGLE ARM STUDY TO EVALUATE THE SAFETY AND EFFICACY OF INTP26 (TRASTUZUMAB BIOSIMILAR) IN PATIENTS WITH HER2 – OVEREXPRESSING BREAST (EARLY OR METASTATIC) CANCER OR METASTATIC GASTRIC CANCER”.

Dr. Maheshkumar Kalloli, Belagavi



ATTESTED Page 16 of 20

[Signature]
Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

IN WITNESS hereof, the parties hereto have caused this Agreement to be executed by their respective duly authorized representatives and the Agreement shall come into effect on the date of signature of all the parties.

LAMBDA:Sign: 

Mr. Rajiv Bhattacharya / Mr. Gautam Vaghela
Clinical Trial Management,
Lambda Therapeutics Research Ltd.

Date: 2/Nov/2019**Witness:**Sign: 

Mr. Naresh Khemani
AGM, Finance,
Lambda Therapeutic Research Ltd.

Date: 02/Nov/19

Witness Address : Lambda Therapeutic Research Ltd.,
Plot No. 38, Near Silver Oak Club,
S. G. Highway, Gota,
Ahmedabad 380061, Gujarat

Institute: KLES Dr. Prabhakar Kore Hospital and MRC

Sign: 

Name: Dr M.V. Jali
Designation: MD and CE
KLES Dr. Prabhakar Kore Hospital and MRC
Second Floor, SMO, Nehru Nagar,
Belagavi – 590010, Karnataka, India

Date: 06/11/19

Investigator: Dr Mahesh Kalloli

ACKNOWLEDGMENT: In signing below, I, the Investigator, acknowledge that there is no real or perceived conflict-of-interest in the execution of this clinical trial project (e.g. stock or equity in companies which manufacture products being tested in the clinical trial, or obligations or restrictions which will conflict with the performance of this Agreement). I hereby agree to act in accordance with all the terms and conditions of this Agreement and further agree to ensure that all participants in the clinical trial are informed of their obligations under such terms and conditions.

Dr. Maheshkumar Kalloli, Belagavi



ATTESTED 14 of 20


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

15.4 In the event that the Institution and/or the Investigator is or are unable to maintain the Clinical Trial records due to any unforeseen event/s during the study or retention period, the Institution and/or the Investigator shall, no later than **30** days prior to the day when the Clinical Trial records were planned to be removed, notify Sponsor in writing of such occurrence to permit Sponsor to fulfill its record retention obligation in connection with the Clinical Trial.

15.5 In the event that Sponsor removes the Clinical Trial records, Institution and/or Investigator may nevertheless retain a copy of Clinical Trial records (1) as required by law, regulation, regulatory guidelines or ICH GCP and (2) in order to ascertain and fulfill their obligations of confidentiality under this Agreement.

15.6 In the event that the Investigator/Institute is to destroy the Site Investigator File or source data, the Investigator/Institute should inform LAMBDA prior to destruction to confirm it is acceptable for them to be destroyed.

16 Representation and Warranty

16.1 The Investigator and Institution represent and warrant that they have and will keep throughout the Clinical Trial study all such qualifications, approvals, permits, licenses and conditions as necessary for performance of the Clinical Trial hereunder as required by laws and regulations of India.

17 Laws and Jurisdiction

17.1 This Agreement shall be governed by and interpreted in accordance with the laws of India in Ahmedabad.

18 Notice

18.1 All notices shall be delivered to the following addresses:

CRO	:	Lambda Therapeutic Research Ltd
Address:	:	Lambda House, Plot No. 38, Survey No. 388, Near Silver Oak Club, S.G. Highway, Ahmedabad-382481, Gujarat, India.
Telephone	:	+91 79 4020 2020
Fax	:	+91 79 4020 2021
Contact Person	:	Dr. Kiran Marthak

Institution	:	KLES Dr. Prabhakar Kore Hospital and MRC
Address	:	KLES Dr. Prabhakar Kore Hospital and MRC Second Floor, SMO, Nehru Nagar, Belagavi – 590010, Karnataka, India
Telephone	:	+918312470400
Fax	:	+918312493099

Investigator	:	Dr. Maheshkumar Kalloli
Address	:	KLES Dr. PrabhakarKore Hospital and MRC Second Floor, SMO, Nehru Nagar, Belagavi – 590010, Karnataka, India

Dr. Maheshkumar Kalloli, Belagavi



ATTESTED
Page 12 of 20

[Signature]
Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- d) Is disclosed to the Institution/Investigator by a third party who has the right to disclose and who is not under a direct or indirect obligation of confidentiality to Sponsor.
- e) Has been permitted to be disclosed by Sponsor.
- 11.8 All Confidential Information disclosed to a party under this Agreement will remain the property of the disclosing party (or the Sponsor, if such information was disclosed through LAMBDA) and may be re-called and withdrawn by the disclosing party at any time. Upon receipt of a written request from the disclosing party for return or destroy of such Confidential Information, the receiving party will immediately cease using such Confidential Information and shall deliver to the disclosing party all such Confidential Information including all copies, reproduction, facsimiles and any other tangible records of such information.
- 11.9 Any previous Confidentiality Agreement between Sponsor and/or LAMBDA and the Investigator or the Institution shall be superseded by the confidentiality obligations in this Agreement.
- 12 **Privacy**
- 12.1 Sponsor, LAMBDA, the Investigator and the Institution will adhere to applicable privacy laws, regulations, and other standards.
- 12.2 The Investigator and Institute/Institution consents to LAMBDA and Sponsor and its affiliates collecting and/or otherwise processing personal data provided by or relating to the Investigator for purposes of any necessary sharing with regulatory authorities and for any use by Sponsor and its affiliates and their agents.
- 12.3 The Investigator and Institute consents to Sponsor or LAMBDA transferring such personal data to Sponsor's facilities, Sponsor's affiliated companies, regulatory authorities, and third party vendors that may be utilized in other countries. For such purposes, the Investigator and Institute acknowledge that such other countries may not provide the same level of data protection as the laws in India.
- 12.4 The Investigator and Institution will inform each study subject of the potential for disclosure of their personal or health information to Sponsor, Sponsor's affiliated companies, LAMBDA, the Ethics Committee, and the regulatory authorities and the measures being taken to ensure their privacy.
- 13 **Independent Contractor**
- 13.1 Investigator is an independent contractor engaged by LAMBDA to perform the Services in accordance with the provisions of this Agreement, and the relationship hereby created is specifically governed by, limited to, and subject to all of the terms and conditions contained in this Agreement. The parties further agree that LAMBDA does not have the authority to hire or fire employees of the Investigator / Institution, nor does LAMBDA determine the rate or method of pay of such employees. Additionally, nothing contained in this Agreement shall entitle Investigator/Institute to the right or authority to make any representation on behalf of LAMBDA or the Sponsor, bind LAMBDA or Sponsor to others in any manner, or use LAMBDA's / Sponsor's name or trademarks in any public disclosure, without LAMBDA's / Sponsor's prior written permission.

Dr. Maheshkumar Kalloli, Belagavi



ATTESTED

Page 10 of 20

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

7.10 It would be the primary responsibility of the institution to maintain custody of study records and all other applicable study items in purview of the study protocol and this agreement, irrespective of the PI presence in the institution. Institution will allow regulatory authorities, sponsor and CRO to perform inspections of study data. In case the PI has to leave the institution, the PI should handover charge of the study to any other designee in form of document and forward all future communications received to institute pertaining to trial. PI is responsible to update CRO and / or sponsor for this change and all applicable communications, henceforth. Designee will execute all PI responsibilities, henceforth. In case of change in institution management, the institute will inform CRO and / or sponsor

8 Publication

8.1 Study results are Sponsor's property and as a result of this, no publication can be performed without the written approval by the sponsor.

9 Indemnity / Liability

9.1 In no event, shall LAMBDA, Sponsor, Investigator or Institution/Site be liable for any indirect, incidental, special, or consequential damages or lost profits arising under or as a result of this agreement (or the termination hereof).

9.2 In the event of a material error by Investigator/Institute in the performance of the Services, which renders the Services invalid, Investigator/Institute shall repeat the Services at no additional expense to LAMBDA, if Lambda requests or Investigator/ Institute should reimburse the payment already made by Lambda. Lambda has the right to terminate the services of Investigator due to any breach of this agreement.

9.3 Sponsor will indemnify the Investigator and/or Institution from any claims due to acts of omission or wrong by Sponsor.

9.4 Sponsor will indemnify liability arising from design or manufacture of the Compound, sale and use of the Compound following the Clinical Trial and injury to study subject directly attributable to Compound, which is jointly identified by a medical monitor/ Sponsor's medical expert and the Investigator.

9.5 The Investigator and/or the Institution will indemnify LAMBDA and Sponsor from any claims due to acts of negligence, omission or wrong by the Investigator or Institution.

9.6 The Investigator and/or the Institution are responsible and liable for conduct of the Clinical Trial at the Institution according to the Protocol and the Agreement.

9.7 Each party will notify other parties of any claim related to the Clinical Trial.

9.8 Sponsor will cover medical expenses for the treatment of any SAE as identified by the Investigator, which arise from using the Compound and study procedures in accordance with the Protocol, to the extent not covered by any other insurance by patient and provided the patient did nothing to cause or contribute to the injury.

10 Compensation / Insurance

10.1 Sponsor/LAMBDA shall maintain appropriate insurance coverage for the Study subjects against financial losses caused by personal injury, which are study and/or Compound related.

Dr. Maheshkumar Kalloli, Belagavi



ATTESTED
Page 8 of 20


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

3.6 LAMBDA will transfer on behalf of Sponsor the financial support to the Institution or Investigator according to the budget agreed by Sponsor, Investigator and the Institution as set out in Schedule B subject to the terms of this Agreement.

4 **Performance standards of the work to be conducted by the Investigator**

4.1 The Investigator and/or the Institution shall use all reasonable endeavors to enroll at least **01-02 patient** within **1 months**; minimum expected recruitment rate from the site is **01-02 patients** per month on an average. The parties may agree in writing to extend the time for recruitment of eligible patients if so desired. Recruitment period will be **6 months** as per study design; however recruitment will be competitive among participating sites hence the site may have recruitment period even less or more than specified.

"Eligible Patients" is defined as those who fulfill inclusion and exclusion criteria specified in the Protocol which is verifiable from source documents.

4.2 In the event that the study is part of a multi-center trial, Sponsor may amend the number of Eligible Patients to be recruited as follows:

- a) if in the reasonable opinion of LAMBDA or Sponsor recruitment of Eligible Patients is proceeding at a rate below that required for the relevant timelines to be met, LAMBDA may by notice to the Investigator or the Institution require recruitment at the Site to cease and the terms of this Agreement shall relate to the number of patients that have been accepted for entry into the Study at the date of such notice; or
- b) If recruitment of Eligible Patients is proceeding at a rate above that required meeting the relevant timelines, LAMBDA may, with the agreement of the Investigator or the Institution increase the number of cases to be recruited.

4.3 The Investigator or the Institution shall use all reasonable endeavors to comply with the time frames as agreed with LAMBDA.

4.4 The Investigator shall enter the data into the eCRF within 3 working days after completion of each visit.

4.5 The Investigator shall participate in teleconference and meeting as required by LAMBDA or Sponsor to update the Compound information and to resolve issues, if any.

4.6 The Investigator shall strictly adhere to the SAE reporting timelines in accordance with requirement of ICH GCP, New Drugs and Clinical Trials Rules, 2019 and standard operating procedure ("SOP") of LAMBDA, whichever is tightest.

5 **Payment terms**

5.1 LAMBDA confirms the Sponsor agrees to support the Clinical Trial as outlined in the Protocol and as described in and in accordance with the provisions of this Agreement and the Payment Agreement as set out in Schedule B. Lambda will have oversight on patient reimbursement records maintain at the site.

6 **Period of validity of the Agreement**

Dr. Maheshkumar Kalloli, Belagavi



ATTESTED
Page 6 of 20


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- 2.6 The Investigator shall communicate all relevant aspects of the Clinical Trial to the patients intending to participate in the trial and their legally acceptable representatives and shall obtain voluntary signed written informed consent from all prospective patients and their legally acceptable representatives prior to start of any study related procedures.
- 2.7 During the performance of the Clinical Trial and for a period of 15 years after expiry/termination of the agreement, the Investigator and/or Institute is responsible for, but are not limited to, the following aspects:
- provision of required study documents (e.g. curriculum vitae(s), medical registration certificates and/or other relevant documents evidencing qualifications of investigator(s) and sub-investigator(s), confirmation of adequate site facilities, etc.);
 - progress reporting (including recruitment figures) to ethics committee and LAMBDA on a regular basis;
 - ensuring direct access by Lambda monitors, Lambda auditors, Sponsor representative and regulatory authority to original study documents, medical records, study materials, etc and providing appropriate working conditions for monitors, auditors and regulatory authority to perform study-related monitoring, audit and inspection respectively;
 - to allow any regulatory audit by DCGI or any applicable regulatory authority within 15 years of submission of report and ensure compliance of any regulatory deficiency raised by such authorities in reasonable period of time; If Investigator is to submit any information to such regulatory authorities agencies, such submissions shall not be made without Lambda's prior review and written approval, and any changes (other than entry of required information) also shall be subject to such prior written approval.
 - Safe handling, storage, transportation and disposal of infectious materials and wastes involved in the Clinical Trial;
 - Inform the Ethics Committee of study closure.
 - Maintenance of drug accountability records, study documents including study drug acknowledgement receipts, study supply receipts, payment receipts, EC approvals etc.;
 - Handling and storage of compound according to protocol.
 - Archival of study documents including source data/patient medical records in accordance with ICH-GCP for at least 15 years after completion of study as per the site archival fees which will be paid by sponsor on actual.
- 2.8 All SAEs has to be promptly reported by the Investigator to LAMBDA and/or Sponsor, Ethics Committee, Head of institution, DCGI and Expert Committee (In case of Death). The Investigator is responsible for reporting, and shall report, all such findings in the manner and within the time limits as set out in the applicable provisions of ICH GCP and the applicable legislation. LAMBDA and/or Sponsor confirms an effective system for centralized tracking and notification to investigators and to applicable regulatory authorities of all findings that could adversely affect the safety of Clinical Trial subject, including, without limitation, all unexpected serious adverse drug reactions experienced by any subject taking part in the Clinical Trial at any site has been established. Notwithstanding anything in

Dr. Maheshkumar Kalloli, Belagavi



ATTESTED

Page 4 of 20

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

KLES Dr. Prabhakar Kore Hospital and MRC
 Second Floor, SMO, Nehru Nagar,
 Belagavi – 590010, Karnataka, India
 (Hereinafter referred to as the “Institution” or “Site”)

AND

Dr. Maheshkumar Kalloli
 KLES Dr. Prabhakar Kore Hospital and MRC
 Second Floor, SMO, Nehru Nagar,
 Belagavi – 590010, Karnataka, India
 (Hereinafter referred to as the “Investigator”)

WHEREAS:

LAMBDA is acting as a Contract/Clinical Research Organization (CRO) under a Service Agreement on behalf of Intas Pharmaceuticals Limited.

Intas Pharmaceuticals Limited has asked LAMBDA to handle and negotiate site Agreements on its behalf;

LAMBDA on behalf of Sponsor wishes the Investigator and Institute to participate in a clinical trial entitled “**A multicentric, open label, single arm study to evaluate the safety and efficacy of INTP26 (trastuzumab biosimilar) in patients with HER2-overexpressing breast (early or metastatic) cancer or metastatic gastric cancer.**” (“Clinical Trial”) to be conducted under the direction and supervision of the Investigator using the facilities of the Institution; and,

The Investigator and Institute is willing to participate in the Clinical Trial; and,

The Investigator is authorized to conduct the clinical trial at the Institution. The Investigator will review the Clinical Trial for patient safety, scientific validity, and utilization of hospital resources.

IN CONSIDERATION of the mutual promises and covenants herein, the parties agree as follows:

1 Definitions

1.1 In this Agreement, the following terms shall have the following meanings:

<u>Term</u>	<u>Meaning</u>
“Compound”	INTP26 – Trastuzumab Biosimilar 150mg/vial and 440mg/vial of Intas Pharmaceuticals Limited, India
“CRF”	Case Report Form
“CRO”	Contract/Clinical Research Organization
“Declaration of Helsinki”	The 2013 version of the Helsinki Declaration of the World Medical Association and amendments.
“DCGI”	Drug Controller General of India.

Dr. Maheshkumar Kalloli, Belagavi



ATTESTED

Page 2 of 20

Dr. V.A.Kothiwale
 Registrar

KLE Academy of Higher Education and Research,
 (Deemed-to-be-University u/s 3 of the UGC Act, 1956)
 Belagavi-590 010, Karnataka



सत्यमेव जयते

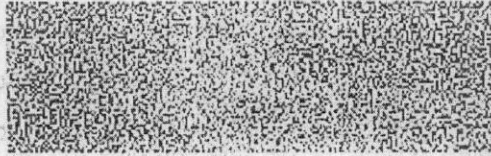
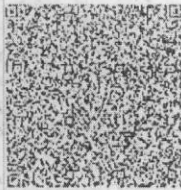
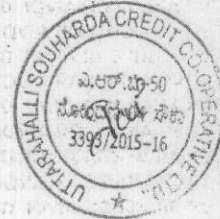
INDIA NON JUDICIAL

Government of Karnataka

Rs. 300

e-Stamp

Certificate No. : IN-KA41726105066833R
 Certificate Issued Date : 01-JUL-2010 05:28 PM
 Account Reference : NONACC (FI)/ kaksfcd09/ UTTARHALLI/ KA-BA
 Unique Doc. Reference : SUBIN-KAKAKSFCL0810368694584498R
 Purchased by : IQVIA RDS INDIA PVT LTD
 Description of Document : Article 12 Bond
 Description : CLINICAL TRIAL AGREEMENT
 Consideration Price (Rs.) : 0
 (Zero)
 First Party : IQVIA RDS INDIA PVT LTD
 Second Party : KLES DR PRABHAKAR KORE HOSPITAL AND M R C
 Stamp Duty Paid By : IQVIA RDS INDIA PVT LTD
 Stamp Duty Amount (Rs.) : 300
 (Three Hundred only)



Please write or type below this line

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Statutory Alert:

1. The authenticity of this Stamp Certificate should be verified at "www.sndteestamp.com". Any discrepancy in the details on this Certificate and as available on the website renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

CLINICAL TRIAL AGREEMENT

The Clinical Trial Agreement ("**Agreement**") is made by and between:

- **KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre**, having a place of business at Nehru Nagar, Belagavi - 590010, Karnataka, India (the "**Institution**"), and
- **Dr. Rohan Bhise**, having a place of business at KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi - 590010, Karnataka, India (the "**Investigator**"), and
- **GDD Experts India Private Limited**, having a place of business at Ground Floor, Gulmohar Complex, Opposite Hislop College, Civil Lines, Nagpur-440001, Maharashtra, India (the "**Research Company**")
- **IQVIA RDS (India) Private Limited**, (formerly **Quintiles Research (India) Private Limited**), having a place of business at III Floor, Etamin Block, Prestige Technology Park, Sarjapur - Marathahalli Outer Ring Road Bangalore - 560103, Karnataka, India ("**IQVIA**").

Each a "**Party**" and together the "**Parties**".

Protocol Number:	SAMSON-II
Protocol Title:	A Randomized, Double-blind, Parallel Group, Equivalence, Multicenter Phase III Trial to Compare the Efficacy, Safety, Pharmacokinetics and Immunogenicity of HD204 to Avastin [®] in patients with Metastatic or Recurrent Non-squamous Non-small Cell Lung Cancer. EudraCT no.: 2017-005175-78
Protocol Date:	Version 1.0 - 22 April 2019
Sponsor:	Prestige BioPharma Pte Ltd
Country where Site is Conducting Study	India
Investigator:	Dr. Rohan Bhise
Key Enrollment Date:	100 Calendar Days after Site Initiation Visit (being the date by which Site must enrol at least one (1) subject as more specifically set out in section 1.7 "Key Enrollment Date" below)
IRB/IEC	Name: Institutional Ethics Committee, KLE University Address: KLE University, JMNC Campus, Nehru Nagar, Belagavi - 590010, Karnataka, India. Chairperson Name: Dr. Subarna Roy Chairperson contact number: +91 9449033133


The following additional definitions shall apply to this Agreement:

Prestige BioPharma Pte Ltd
Protocol Number: SAMSON-II
Clinical Trial Agreement - IQVIA India Template - 12 July 2019
KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre_Dr. Rohan Bhise_15July2019_TM_final

CONFIDENTIAL
Page 1 of 25



ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Protocol: the clinical protocol referenced above as it may be modified from time to time by the Sponsor (defined below).

Case Report Form or CRF: case report form (paper or electronic) to be used by Site to record all of the Protocol-required information to be reported to Sponsor on each Study Subject (defined below).

Study: the clinical trial that is to be performed in accordance with this Agreement and the Protocol for purposes of gathering information about the compound/medical device identified in the Protocol.

Study Subject: an individual who participates in the Study, either as a recipient of the Investigational Product (defined below) or as a control.

Study Staff: the individuals involved in conducting the Study under the direction of the Investigator.

Investigational Product: the compound/medical device identified in the Protocol that is being tested in the Study.

Good Clinical Practices or GCPs: International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Harmonised Tripartite Guideline for Good Clinical Practice as amended from time to time and the principles set out in the Declaration of Helsinki as revised from time to time.

Sponsor: the sponsor of the Study.

Medical Records: the Study Subjects' primary medical records kept by the Institution on behalf of the Investigator, including, without limitation, treatment entries, x-rays, biopsy reports, ultrasound photographs and other diagnostic images.

MCI Regulations: Indian Medical Council (Professional Conduct, Etiquette and Ethics) (Amendment) Regulations, 2009 – Part -1, as may be amended from time to time or any replacement regulations.


Study Data: all records and reports, other than Medical Records, collected or created pursuant to or prepared in connection with the Study including, without limitation, reports (e.g., CRFs, data summaries, interim reports and the final report) required to be delivered to Sponsor pursuant to the Protocol and all records regarding inventories and dispositions of all Investigational Product.

Government Official: any officer or employee of a government or of any ministry, department, agency, or instrumentality of a government; any person acting in an official capacity on behalf of a government or of any ministry, department, agency, or instrumentality of a government; any officer or employee of a company or of a business owned in whole or part by a government; any officer or employee of a public international organization such as the World Bank or the United Nations; any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or any candidate for political office; any doctor, pharmacist, or other healthcare professional who works for or in any hospital, pharmacy or other healthcare facility owned or operated by a government agency, ministry or department.

Item(s) of Value: should be interpreted broadly and may include, but is not limited to, money or payments or equivalents, such as gift certificates; gifts or free goods; meals, entertainment, or hospitality; travel or payment of expenses; provision of services; purchase of property or services at inflated prices; assumption or forgiveness of indebtedness; intangible benefits, such as enhanced social or business standing (e.g., making donations to government official's favored charity); and/or benefits to third persons related to government officials (e.g., close family members).

Prestige BioPharma Pte Ltd
Protocol Number: SAMSON-II
Clinical Trial Agreement – IQVIA India Template – 12 July 2019
KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre_Dr. Rohan Bhise_15July2019_TM_final

.CONFIDENTIAL
Page 2 of 25



ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

RECITALS:

WHEREAS, IQVIA is providing clinical research organisation services to Sponsor under a separate contract between IQVIA and Sponsor. IQVIA's services include monitoring of the Study and contracting with clinical research sites;

WHEREAS, the Institution and Investigator (hereinafter jointly the "Site") are willing to conduct the Study and IQVIA requests the Site to undertake such Study.

NOW THEREFORE, the following is agreed:

1. CONDUCT OF THE STUDY

1.1. Compliance with Laws, Regulations, and Good Clinical Practices

Site agrees that Site and Study Staff shall perform the Study at Institution in strict accordance with this Agreement, the Protocol, any and all applicable local, national and international laws regulations and guidelines, including in particular, but without limitation, GCPs, MCI Regulations, and state and local tax and finance regulations. Site and Study Staff acknowledge that IQVIA and Sponsor, and their respective affiliates, need to adhere to the provisions of (i) the Bribery Act 2010 of the United Kingdom (Bribery Act); (ii) the Foreign Corrupt Practices Act 1977 of the United States of America (FCPA) and (iii) any other applicable anti-corruption legislation.

1.2. Informed Consent Form

Site agrees to use an informed consent form that has been approved by Sponsor and is in accordance with applicable regulations and the requirements of the Institutional Review Board ("IRB") or Independent Ethics Committee ("IEC") that is responsible for reviewing the Study. Site shall obtain the prior written informed consent of each Study Subject.


1.3. Medical Records and Study Data

1.3.1. Collection, Storage and Destruction: Site shall ensure the prompt, complete, and accurate collection, recording and classification of the Medical Records and Study Data.

Site shall:

- (i) maintain and store Medical Records and Study Data in a secure manner with physical and electronic access restrictions, as applicable and environmental controls appropriate to the applicable data type and in accordance with applicable laws, regulations and industry standards; and
- (ii) protect the Medical Records and Study Data from unauthorized use, access, duplication, and disclosure. If directed by Sponsor or IQVIA, Site will submit Study Data using the electronic system provided by Sponsor or IQVIA or their designated representative and in accordance with Sponsor's instructions for electronic data entry. Site shall prevent unauthorized access to the Study Data by maintaining physical security of the electronic system and ensuring that Study Staff maintain the confidentiality of their passwords. Investigator agrees to collect all Study Data in Medical Records prior to entering it into the CRF. Site shall ensure the prompt submission of CRFs; and
- (iii) take measures to prevent accidental or premature destruction or damage of these documents, for as long as required by applicable laws and regulations. Neither Institution nor Investigator shall destroy or permit the destruction of any Medical Records or Study Data without prior written notification to the Sponsor, and Institution shall continue to store Medical Records and Study Data, at the Sponsor's

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

expense, for any period that the Sponsor may request in writing after retention is no longer required by any applicable law or regulation.

If the Investigator leaves the Institution, then responsibility for maintaining Medical Records and Study Data shall be determined in accordance with applicable regulations but Institution will not in any case be relieved of its obligations under this Agreement for maintaining the Medical Records and Study Data.

1.3.2. Ownership. Institution shall retain ownership of Medical Records. The Institution and the Investigator hereby assign to Sponsor all of their rights, title and interest, including intellectual property rights, to all Confidential Information (as defined below) and any other Study Data.

1.3.3. Access, Use, Monitoring and Inspection. Site shall provide original or copies (as the case may be) of all Study Data to IQVIA and Sponsor for Sponsor's use. Site shall afford Sponsor and IQVIA and their representatives and designees reasonable access to Site's facilities and to Medical Records and Study Data so as to permit Sponsor and IQVIA and their representatives and designees to monitor the Study.

Site shall afford regulatory authorities reasonable access to Site's facilities and to Medical Records and Study Data, and the right to copy Medical Records and Study Data.

The Site agrees to cooperate with the representatives of IQVIA and Sponsor, and the Site agrees to ensure that the employees, agents and representatives of the Site do not harass, or otherwise create a hostile working environment for such representatives.

The Site shall immediately notify IQVIA of, and provide IQVIA copies of, any inquiries, correspondence or communications to or from any governmental or regulatory authority relating to the Study, including, but not limited to, requests for inspection of the Site's facilities, and the Site shall permit IQVIA and Sponsor to attend any such inspections. The Site will make reasonable efforts to separate, and not disclose, all Confidential Information that is not required to be disclosed during such inspections.

1.3.4. License. Sponsor hereby grants to Institution a perpetual, non-exclusive, nontransferable, paid-up license, without right to sublicense, to use Study Data (i) subject to the obligations set forth in section 3 "Confidentiality", for internal, non-commercial research and for educational purposes, and (ii) for preparation of publications in accordance with Section 5 "Publication Rights".

1.3.5. Survival. This section 1.3 "Medical Records and Study Data" shall survive termination or expiration of this Agreement.

1.4. Duties of Investigator

Investigator is responsible for the conduct of the Study at Institution and for supervising any individual or party to whom the Investigator delegates Study-related duties and functions. In particular, but without limitation, it is the Investigator's duty to review and understand the information in the Investigator's Brochure or device labeling instructions, to ensure that all informed consent requirements are met, to ensure that all required reviews and approvals by applicable regulatory authorities and IRBs or IECs are obtained, and to review all CRFs to ensure their accuracy and completeness.

If the Investigator and Institution retain the services of any individual or party to perform Study-related duties and functions, the Institution and Investigator shall ensure this individual or party is qualified to perform those Study-related duties and functions and shall implement procedures

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

to ensure the integrity of the Study-related duties and functions performed and any data generated.

Investigator agrees to provide a written declaration revealing Investigator's possible economic or other interests, if any, in connection with the conduct of the Study or the Investigational Product.

Investigator agrees to provide a written declaration revealing Investigator's disclosure obligations, if any, with the Institution in connection with the conduct of the Study and the Investigational Product.

Site agrees to provide prompt advance notice to Sponsor and IQVIA if Investigator will be leaving the Institution or is otherwise no longer able to perform the Study. The appointment of a new Investigator must have the prior approval of Sponsor and IQVIA.

1.5. Adverse Events

The Site shall report adverse events and serious adverse events as directed in the Protocol and by applicable laws and regulations. The Site shall cooperate with Sponsor in its efforts to follow-up on any adverse events. The Site shall comply with its IRB/IEC reporting obligations.

Sponsor will promptly report to the Site, the Site's IRB/IEC, and IQVIA, any finding that could affect the safety of participants or their willingness to continue participation in the Study, influence the conduct of the Study, or alter the Site's IRB/IEC approval to continue the Study.

1.6. Use and Return of Investigational Product and Equipment

Sponsor or a duly authorized agent of Sponsor, shall supply Institution or Investigator with sufficient amount of Investigational Product as described in the Protocol.

The Site shall use the Investigational Product and any comparator products provided in connection with the Study, solely for the purpose of properly completing the Study and shall maintain the Investigational Product as specified by Sponsor and according to applicable laws and regulations, including storage in a locked, secured area at all times.

Upon completion or termination of the Study, the Site shall return or destroy, at Sponsor's option, the Investigational Product, comparator products, and materials and all Confidential Information (as defined below) at Sponsor's sole expense.

Institution and Investigator shall comply with all laws and regulations governing the disposition or destruction of Investigational Product and any instructions from IQVIA that are not inconsistent with such laws and regulations.


The Site shall return any equipment or materials provided by Sponsor for use in the Study unless Sponsor and Site have a written agreement for Site to acquire the equipment. Equipment provided to Site for the Study, if any, is listed on Attachment C hereto. If there are Site facility improvements provided by IQVIA or Sponsor in relation to the Study, then Site shall enter a separate written agreement with IQVIA or Sponsor with respect to such facility improvements.

1.7. Enrollment of Study Subjects

Site shall not be permitted to screen potential Study Subjects, randomize Study Subjects, receive Investigational Product or receive any payment until the Effective Date of this Agreement is reached.

1.8. Key Enrollment Date

ATTESTED


Dr. V.A. Kothiwale
Registrar


KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

The Site understands and agrees that if Site has not enrolled at least one (1) Study Subject by the Key Enrollment Date then IQVIA may terminate this Agreement in accordance with Section 15 "Term & Termination" Sponsor/IQVIA has the right to limit enrollment at any time.

1.9. Attendance at Start Up Meeting

If Sponsor or IQVIA requests Site's attendance at a Study startup meeting or other meeting necessary to provide information regarding the Study or Investigational Product, Site will be reimbursed for reasonable and necessary travel and lodging expenses (including meals) incurred to attend such meetings. Reimbursement will be as set forth in Attachment A.

2. PAYMENT

In consideration for the proper performance of the Study by Site in compliance with the terms and conditions of this Agreement, payments shall be made in accordance with the provisions set forth in Attachment A, with the last payment being made after the Site completes all its obligations hereunder, and IQVIA has received all properly completed CRFs and, if IQVIA requests, all other Confidential Information (as defined below).

3. CONFIDENTIALITY

3.1 Definition

"Confidential Information" means the confidential and proprietary information of Sponsor and includes (i) all information disclosed by or on behalf of Sponsor to Institution, Investigator or other Institution personnel, including without limitation, the Investigational Product, technical information relating to the Investigational Product, all Pre-Existing Intellectual Property (as defined in Section 4) of Sponsor, and the Protocol; and (ii) Study enrollment information, information pertaining to the status of the Study, communications to and from regulatory authorities, information relating to the regulatory status of the Investigational Product, and Study Data and Inventions (as defined in Section 4).

Confidential Information shall not include information that:

- (i) can be shown by documentation to have been public knowledge prior to or after disclosure by Sponsor, other than through wrongful acts or omissions attributable to Investigator, Institution or any of its personnel;
- (ii) can be shown by documentation to have been in the possession of Investigator, Institution or any of its personnel prior to disclosure by Sponsor, from sources other than Sponsor that did not have an obligation of confidentiality to Sponsor;
- (iii) can be shown by documentation to have been independently developed by Investigator, Institution or any of its personnel; or
- (iv) is permitted to be disclosed by written authorization from Sponsor.

3.2 Obligations

Site and Site's personnel, including Study Staff shall not:

- (i) use Confidential Information for any purpose other than the performance of the Study or
- (ii) disclose Confidential Information to any third party, except as permitted by this Section 3 or by Section 5 "Publication Rights", or as required by law or by a regulatory authority or as authorized in writing by the disclosing party.

To protect Confidential Information, Site agrees to:

- (i) limit dissemination of Confidential Information to only those Study Staff having a need to know for purposes of performing the Study;
- (ii) advise all Study Staff who receive Confidential Information of the confidential nature of such information; and
- (iii) use reasonable measures to protect Confidential Information from disclosure.

Prestige BioPharma Pte Ltd
Protocol Number: SAMSON-II
Clinical Trial Agreement – IQVIA India Template – 12 July 2019
KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre_Dr. Rohan Bhise_15July2019_TM_final

ATTESTED

CONFIDENTIAL
Page 6 of 25



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Nothing herein shall limit the right of Site to disclose Study Data as permitted by Section 5 "Publication Rights."

3.3 Compelled Disclosure

In the event that Institution or Investigator receives notice from a third party seeking to compel disclosure of any Confidential Information, the notice recipient shall provide Sponsor with prompt notice so that Sponsor may seek a protective order or other appropriate remedy. In the event that such protective order or other remedy is not obtained, the notice recipient shall furnish only that portion of the Confidential Information which is legally required to be disclosed, and shall request confidential treatment for the Confidential Information.

3.4 Return or Destruction

Upon termination of this Agreement or upon any earlier written request by Sponsor at any time, Site shall return to Sponsor, or destroy, at Sponsor's option, all Confidential Information other than Study Data.

3.5 Survival

This Section 3 "Confidentiality" shall survive termination or expiration of this Agreement for ten (10) years.

4. INTELLECTUAL PROPERTY

4.1 Pre-existing Intellectual Property

Ownership of inventions, discoveries, works of authorship and other developments existing as of the Effective Date and all patents, copyrights, trade secret rights and other intellectual property rights therein (collectively, "**Pre-existing Intellectual Property**"), is not affected by this Agreement, and no Party or Sponsor shall have any claims to or rights in any Pre-existing Intellectual Property of another, except as may be otherwise expressly provided in any other written agreement between them.

4.2 Inventions

For purposes hereof, the term "**Inventions**" means all inventions, discoveries and developments conceived, first reduced to practice or otherwise discovered or developed by a Party or Sponsor or any of such entity's personnel in performance of the Study. Sponsor shall own all Inventions, that are conceived, first reduced to practice or otherwise discovered or developed by the Institution, the Investigator or any of their personnel in performance of the Study.

4.3 Assignment of Inventions

Site shall, and shall cause its personnel to, disclose all Inventions promptly and fully to Sponsor in writing, and Site, on behalf of itself and its personnel, hereby assigns to Sponsor all of its rights, title and interest in and to Inventions, including all patents, copyrights and other intellectual property rights therein and all rights of action and claims for damages and benefits arising due to past and present infringement of said rights. Site shall cooperate and assist Sponsor by executing, and causing its personnel to execute, all documents reasonably necessary for Sponsor to secure and maintain Sponsor's ownership rights in Inventions.

4.4 License

Sponsor hereby grants to Institution a perpetual, non-exclusive, non-transferable, paid-up license, without right to sublicense, to use Inventions, subject to the obligations set forth in Section 3 "Confidentiality," for internal, non-commercial research and for educational purposes.

4.5 Patent Prosecution

Prestige BioPharma Pte Ltd
Protocol Number: SAMSON-II
Clinical Trial Agreement – IQVIA India Template – 12 July 2019
KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre_Dr. Rohan Bhise_15July2019_TM_final

CONFIDENTIAL
Page 7 of 25



ATTESTED
↓

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Site shall cooperate, at Sponsor's request and expense, with Sponsor's preparation, filing, prosecution, and maintenance of all patent applications and patents for Inventions.

4.6 Survival

This Section 4 "Intellectual Property" shall survive termination or expiration of this Agreement.

5. PUBLICATION RIGHTS

5.1 Publication and Disclosure

Institution and Investigator shall have the right to publish or present the results of Institution's and Investigator's activities conducted under this Agreement, including Study Data, only in accordance with the requirements of this Section. Institution and Investigator agree to submit any proposed publication or presentation to Sponsor for review at least thirty (30) days prior to submitting any such proposed publication to a publisher or proceeding with such proposed presentation. Within thirty (30) days of its receipt, Sponsor shall advise Institution and/or Investigator, as the case may be, in writing of any information contained therein which is Confidential Information (other than Study Data) or which may impair the availability of patent protection for Inventions. Sponsor shall have the right to require Institution and/or Investigator, as applicable, to remove specifically identified Confidential Information (other than Study Data) and/or to delay the proposed publication or presentation for an additional sixty (60) days to enable Sponsor to seek patent protection for Inventions.

5.2 Multi-Center Publications

If the Study is a multi-center study, Institution and Investigator agree that they shall not, without the Sponsor's prior written consent, independently publish, present or otherwise disclose any results of or information pertaining to Institution's and Investigator's activities conducted under this Agreement until a multi-center publication is published; provided, however, that if a multi-center publication is not published within eighteen (18) months after completion of the Study and lock of the database at all research sites or any earlier termination or abandonment of the Study, Institution and Investigator shall have the right to publish and present the results of Institution's and Investigator's activities conducted under this Agreement, including Study Data, solely in accordance with the provisions of Section 5.3 "Confidentiality of Unpublished Data."

5.3 Confidentiality of Unpublished Data

Institution and Investigator acknowledges and agrees that Study Data that is not published, presented or otherwise disclosed in accordance with Section 5.1 or Section 5.2 ("**Unpublished Data**") remains within the definition of Confidential Information, and Institution and Investigator shall not, and shall require their personnel not to, disclose Unpublished Data to any third party or disclose any Study Data to any third party in greater detail than the same may be disclosed in any publications, presentations or disclosures made in accordance with Section 5.1 or Section 5.2.

5.4 Media Contacts

Institution and Investigator shall not, and shall ensure that its personnel do not engage in interviews or other contacts with the media, including but not limited to newspapers, radio, television and the Internet, related to the Study, the Investigational Product, Inventions, or Study Data without the prior written consent of Sponsor. This provision does not prohibit publication or presentation of Study Data in accordance with this Section.

5.5 Use of Name, Registry and Reporting

No Party hereto shall use any other Party's name, or Sponsor's name, in connection with any advertising, publication or promotion without prior written permission, except that the Sponsor and IQVIA may use the Site's name in Study publications and communications, including clinical trial websites and Study newsletters. Sponsor will register the Study with a public

Prestige BioPharma Pte Ltd


Protocol Number: SAMSON-II

Clinical Trial Agreement – IQVIA India Template – 12 July 2019

KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre_Dr. Rohan Bhise_15July2019_TM_final

ATTESTED

CONFIDENTIAL
Page 8 of 25


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

clinical trials registry in accordance with applicable laws and regulations and will report the results of the Study publicly when and to the extent required by applicable laws and regulations.

5.6 Survival

This Section 5 "Publication Rights" shall survive termination or expiration of this Agreement.

6. PERSONAL DATA

6.1 Personal Data

Both prior to and during the course of the Study, the Investigator and his/her teams may be called upon to provide personal data. This data falls within the scope of the law and regulations relating to the protection of personal data and may be used by IQVIA, Sponsor, and their affiliates in compliance with applicable law, including as set forth below and for the length of time reasonably necessary for the purpose below.

For the Investigator, this personal data may include names, contact information, work experience and professional qualifications, publications, resumes, educational background and information related to financial disclosures or other potential conflict of interest, and payments made to Payee(s) under this Agreement for the following purposes:

- (i) the conduct of clinical trials and/or statistical analysis;
- (ii) verification by governmental or regulatory agencies, the Sponsor, IQVIA, and their agents and affiliates;
- (iii) compliance with legal and regulatory requirements;
- (iv) publication on www.clinicaltrials.gov and websites and databases that serve a comparable purpose;
- (v) storage in databases to facilitate the selection of investigators for future clinical trials or other business and;
- (vi) anti-corruption compliance.

Investigator's personal data may be transferred to countries outside of Investigator's country, which may not provide for the same level of protection as is applicable in Investigator's country. In such event, IQVIA or Sponsor, as applicable, will make sure that appropriate safeguards are secured in advance of any transfer in accordance with IQVIA's or Sponsor's, as applicable, legal obligations to ensure the protection of Investigator's personal data according to the data protection laws and regulations applicable in Investigator's country.

Names of members of Study Staff may be processed in IQVIA's study contacts database for study-related purposes only.

6.2 Study Subject Personal Data

The Investigator shall obtain Study Subject written consent for the collection and use of Study Subject personal data for Study purposes, including the disclosure, transfer and processing of data collected in accordance with the Protocol, in compliance with applicable data protection provisions.

6.3 Data Controller

The Sponsor shall be the data controller for such personal data except that, if IQVIA deals with any personal data under this Agreement in the manner of a data controller, IQVIA shall be the data controller of such personal data to the extent of such dealings.



ATTESTED

CONFIDENTIAL
Page 9 of 25

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

IQVIA may process "personal data", as defined in the applicable data protection legislation enacted under the same or equivalent/similar national legislation (collectively "Data Protection Legislation"), of the Investigator and Study Staff for study-related purposes and all such processing will be carried out in accordance with the Data Protection Legislation.

6.4 Survival

This Section 6 "Personal Data" shall survive termination or expiration of this Agreement.

7. STUDY SUBJECT INJURY

The Site shall promptly notify IQVIA and Sponsor in writing of any claim of illness or injury or death actually or allegedly due to an adverse reaction to the Investigational Product and cooperate with Sponsor in the handling of the adverse event.

Sponsor shall reimburse Institution for the direct, reasonable and necessary medical expenses incurred by Institution for the treatment of any adverse event experienced by, illness of or bodily injury to a Study Subject that is caused by treatment of the Study Subject in accordance with the Protocol, except to the extent that such adverse event, illness or personal injury is caused by:

- (a) failure by Institution, Investigator or Research Company or any of their respective personnel to comply with this Agreement, the Protocol, any written instructions of Sponsor concerning the Study, or any applicable law, regulation or guidance, including GCPs, issued by any regulatory authority, or
- (b) negligence or willful misconduct by Institution, Investigator or Research Company or any of their respective personnel, or
- (c) failure of the Study Subject to follow the reasonable instructions of the Investigator relating to the requirements of the Study.

This Section 7 "Study Subject Injury" shall survive termination or expiration of this Agreement.

8. IQVIA DISCLAIMER

IQVIA expressly disclaims any liability in connection with the Investigational Product, including any liability for any claim arising out of a condition caused by or allegedly caused by any Study procedures associated with such product except to the extent that such liability is caused by the negligence, willful misconduct or breach of this Agreement by IQVIA.

This Section 8 "IQVIA Disclaimer" shall survive termination or expiration of this Agreement.

9. CONSEQUENTIAL DAMAGES

Neither IQVIA nor Sponsor shall be responsible to the Site for any lost profits, lost opportunities, or other consequential damages, nor shall Site be responsible to IQVIA or Sponsor for any lost profits, lost opportunities, or other consequential damages.

This Section 9 "Consequential Damages" shall survive termination or expiration of this Agreement.

10. DEBARMENT

The Site represents and warrants that neither Institution nor Investigator, nor any of Institution's or Investigator's employees, agents or other persons performing the Study at Institution, have been debarred, disqualified or banned from conducting clinical trials or are under investigation by any

Prestige BioPharma Pte Ltd
Protocol Number: SAMSON-II
Clinical Trial Agreement – IQVIA India Template – 12 July 2019
KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre_Dr. Rohan Bhise_15July2019_TM_final



ATTESTED

CONFIDENTIAL
Page 10 of 25



Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

regulatory authority for debarment or any similar regulatory action in any country, and the Site shall notify IQVIA immediately if any such investigation, disqualification, debarment, or ban occurs.

This Section 10 "Debarment" shall survive termination or expiration of this Agreement.

11. FINANCIAL DISCLOSURE AND CONFLICT OF INTEREST

Upon Sponsor's or IQVIA's request, Site agrees that, for each listed or identified investigator or sub-investigator who is directly involved in the treatment or evaluation of Study Subjects, it shall promptly return to IQVIA a financial and conflict of interest disclosure form that has been completed and signed by such investigator or sub-investigator, which shall disclose any applicable interests held by those investigators or sub-investigators or their spouses or dependent children.

IQVIA may withhold payments if it does not receive a completed form from each such investigator and sub-investigator.

Site shall ensure that all such forms are promptly updated as needed to maintain their accuracy and completeness during the Study and for one (1) year after Study completion.

Site agrees that the completed forms may be subject to review by governmental or regulatory agencies, Sponsor, IQVIA, and their agents, and the Site consents to such review.

The Site further consents to the transfer of its financial disclosure data to the Sponsor's country of origin and to the U.S., even though data protection may not exist or be as developed in those countries as in the Site's own country.

This Section 11 "Financial Disclosure and Conflict of Interest" shall survive termination or expiration of this Agreement.

12. ANTI-KICKBACK AND ANTI FRAUD

Institution and Investigator agree that their judgment with respect to the advice and care of each Study Subject will not be affected by the compensation they receive from this Agreement, that such compensation does not exceed the fair market value of the services they are providing, and that no payments are being provided to them for the purpose of inducing them to purchase or prescribe any drugs, devices or products.

If the Sponsor or IQVIA provides any free products or items for use in the Study, Institution and Investigator agree that they will not bill any Study Subject, insurer or governmental agency, or any other third party, for such free products or items.

Institution and Investigator agree that they will not bill any Study Subject, insurer, or governmental agency for any visits, services or expenses incurred during the Study for which they have received compensation from IQVIA or Sponsor, or which are not part of the ordinary care they would normally provide for the Study Subject, and that neither Institution nor Investigator will pay another physician to refer subjects to the Study.

13. ANTI-BRIBERY

Institution and Investigator agree that the fees to be paid pursuant to this Agreement represent fair compensation for the services to be provided by Site. Institution and Investigator represent and warrant that payments or Items of Value received pursuant to this Agreement or in relation to the Study will not influence any decision that Institution, Investigator or any of their respective owners,

Prestige BioPharma Pte Ltd

Protocol Number: SAMSON-II

Clinical Trial Agreement – IQVIA India Template – 12 July 2019

KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre_Dr. Rohan Bhise_15July2019_TM_final

CONFIDENTIAL
Page 11 of 25

ATTESTED

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

directors, employees, agents, consultants, or any payee under this Agreement may make, as a Government Official or otherwise, in order to assist Sponsor or IQVIA to secure an improper advantage or obtain or retain business.

Institution and Investigator further represent and warrant that neither they nor any of their respective owners, directors, employees, agents, or consultants, nor any payee under this Agreement, will, in order to assist Sponsor or IQVIA to secure an improper advantage or obtain or retain business, directly or indirectly pay, offer or promise to pay, or give any Items of Value to any person or entity for purposes of (i) influencing any act or decision; (ii) inducing such person or entity to do or omit to do any act in violation of their lawful duty; (iii) securing any improper advantage; or (iv) inducing such person or entity to use influence with the government or instrumentality thereof to affect or influence any act or decision of the government or instrumentality.

In addition to other rights or remedies under this Agreement or at law, IQVIA may terminate this Agreement if Site breaches any of the representations or warranties contained in this Section or if IQVIA or Sponsor learns that improper payments are being or have been made to or by Institution or Investigator or any individual or entity acting on its or their behalf.

14. INDEPENDENT CONTRACTORS

The Investigator and Institution and Research Company and Study Staff are acting as independent contractors of IQVIA and Sponsor and shall not be considered the employees or agents of IQVIA or Sponsor.

Neither IQVIA nor Sponsor shall be responsible for any employee benefits, pensions, workers' compensation, withholding, or employment-related taxes as to the Investigator or Institution or Research Company or their staff.

It is hereby agreed and acknowledged by the Parties and Sponsor that IQVIA has no relationship whatsoever with the Research Company and that the Research Company is acting as an independent contractor of the Institution.

15. TERM & TERMINATION

15.1 Term

This Agreement will become effective on the date of approval of the Study by Drugs Controller General India or the date on which it is last signed by the parties, whichever date is later, (the "Effective Date") and shall continue until completion or until terminated in accordance with this Section 15 "Term & Termination". IQVIA shall attach a copy of the approval from the Drugs Controller General India approving the Study to this Agreement as Attachment B, and the Parties agree that such approval shall be incorporated by reference herein. If such approval has not been received as of the date the Parties sign this Agreement, IQVIA shall keep the original signed Agreements until receipt of such approval, and upon receipt of such approval, IQVIA shall attach a copy of the approval to each original Agreement as Attachment B and forward an original Agreement to each other Party thereafter, while retaining one original Agreement in its files. If such approval was received prior to the signatures of the Parties, IQVIA shall attach a copy of the approval hereto as Attachment B, and upon signature of all Parties, each Party shall receive an original of the Agreement, which shall include such approval as Attachment B.

15.2 Termination

IQVIA may terminate this Agreement for any reason effective immediately upon written notice. The Site may terminate upon written notice if circumstances beyond the Site's reasonable



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

control prevent completion of the Study, or if it reasonably determines that it is unsafe to continue the Study. Upon receipt of notice of termination, the Site shall immediately cease any subject recruitment, follow the specified termination procedures, ensure that any required subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs, and IQVIA shall make a final payment for visits or milestones properly performed pursuant to this Agreement in the amounts specified in Attachment A; provided, however, that ten percent (10%) of this final payment will be withheld until final acceptance by Sponsor of all CRF pages and all data clarifications issued and satisfaction of all other applicable conditions set forth herein. If a material breach of this Agreement appears to have occurred and termination may be required, then, except to the extent that Study Subject safety may be jeopardized, IQVIA may suspend performance of all or part of this Agreement, including, but not limited to, subject enrollment.

16. NOTICE

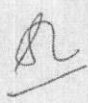
Any notices required or permitted to be given hereunder shall be given in writing and shall be delivered:

- (a) in person;
- (b) by certified mail, postage prepaid, return receipt requested;
- (c) by e-mail of .pdf/scan or other non-editable format notice with confirmed transmission report; or
- (d) by a commercial overnight courier that guarantees next day delivery and provides a receipt, and such notices shall be addressed as follows:

To Sponsor:	Prestige BioPharma Pte Ltd 2 Science Park Drive, Ascent Tower B, #04-13/14, Singapore 118222 Phone : +65-6924 6535 Fax : +65-6924 2053
To IQVIA	IQVIA RDS (India) Private Limited III Floor, Etamin Block, Prestige Technology Park, Sarjapur - Marathahalli Outer Ring Road Bangalore – 560103, Karnataka, India Tel: +91 8071317778 and IQVIA Inc. Global Legal Department 100 IMS Drive Parsippany, NJ 07054 USA Attention: General Counsel Email: officeofgeneralcounsel@iqvia.com
To Institution	Name: Dr. M. V. Jali Address: KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi - 590010, Karnataka, India Tel: 0831-2473777
To Investigator	Name: Dr. Rohan Bhise

Prestige BioPharma Pte Ltd
Protocol Number: SAMSON-II
Clinical Trial Agreement – IQVIA India Template – 12 July 2019
KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre_Dr. Rohan Bhise_15July2019_TM_final

CONFIDENTIAL
Page 13 of 25



ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

	Address: KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi - 590010, Karnataka, India Tel: +91 8312470400
To Research Company	Name: Dr. Vinod Gyanchandani Address: GDD Experts India Pvt. Ltd, Ground Floor, Gulmohar Apartment, Opposite Hislop College, Civil Lines, Nagpur-440001, Maharashtra, India Tel: +91 9923000560

17. FORCE MAJEURE

The performance by either Party of any obligation on its part to be performed hereunder shall be excused by floods, fires or any other Act of God, accidents, wars, riots, embargoes, delay of carriers, inability to obtain materials, failure of power or natural sources of supply, acts, injunctions, or restraints of government or other force majeure preventing such performance, whether similar or dissimilar to the foregoing, beyond the reasonable control of the Party bound by such obligation, provided, however, that the Party affected shall exert its reasonable efforts to eliminate or cure or overcome any of such causes and to resume performance of its obligations with all possible speed.

18. MISCELLANEOUS

18.1 Entire Agreement

This Agreement, including its attachment(s), constitutes the sole and complete agreement between the Parties and replaces all other written and oral agreements relating to the Study.

18.2 No Waiver/Enforceability

Failure to enforce any term of this Agreement shall not constitute a waiver of such term.

If any part of this Agreement is found to be unenforceable, the rest of this Agreement will remain in effect.

18.3 Assignment of the Agreement

This Agreement shall be binding upon the Parties and their successors and assigns.

The Site shall not assign or transfer any rights or obligations under this Agreement without the written consent of IQVIA and Sponsor.

Upon Sponsor's request, IQVIA may assign this Agreement to Sponsor or to a third party, and IQVIA shall not be responsible for any obligations or liabilities under this Agreement that arise after the date of the assignment, and the Site hereby consents to such an assignment. Site will be given prompt notice of such assignment by the assignee.

18.4 Third Party Beneficiary

The Parties agree that Sponsor shall have the right to enforce any of the provisions of this Agreement as a third party beneficiary.

Each Party to this Agreement acknowledges that except for the Sponsor, there are no third party beneficiaries with any rights to enforce any of the provisions of this Agreement.

18.5 Applicable Law

Prestige BioPharma Pte Ltd
Protocol Number: SAMSON-II
Clinical Trial Agreement – IQVIA India Template – 12 July 2019
KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre_Dr. Rohan Bhise_15July2019_TM_final

*CONFIDENTIAL
Page 14 of 25

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

This Agreement shall be interpreted under the laws of the state or province and country in which Site conducts the Study.

18.6 Survival


The terms of this Agreement that contain obligations or rights that extend beyond the completion of the Study shall survive termination or completion of this Agreement, even if not expressly stated herein.

THIS SECTION IS INTENTIONALLY LEFT BLANK

Prestige BioPharma Pte Ltd
Protocol Number: SAMSON-II
Clinical Trial Agreement – IQVIA India Template – 12 July 2019
KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre_Dr. Rohan Bhise_15July2019_TM_final

CONFIDENTIAL
Page 15 of 25

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

ACKNOWLEDGED AND AGREED BY IQVIA RDS (INDIA) PRIVATE LIMITED
(formerly Quintiles Research (India) Private Limited):

By: Tanuka Ganguly

Title: Director, Site & Patient Networks

Signature: Tanuka Ganguly

Date: 26/July/2019

ACKNOWLEDGED AND AGREED BY THE INVESTIGATOR:

Name: Dr. Rohan Bhise

Title: Principal Investigator

Signature: Rohan

Date: 29-July 2019

ACKNOWLEDGED AND AGREED BY KLES DR. PRABHAKAR KORE HOSPITAL & MEDICAL
RESEARCH CENTRE:

By: Dr. M. V. Jali

Title : Medical Director

Signature: M. V. Jali

Date: 14 Aug 2019

Research Company agrees to abide by all obligations placed on Institution in the provisions of this Agreement concerning Confidentiality (Section 3); Intellectual Property (Section 4); Publication Rights (Section 5); Debarment (Section 10); Anti Kickback and Anti Fraud (Section 12); and Anti-Bribery (Section 13)

ACKNOWLEDGED AND AGREED BY GDD EXPERTS INDIA PVT. LTD :

By: Dr. Vinod Gyanchandani

Title : Head-Clinical Operations

Signature: Vinod Gyanchandani

Date: 22/Aug/2019

Prestige BioPharma Pte Ltd
Protocol Number: SAMSON-II
Clinical Trial Agreement - IQVIA India Template - 12 July 2019
KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre_Dr. Rohan Bhise_15July2019_TM_final

CONFIDENTIAL
Page 16 of 25

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

ATTACHMENT A
BUDGET & PAYMENT SCHEDULE

A. PAYEE DETAILS

The Parties agree that the payee designated below is the proper payee for this Agreement, and that payments under this Agreement will be made only to the following payee ("Payee"):

Payee Name	GDD EXPERTS INDIA PVT. LTD.
Payee Address	Ground Floor, Gulmohar Apartment, Opposite Hislop College, Civil Lines, Nagpur-440001, Maharashtra, India
Payee Phone and E-Mail address	Phone Number: +91 9923000560 Email ID: vgyanchandani@gddexperts.com
Bank Name	Axis Bank Ltd
Bank Account Number	910020034162231
IFSC code	UTIB0000048
GST Registration Number	27AADCG0363Q1ZA
Permanent Account Number (PAN) of Payee	AADCG0363Q
PAYMENT METHOD	Electronic Fund Transfer

In case of changes in the Payee's bank details, Site is obliged to inform IQVIA in writing. The Parties agree that in case of changes in bank details which do not involve a change of Payee/Bank Account Name or change of country location of bank account, no further amendments are required.

The Parties acknowledge that the designated Payee is authorized to receive all of the payments for the services performed under this Agreement.

If the Investigator is not the Payee, then the Payee's obligation to reimburse the Investigator, if any, is determined by a separate agreement between Investigator and Payee, which may involve different payment amounts and different payment intervals than the payments made by IQVIA to the Payee.

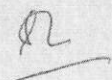
Investigator acknowledges that if Investigator is not the Payee, IQVIA will not pay Investigator even if the Payee fails to reimburse Investigator.

B. PAYMENT TERM


IQVIA will pay the Payee **quarterly**, on a completed visit per subject basis in accordance with the attached budget. Ninety percent (90%) of each payment due, including any Screening Failure that may be payable under the terms of this Agreement, will be made based upon prior 3 months' enrollment data confirmed by subject CRFs received from the Site supporting subject visitation.

The balance of monies earned, up to ten percent (10%), will be pro-rated upon verification of actual subject visits, and will be paid by IQVIA to the Payee upon final acceptance by Sponsor of all CRFs pages, all data clarifications issued, the receipt and approval of any outstanding regulatory documents as required by IQVIA and/or Sponsor, the return of all unused supplies to IQVIA, and upon satisfaction of all other applicable conditions set forth in the Agreement.

Prestige BioPharma Pte Ltd
Protocol Number: SAMSON-II
Clinical Trial Agreement – IQVIA India Template – 12 July 2019
KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre_Dr. Rohan Bhise_15July2019_TM_final



CONFIDENTIAL
Page 17 of 25
ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Any expense or cost incurred by Site in performing this Agreement that is not specifically designated as reimbursable by IQVIA or Sponsor under the Agreement (including this Budget and Payment Schedule) is Site's sole responsibility.

Site shall be responsible to comply with all obligations in respect of taxes and social security contributions, if applicable, which relate to the subject matter of this Agreement including, without limitation, those that relate to the Investigator, the Institution and its employees and/or collaborators.

Site represents that the services it provides under this Agreement are taxable services under the laws governing Goods and Services Tax ("GST") in India, and that it is required to charge GST for the services rendered to IQVIA at the prevailing rate. Site represents that it is entitled to require such payment of the GST under the laws of India. Site undertakes to provide IQVIA with an invoice, to be sent to IQVIA at the address mentioned in Section F of this Attachment A, in respect of such taxable services and such invoice shall be in accordance with the applicable legislation as may be amended from time to time or any successor legislation.

All amounts specified in this Agreement are in Indian Rupees (INR) and are inclusive of all overhead fees. For the avoidance of doubt, overhead fees include any applicable overhead fees.

Major, disqualifying Protocol violations are not payable under this Agreement

C. PAYMENT DISPUTE

Site will have thirty (30) days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

D. MINIMUM ENROLMENT GOAL

Site acknowledges that Site's minimum enrollment goal is 3 (three) subjects and that Site will use best efforts to reach the enrollment goal within a reasonable time after commencement of the Study at Site. If Site fails to adhere to this principle IQVIA may reconsider Site's suitability to continue participation in the Study.

E. DISCONTINUED OR EARLY TERMINATION

Reimbursement for discontinued or early termination subjects will be prorated based on the number of confirmed completed visits.

F. SCREENING FAILURE

Reimbursement for all screen failures will be made at the amount indicated on the screening visit of the attached Budget.

To be eligible for reimbursement of a screening visit, completed screening CRF pages must be submitted to IQVIA along with any additional information, which may be requested by IQVIA to appropriately document the subject screening procedures.

G. UNSCHEDULED VISITS

Payment for unscheduled visits will be reimbursed in the amount of is **Twelve Thousand Seven Hundred Fifty Nine Indian Rupees (INR 12,759)**. To be eligible for reimbursement for unscheduled visits, completed CRF pages must be submitted to IQVIA along with any additional information which may be requested by IQVIA to appropriately document the unscheduled visit.

H. INVOICES

Prestige BioPharma Pte Ltd
Protocol Number: SAMSON-II
Clinical Trial Agreement – IQVIA India Template – 12 July 2019
KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre_Dr. Rohan Bhise_15July2019_TM_final



ATTESTED

CONFIDENTIAL
Page 18 of 25

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Original Invoices pertaining to this Study for the following items must be submitted to IQVIA for reimbursement at the following address:

IQVIA RDS (India) Private Limited
 (formerly **Quintiles Research (India) Private Limited**)
 Attn: Finance PSC – Accounts Payable (Investigator Payments)
 Address: III Floor, Etamin Block,
 Prestige Technology Park,
 Sarjapur - Marathahalli Outer Ring Road
 Bangalore – 560103, India
 Phone: +91 8071317779

Please note that invoices will not be processed unless they reference the Sponsor name, Protocol number, Investigator name, Site number and Payee GST registration number. Upon receipt and verification of the invoices, reimbursement for invoices will be included with the next regularly scheduled payment for subject activity.

• **CONDITIONAL PROCEDURES:**

Payment for conditional procedures performed out of a visit, may be reimbursed including overhead upon receipt of original invoice. Invoice must reference date when the procedure was performed, list of procedures, and subject numbers.

Conditional Procedure	Amount/Currency
Re-consent, Informed consent performed again with the same patient	INR 1,400
Intravenous (IV) infusion for therapy, prophylaxis or diagnosis (HD204/EU-Avastin); initial, up to 1 hour	INR 4,300
Intravenous (IV) infusion for therapy, prophylaxis or diagnosis (Carboplatin/Paclitaxel); initial, up to 1 hour	INR 4,300
Intravenous (IV) infusion for therapy, prophylaxis or diagnosis (Carboplatin/Paclitaxel); each additional hour	INR 2,000
Pharmacy, Complex (Carboplatin/Paclitaxel) - Per Preparation; dispense drug	INR 1,693
Immunogenicity sampling - ADA/NADA - central lab	INR 350
Lab handling and/or shipping to central lab	INR 300
Haematology: Haemoglobin, white blood cell (WBC), Platelets and absolute Neutrophil count	INR 800
Blood chemistry panel: alanine aminotransferase (ALT/SGPT), Alkaline Phosphatase, total Bilirubin, Serum or Plasma creatinine, sodium, Potassium, Total calcium, BUN or Urea, Albumin	INR 1,800
Blood chemistry panel: Magnesium (Mg)	INR 600
Coagulation panel: International Normalized Ratio (INR)	INR 1,000
Coagulation panel: Thromboplastin time, partial (PTT) (aPTT);	INR 900
Urinalysis	INR 500
Urine pregnancy, gonadotropin chorionic (hCG) (BetahCG); qualitative	INR 900

Prestige BioPharma Pte Ltd
 Protocol Number: SAMSON-II
 Clinical Trial Agreement – IQVIA India Template – 12 July 2019
 KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre_Dr. Rohan Bhise_15July2019_TM_final

CONFIDENTIAL
 Page 19 of 25

ATTESTED

Dr. V.A. Kothiwale
 Registrar

KLE Academy of Higher Education and Research,
 (Deemed-to-be-University u/s 3 of the UGC Act, 1956)
 Belagavi-590 010, Karnataka

Serum pregnancy, gonadotropin chorionic (hCG) (BetahCG); quantitative	INR 1,800
12 lead ECG: Includes tracing, interpretation and report	INR 1,390
Meal (Patient) - Per Meal	INR 609
Meal (Caregiver) - Per Meal	INR 609
Patient Reimbursement, Expenses, Patient Travel - Per Visit	INR 1,179
Caregiver Reimbursement, Expenses, Caregiver Travel - Per Visit	INR 1,179
Patient Reimbursement, Stipend - Per Visit	INR 2,180
Caregiver Reimbursement, Stipend - Per Visit	INR 2,180
Daily Facility Charge - Per Day, for Study Infusion Visits only	INR 2,294
Tumor Assessment (RECIST 1.1)	INR 2,106
Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CT Scan); with contrast material(s)	INR 20,000
Interpretation and Report; Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CT Scan); with contrast material(s)	INR 5,000
Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CT Scan); without contrast material; can be used for peripheral artery tomography	INR 17,000
Interpretation and Report; Computerized axial tomography, thorax, thoracic, chest (Cat Scan) (CT Scan); without contrast material	INR 4,800
Computerized axial tomography, abdomen, abdominal (Cat Scan) (CT Scan); with contrast material(s)	INR 40,636
Interpretation and Report; Computerized axial tomography, abdomen, abdominal (Cat Scan) (CT Scan); with contrast material(s)	INR 6,723
Computerized axial tomography, abdomen, abdominal (Cat Scan) (CT Scan); without contrast material	INR 14,456
Interpretation and Report; Computerized axial tomography, abdomen, abdominal (Cat Scan) (CT Scan); without contrast material	INR 4,094
Computerized axial tomography, pelvis, pelvic (Cat Scan) (CT Scan); with contrast material(s)	INR 13,475
Interpretation and Report; Computerized axial tomography, pelvis, pelvic (Cat Scan) (CT Scan); with contrast material(s)	INR 3,631
Computerized axial tomography, pelvis, pelvic (Cat Scan) (CT Scan); without contrast material	INR 11,667
Interpretation and Report; Computerized axial tomography, pelvis, pelvic (Cat Scan) (CT Scan); without contrast material	INR 3,286

Prestige BioPharma Pte Ltd
Protocol Number: SAMSON-II
Clinical Trial Agreement – IQVIA India Template – 12 July 2019
KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre_Dr. Rohan Bhise_15July2019_TM_final

CONFIDENTIAL
Page 20 of 25



ATTESTED

Dr. V.A.Kothiwale
Registrar

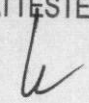
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

Computerized axial tomography, thoracic, abdominal and pelvic combined, chest, abdomen, pelvis combined (Cat Scan) (CT Scan); with contrast material	INR 33,826
Interpretation and Report; Computerized axial tomography, thoracic, abdominal and pelvic combined, chest, abdomen and pelvis(Cat Scan) (CT Scan); with contrast material	INR 4,191
Computerized axial tomography, thoracic, abdominal and pelvic combined, chest, abdomen, pelvis combined (Cat Scan) (CT Scan); without contrast material	INR 30,610
Interpretation and Report; Computerized axial tomography, thoracic, abdominal and pelvic combined, chest, abdomen and pelvis(Cat Scan) (CT Scan); without contrast material	INR 4,247
Computerized axial tomography, head, skull or brain (Cat Scan) (CT Scan); with contrast material(s)	INR 16,300
Interpretation and Report; Computerized axial tomography, head, skull or brain (Cat Scan) (CT Scan); with contrast material(s)	INR 5,000
Computerized axial tomography, head, skull or brain (Cat Scan) (CT Scan); without contrast material	INR 14,000
Interpretation and Report; Computerized axial tomography, head, skull or brain (Cat Scan) (CT Scan); without contrast material	INR 14000
Magnetic resonance imaging, chest, thorax, thoracic (MRI); with contrast material(s) (eg, proton)	INR 56790
Interpretation and Report; Magnetic resonance imaging, chest, thorax, thoracic (MRI); with contrast material(s) (eg, proton)	INR 7578
Magnetic resonance imaging, chest, thorax, thoracic (MRI); without contrast material(s) (eg, proton)	INR 42368
Interpretation and Report; Magnetic resonance imaging, chest, thorax, thoracic (MRI); without contrast material(s) (eg, proton)	INR 6597
Magnetic resonance imaging, abdomen, abdominal (MRI); with contrast material(s) (eg, proton)	INR 51367
Interpretation and Report; Magnetic resonance imaging, abdomen, abdominal (MRI); with contrast material(s) (eg, proton)	INR 6650
Magnetic resonance imaging, abdomen, abdominal (MRI); without contrast material(s) (eg, proton)	INR 38147
Interpretation and Report; Magnetic resonance imaging, abdomen, abdominal (MRI); without contrast material(s) (eg, proton)	INR 5797
Magnetic resonance imaging, brain including brain stem (MRI); without contrast material (eg, proton)	INR 41730

Prestige BioPharma Pte Ltd
Protocol Number: SAMSON-II
Clinical Trial Agreement – IQVIA India Template – 12 July 2019
KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre_Dr. Rohan Bhise_15July2019_TM_final

CONFIDENTIAL
Page 21 of 25

ATTESTED

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

Interpretation and Report; Magnetic resonance imaging, brain including brain stem (MRI); without contrast material (eg, proton)	INR 5343
Magnetic resonance imaging, brain including brain stem (MRI); with contrast material(s) (eg, proton)	INR 46768
Interpretation and Report; Magnetic resonance imaging, brain including brain stem (MRI); with contrast material(s) (eg, proton)	INR 6205
Magnetic resonance imaging, pelvis, pelvic (MRI); without contrast material(s), followed by contrast material(s) and further sections (eg, proton)	INR 53115
Interpretation and Report; Magnetic resonance imaging, pelvis, pelvic (MRI); without contrast material(s), followed by contrast material(s) and further sections (eg, proton)	INR 8023
Magnetic resonance imaging, liver, pancreas (MRI); without contrast material(s)	INR 49712
Interpretation and Report; Magnetic resonance imaging, liver, pancreas (MRI); without contrast material(s)	INR 8931
Bone and/or joint imaging, bone scan, bone scintigraphy, limited area	INR 16,800
Interpretation and Report; Bone and/or joint imaging, bone scan, bone scintigraphy, limited area	INR 3,400
Radiologic examination, chest; single view	INR 1000
Interpretation and Report: Radiologic examination, chest; single view	INR 490
Serious adverse events (SAE)	INR 2800

EC/IRB/IEC FEES

EC/IRB/IEC costs will be reimbursed on a pass-through basis upon receipt of a formal invoice issued by the EC/IRB/IEC and are not included in the attached Budget. Payment will be made directly to the EC/IRB/IEC. Any subsequent re-submissions or renewals, upon approval by IQVIA and Sponsor, will be reimbursed upon receipt of appropriate documentation.

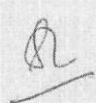
Start-up Fee

A one-time, non-refundable payment will be paid in the amount of Eighty Thousand Indian Rupees (INR 80,000) to cover Study start-up activities upon completion and receipt by IQVIA of all original contractual and regulatory documentation and receipt of an original invoice.

Archiving Fee

A one-time record storage payment will be paid in the amount of Fifty Thousand Indian Rupees (INR 50,000) upon receipt of invoice and are not included in the attached Budget. In accordance with Sponsor's Protocol requirements, Institution shall maintain all Site Study records in a safe and secure location to allow easy and timely retrieval, when needed.

Prestige BioPharma Pte Ltd
 Protocol Number: SAMSON-II
 Clinical Trial Agreement – IQVIA India Template – 12 July 2019
 KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre_Dr. Rohan Bhise_15July2019_TM_final



ATTESTED CONFIDENTIAL
 Page 22 of 25



Dr. V.A. Kothiwale
 Registrar

KLE Academy of Higher Education and Research,
 (Deemed-to-be-University u/s 3 of the UGC Act, 1956)
 Belagavi-590 010, Karnataka

NO OTHER ADDITIONAL FUNDING REQUESTS WILL BE CONSIDERED

These amounts exclude all applicable taxes.

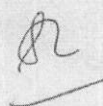
All payments for this Study in accordance with the attached budget will be paid by IQVIA by wire transfer.

BUDGET TABLE

Visits	Amount/Currency
Screening Visit	Rs 40,104
Cycle 1	Rs 37,296
Cycle 2	Rs 38,002
Cycle 3	Rs 34,143
Cycle 4	Rs 38,359
Cycle 5	Rs 24,128
Cycle 6	Rs 27,987
Cycle 7	Rs 24,128
Cycle 8	Rs 24,128
Cycle 9	Rs 24,128
Cycle 10	Rs 26,623
Cycle 11	Rs 24,128
Cycle 12	Rs 24,128
Cycle 13	Rs 24,128
Cycle 14	Rs 26,623
Cycle 15	Rs 24,128
Cycle 16	Rs 24,128
Cycle 17	Rs 24,128
EoT	Rs 31,423
Total amount per subject	Rs 541,840
Safety Follow-Up Visit (not included in Total)	Rs 4,550
Dosing after 12 months (not included in Total)	Rs 23,426

Prestige BioPharma Pte Ltd
Protocol Number: SAMSON-II
Clinical Trial Agreement – IQVIA India Template – 12 July 2019
KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre_Dr. Rohan Bhise_15July2019_TM_final

CONFIDENTIAL
Page 23 of 25



ATTESTED

Dr. V.A.Kothiwale
Registrar


KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

**ATTACHMENT B
APPROVAL LETTER**

Prestige BioPharma Pte Ltd
Protocol Number: SAMSON-II
Clinical Trial Agreement – IQVIA India Template – 12 July 2019
KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre_Dr.Rohan Bhise_15July2019_TM_final



ATTESTED CONFIDENTIAL
Page 24 of 25

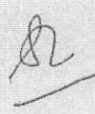


Dr. V.A.Kothiwale
Registrar


KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

ATTACHMENT C
EQUIPMENT (optional)

Prestige BioPharma Pte Ltd
Protocol Number: SAMSON-II
Clinical Trial Agreement – IQVIA India Template – 12 July 2019
KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre_Dr. Rohan Bhise_15July2019_TM_final



ATTESTED CONFIDENTIAL
Page 25 of 25



Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



जिल्हा कोषागार कार्यालय, ठाणे
- 1 JAN 2020
मुद्रांक प्रमुख लिपीक / लिपीक

© 2019 ©

VW 951258

CLINICAL TRIAL AGREEMENT

This clinical study agreement ("Agreement") is executed as of this the 30th day of December 2019 ("Effective Date") by and between:

Mediclin Clinical Research a firm, a Contract Research Organization, having its office at **Fourth Floor, Ambika Industries, Penkar Pada, Opposite Thakur Mall, Mira Road (E), Thane- 401 104, India** through its authorized signatory which expression shall, where the context so permits include his successors in office and assigns (hereinafter referred to as the "CRO").

AND

Doclin Clinical Research Services located at **445, Maruti Galli, Main Road, Hangarge, Mandoli, Belagavi Karnataka -590008, India** which expression shall, where the context so permits include his successors in office and permitted assigns (hereinafter referred to as the "SMO")

Page 1 of 9

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

AND

KLES Dr. P.B. Kore Hospital & Research Center located at **Neharu Nagar Belgaum-590010, Karnataka, India** which expression shall, where the context so permits include his successors in office and permitted assigns (hereinafter referred to as the "**Institution**").

AND

Dr. Smitha K. S. affiliated to the institution, (hereinafter referred to as the "**Investigator**")
(Each a "Party" and collectively, the "Parties")

WHEREAS:

- A. The Institution is a health care organization engaged in the diagnosis, treatment and prevention of disease and clinical research for the improvement of healthcare, and has the facilities and personnel necessary to conduct the clinical trial;
- B. Investigator is interested to conduct clinical trial in the Institution under his / her guidance and supervision.
- C. CRO is a clinical services offering firm. CRO will perform on behalf of **Ajanta Pharma Ltd.** (sponsor)
- D. CRO desires Institution and Investigator to conduct a study entitled "**A Comparative, Randomized, Two Arm, Double Blind, Parallel Group, Multicentric, Phase III Clinical Study to Evaluate the Efficacy, Safety and Tolerability of Netarsudil Ophthalmic Solution 0.02% w/v Versus Timolol Maleate Eye Drops 0.5% w/v in treatment of elevated intraocular pressure (IOP) in subjects with open angle glaucoma or ocular hypertension.**"
- E. **NOW THEREFORE** in consideration of the promises and mutual covenants herein contained, Parties hereby agree as follows:


1. SCOPE

- 1.1 The Study is of mutual interest and benefit to CRO and Institution and will further the Institution's instructional and research objectives in a manner consistent with the terms and conditions of this Agreement.
- 1.2 The Institution shall exercise its best efforts to carry out the research ("Study") set forth in the Protocol entitled "**A Comparative, Randomized, Two Arm, Double Blind, Parallel Group, Multicentric, Phase III Clinical Study to Evaluate the Efficacy, Safety and Tolerability of Netarsudil Ophthalmic Solution 0.02% w/v Versus Timolol Maleate Eye Drops 0.5% w/v in treatment of elevated intraocular pressure (IOP) in subjects with open angle glaucoma or ocular hypertension.**"

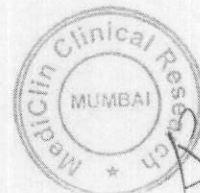
2. CONDUCT AND PERIOD OF THE STUDY

- 2.1 The Investigator and the Institution shall conduct the study in accordance with the Protocol. The CRO, Investigator and Institution shall perform it in accordance with all applicable laws, government regulations and guidelines including but not limited to the Drugs & Cosmetics Act 1940 and Rules 1945: Schedule-Y (as amended from time to time), The Indian Council of Medical Research (ICMR) guidelines, Good Clinical Practices (GCP) and the standards conforming to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).
- 2.2 The Study will be initiated in the institute only after EC associated with the institute approves the study.

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



Page 2 of 9

- 2.3 The Institution agrees that the CRO or its designee as clinical monitor may conduct routine monitoring visit at mutually convenient times and upon reasonable advance notice to the Institution. The clinical monitor will have direct access to all records and documents pertaining to the Study to ensure that it is conducted in accordance with the Protocol and applicable regulatory requirements and in terms of this Agreement.
- 2.4 The Study does not involve any Biological Samples to be tested as part of it.
- 2.5 The Clinical Trial will be effective on the 30th day of December 2019 and continue until the study is completed at Investigational Sites. The parties agree that no patient enrolment will occur until there is IRB/IEC approval of the Protocol by all the involving investigational site.

3. OBLIGATIONS, REPRESENTATIONS & WARRANTIES OF THE PARTIES

- 3.1 The Institution shall ensure proper conduct of Study.
- 3.2 The Investigators appointed by the Institution shall be responsible for obtaining signed informed consent form from each Subject prior to the Subject's participation in the Study from the designee.
- 3.3 Neither the investigator, nor the trial staff, should coerce or unduly influence a study subject to participate or to continue to participate in this Study.
- 3.4 The investigator shall take reasonable efforts to recruit the agreed number of Subjects on a timely basis and the Parties shall take reasonable efforts to conduct the Study in accordance with the agreed time period.
- 3.5 The Institution and Investigator shall not permit the use of the material (instruments provided to capture voice) for any purpose (whether directly or indirectly) other than the conduct of the Study.
- 3.6 To the extent permitted by law, the Institution shall immediately inform CRO of:
- 3.6.1 Any intended or actual inspection, written inquiry or visit to the trial Site by any regulatory authority; or
- 3.6.2 Any queries by State or Central Information Commission under Right to Information Act (amended up to date) in connection with the Study and forward promptly to the CRO copies of any correspondence from any such authority.
- 3.7 The Institution and the Investigator shall keep complete and accurate records of the conduct of the Study and of all data in accordance with generally accepted industry standards and practices and applicable Law. The Institution will retain the documents in a safe and secure lock-and-key facility until the study ends. After the study is over, Institution will hand-over those to the CRO.

4. FINANCIAL ARRANGEMENTS

- 4.1 Cost and payment terms are set forth in **Appendix-B** attached to this Agreement and incorporated by reference.
- 4.2 The Medclin Clinical Research shall reimburse the Investigational Site for all direct and indirect costs incurred in connection with the Clinical Trial up to **INR.19,125/ Subject** ("Cost"). The Medclin Clinical Research shall pay EC fees as per actual cost which is in the amount of **INR. 88500/-** and which is payable upon signing of this agreement. Medclin Clinical Research will pay the EC fees directly to the site Ethics Committee.
- 4.3 The parties agree that the Cost is based upon the reasonable costs for similar studies at like institutions and Investigational Sites have not been induced to participate in

ATTESTED


Dr. V.A. Kothiwate
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



Page 3 of 9

this Clinical Trial based on inducements from Mediclin Clinical Research. The parties estimate that the Cost is sufficient to support the Clinical Trial, but if certain patient care costs are expected to be covered by insurance or another third party payers and such patient care costs are denied, Sponsor on behalf of Mediclin Clinical Research agrees to reimburse the Investigator for the patient care costs not covered by insurance or third party payer which are necessary to conduct the Clinical Trial.

- 4.4 The Mediclin Clinical Research will not be liable for any payment in excess of the Cost except upon Investigator's written agreement.
- 4.5 Mediclin Clinical Research in turn will make the payment in accordance with the Payment Schedule to the Investigator as attached in **Appendix-B** incorporated herein.
- 4.6 Mediclin Clinical Research will pay amount to investigator by Cheque/ NEFT/ RTGS, as per terms and conditions applied.

5. TERM AND TERMINATION

- 5.1 Unless otherwise terminated earlier, this Agreement shall commence upon Effective date and will continue for a period of 5 years from the Effective Date or upon completion of the Study, whichever is earlier. 'Effective Date' means the date when this Agreement becomes effective which shall be the date of last signature hereto by the Parties.
- 5.2 Any Party may terminate this Agreement with immediate effect, at any time, if another Party is in breach of any of the defaulting Party's obligations hereunder (including a material failure without just cause to meet a timeline) and fails to remedy such breach, where it is capable of remedy, within thirty (30) days of a written notice from the terminating Party specifying the breach and requiring its remedy. It is explicitly agreed and acknowledged by the Investigator and Institution that in case of termination of study, no further payment shall be made by CRO to the Institution or any other person under this agreement.
- 5.3 CRO may terminate this Agreement upon thirty (30) days prior written notice to the Institution or such shorter notice period as required by a Regulatory Authority, for any reason whatsoever.
- 5.4 Without limiting the generality of the foregoing, CRO may terminate this Agreement:
- 5.4.1 if the Institution is not performing the Study as required in the protocol;
- 5.4.2 in case of failure of the Institution to provide access to CRO representatives /Clinical monitor /Auditors all original medical records necessary to verify entries on study case report forms;
- 5.4.3 in case of an unauthorized replacement of Investigator;
- 5.4.4 if CRO determines that business or scientific considerations require termination of this Agreement (either full or in part);
- 5.4.5 if any malpractices adopted either by the Investigator or Institution or both.
- 5.5 Within Thirty days after the termination of this Agreement, the Investigator shall deliver to CRO completed CRF pages.

6. INDEMNIFICATION

- 6.1 To the maximum extent permitted by applicable laws, the Institution agrees to defend, indemnify and hold harmless the CRO and its respective directors, officers, employees and agents (the "Indemnities") and those of its affiliates against all claims, actions, suits, proceedings, liability, losses, damages, charges, orders, fines and expenses, including assessable legal fees and disbursements made or brought by a

ATTESTED

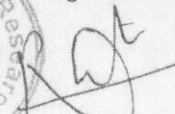


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



Page 4 of 9



third party against an Indemnity for harm:

- 6.1.1 Arising out of or relating to the negligence or wilful misconduct or malpractices of the Institution, its employees and agents in performing their obligations under this Agreement;
 - 6.1.2 Arising out of errors or omissions by Institution;
 - 6.1.3 Arising out of or relating to the failure of the Institution, its employees and agents to comply with the provisions of this Agreement, the Protocol, or any written instructions of CRO concerning the Clinical Study; or
 - 6.1.4 Arising out of the violation of applicable Law related to the conduct of the Clinical Study by the Institution, its employees or agents.
- 6.2 To the maximum extent permitted by applicable laws, CRO agrees to indemnify and hereby indemnifies, defend and hold the Site, its Principal Investigator, Sub-Investigators and study team, directors, officers and the support staff, agents, the trustees of the Institution harmless from and against any proven liability, loss, damage, costs, expenses, claims, demands and suits (including reasonable attorney's fees and expenses) including arising from and resulting out of (i) the breach of any of CRO representations, warranties or covenants set forth in this Agreement or (ii) the performance of the Study or any of its results / outcome including, adverse drug experiences or an injury, death to/of a Study subject directly or indirectly caused by or attributed to the Study , (iii) any injury or claim arising due to any defect / malfunction of the device used during the Study in accordance with the provisions of the Protocol and this Agreement.
- 6.3 Each Party shall use reasonable efforts to inform the other Party promptly of any circumstances of which it is aware that are reasonably likely to give rise to a claim or proceeding and shall keep the other Party reasonably informed of developments in relation to any claim or proceeding, even where a Party decides not to make a claim for indemnification under this Section 6. The Parties further agree that they have a right to retain their own counsel to conduct a full defence of any such claim or proceeding.
- 6.4 The Institution and CRO shall each give to the others such help as may reasonably be required for the efficient conduct and prompt handling of any claim or proceeding concerning the Clinical Study.
- 6.5 No settlement or compromise of a claim or proceeding subject to indemnification under this Section 6 shall be binding on a Party without the prior written consent of the other affected Party (ies). A Party shall not unreasonably withhold such consent of a settlement or compromise. Without limiting the generality of the preceding, no Party shall admit fault on behalf of an indemnity or enter into a non-monetary settlement that places future obligations on an indemnity without the written approval of the indemnity.

7. CONFIDENTIALITY

"Confidential Information" means all information (including, without limitation, subject identity, Study Protocol(s), informed consent form, subject cards, case report forms, clinical data, other data, reports, specifications, computer programs or models and related documentation, know-how, trade secrets, or business or research plans) of CRO or CRO's Affiliates that are: (1) provided to the Institution in connection with this Agreement or a Study; (2) cumulative Study data, results, and reports from all sites conducting the Study.

ATTESTED

Dr. V.A.Kothiwale
Registrar



Page 5 of 9

- 7.1 Confidential Information and all tangible expressions, in any media, of CRO are the sole property of CRO. Each party shall endeavour to identify tangible Confidential Information provided to the other party as "Confidential" given the understanding that failure to do so does not constitute a designation of non-confidentiality when the confidential nature is apparent from context and subject matter. Institution agrees to treat CRO's Confidential Information as it would be its own proprietary and confidential information. Institution will only accept information from CRO which is required for conduct of the Study and which must be maintained for Institution's records.
- 7.2 Institution will make sure that it and Investigator agrees for a period of ten (10) years after the expiration or termination of the Study not to use and disclose CRO's Confidential Information to any third party. Institution agrees not to disclose CRO's Confidential Information to third parties or use except as necessary to conduct a Study and under an agreement by the third party to be bound by the obligations of this Section. The parties understand and agree that information communicated to EC is "Confidential and Privileged".
- 7.3 The Parties agree to abide by applicable Law relating to the protection of Clinical Trial Subject Personal Information and where Confidential Information is also Personal Information, the obligations in this Section 7 shall remain in force for the period required under such law. The Party that received Personal Information hereunder shall only use or disclose the Personal Information as set out in the Clinical Trial Subject's consent form or as required by applicable Law. Each Party shall give prompt notice to the other Parties of any privacy or security breach it has experienced that affects Clinical Trial Subject Personal Information.

8. INTELLECTUAL PROPERTY RIGHTS

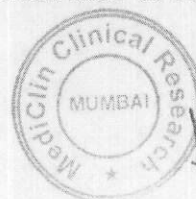
- 8.1 All Intellectual Property Rights owned by or licensed to CRO prior to and after the date of this Agreement are and shall remain the exclusive property of CRO.
- 8.2 All Intellectual Property Rights owned by or licensed to the Institution prior to and after the date of this Agreement, other than any Intellectual Property Rights arising from the clinical study, are and shall remain the exclusive property of the Institution.
- 8.3 All Intellectual Property Rights (including Clinical trial data and clinical trial documentation) arising from and relating to the Clinical Studies, the Investigational drugs, mobile application or the Protocols (the "Clinical Trial Intellectual Property") shall be the exclusive property of CRO/Sponsor and for this purpose, the Institution hereby assign and transfer, and shall cause the trial site team members to assign and transfer, without additional consideration, to CRO (or its nominate designee), all their rights and title in and to the Study tool throughout the world on perpetual basis. The Institution shall execute and deliver, and shall cause the trial site team members to execute and deliver, all such documents and, at CRO's expense, do all such other acts as CRO may reasonably require in order to vest fully and effectively all Clinical Trial Intellectual Property in CRO or its nominate designee.
- 8.4 The Institution shall promptly disclose to CRO any Clinical Trial Intellectual Property generated pursuant to this Agreement and shall treat the Clinical Trial Intellectual Property as Confidential Information.

9. MISCELLANEOUS

- 9.1 All notices required to be given by one Party to the other shall be deemed to have

ATTESTED


Dr. V.A. Kothiwale
Registrar



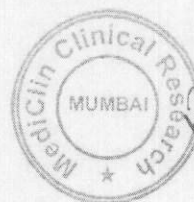
Page 6 of 9

- been properly served when sent by a registered post or any other means of communication acceptable in law to the addresses mentioned in the first page of this Agreement or such appropriate addresses available in public domain.
- 9.2 No forbearance or tolerance on the part of the either Party of any breach of this Agreement by the other shall constitute waiver of the requirements of this Agreement.
- 9.3 Each Party acknowledges that it is entering into this Agreement solely on its own behalf, and will perform any and all of its obligations or work under this Agreement as an independent contractor. Nothing under this Agreement shall create any other relationship between the Parties including without limitation one of principal and agent, employer and employee, or partnership.
- 9.4 The Institution will be responsible for payment to its employee study team members and/or agents of all salaries, wages, benefits, workman compensations reimbursable travel, lodging, and other expenses to which the Investigators, study team members or employees or agents may be entitled to receive for performing services. Institution will be solely responsible for withholding and paying all applicable taxes of whatsoever in nature, statutory contributions, benefits, dues etc. that may be payable to its employees and/or agents.
- 9.5 This Agreement constitutes the entire Agreement between the Parties and supersedes all prior oral and written understandings between the Parties on the subject matter of this Agreement. Any Exhibit, Annexure or otherwise any documents, including but not limited amendment or modification made in reference with this Agreement shall be valid if the same is incorporated in writing on the terms that may be mutually agreed and signed by the authorized signatories of the respective parties.
- 9.6 The Parties hereby agree that any provision/s of this Agreement which is held to be invalid and unenforceable in law shall not by itself make this Agreement invalid nor effect the other provisions of this Agreement and the other terms shall remain fully enforceable and valid in law.
- 9.7 Institution will not assign this Agreement without the prior written consent of CRO. CRO may assign any or all of its rights and obligations under this Agreement at any time, provided that CRO ensures the assignee is bound by the terms hereof.
- 9.8 Institution shall not subcontract the whole or any part of the performance of the clinical Studies without the prior written consent of CRO. This Agreement ensures to the benefit of and binds the Parties and their respective administrators, successors and permitted assigns, and with respect to the Investigator, heirs and executors.
- 9.9 This Agreement and the obligations of the Parties shall be governed by and construed in accordance with the laws of India. The Parties agree to submit to the exclusive jurisdiction of courts at Pune in connection with this Agreement.
- 9.10 Neither Party to this Agreement shall be liable for breach of this Agreement to the extent caused by or arising from prohibition or restriction by law or regulation of any Government, fire, flood, storms, weather, strike, lock-out or other labour problems, accident, riots, acts of God, breakdown of communication facilities, breakdown of web host, breakdown of internet service provider or other events beyond that Party in breach. The Party affected by such circumstances shall promptly notify the other Parties in writing when such circumstances cause a delay or failure in performance and shall take whatever reasonable steps are necessary to relieve the effect of such cause as rapidly as reasonably possible. In the event of a delay lasting for four (4) weeks or more, the non-affected Parties shall have the right to terminate this Agreement in accordance the term of this Agreement.

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



Page 7 of 9

9.11 The provisions of this Agreement which, by their terms, require performance after the termination or expiration of this Agreement, or have application to events that may occur after the termination or expiration of this Agreement, will survive the termination or expiration of this Agreement. All indemnity obligations and any applicable indemnification procedures will be deemed to survive the termination or expiration of this Agreement.

10. INTERPRETATION

10.1 Unless the context requires otherwise:

10.1.1 References to this Agreement are to this Agreement as it is from time to time amended;

10.1.2 Headings are for convenience only and shall not affect interpretation;

10.1.3 References to the singular include the plural and vice versa, and references to one gender include all genders;

10.1.4 Any phrase introduced by the expressions "including", "include" or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms;

10.1.5 Reference to any law: shall be deemed to include any bye-laws, licences, statutory instruments, rules, regulations, orders, notices, directions, consents or permissions made under that law; and shall be construed as referring to any law which replaces, re-enacts, amends or consolidates such law (with or without modification) at any time;

10.1.6 References to "writing" or "written" include any modes of reproducing words in a legible and non-transitory form but do not include writing on the screen of a visual display unit or other similar device;

10.1.7 References to a numbered clause are references to the clause of or to this Agreement so numbered.

10.2 The parties hereto have participated jointly in the negotiation and drafting of this Agreement and, in the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as jointly drafted by the parties hereto and no presumption or burden of proof shall arise favouring or disfavouring any party by virtue of the authorship of any provision of this Agreement.

IN WITNESS WHEREOF the parties have executed this Agreement after carefully reading the contents of this Agreement out of their free will and consent without any kind of force or coercion on them.

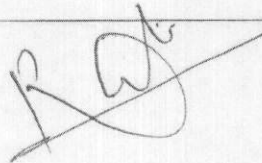
BY CRO

Name: Dr. Ravindra Mote

Designation: Director

Signature with Stamp:

Date:



30 DEC 2019

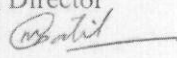
BY SMO

Name: Mr. Maruti Patil

Designation: Managing Director

Signature with Stamp:

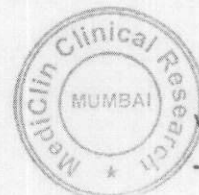
Date: 21 JAN 2020



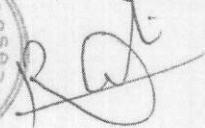
ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



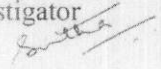
Page 8 of 9



BY INVESTIGATOR

Name: Dr. Smitha K. S.

Designation: Principal Investigator

Signature with Stamp: 

Date: 21 JAN 2020

Dr. Smitha K.S.

Consultant in Ophthalmology

KLES Dr. Prabhakar Kore

Hospital & MRC,


BELGAUM.

BY INSTITUTION

Name of Hospital: KLES Dr. P.B. Kore Hospital & Research Center, Neharu Nagar Belgaum-590010, Karnataka, India


Name: M.V. Jali

Designation: MD and CEO

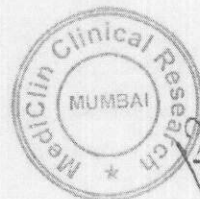
Signature with Stamp: 

Date: 05 Feb 2020

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



Page 9 of 9

APPENDIX-A

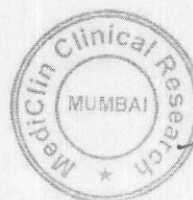
Study Name	A Comparative, Randomized, Two Arm, Double Blind, Parallel Group, Multicentric, Phase III Clinical Study to Evaluate the Efficacy, Safety and Tolerability of Netarsudil Ophthalmic Solution 0.02% w/v Versus Timolol Maleate Eye Drops 0.5% w/v in treatment of elevated intraocular pressure (IOP) in subjects with open angle glaucoma or ocular hypertension.
Protocol ID	APL/CT/18/03
Site Name	KLES Dr. P.B. Kore Hospital & Research Center, Neharu Nagar Belgaum-590010, Karnataka, India
Name of Investigator	Dr. Smitha K. S.

Instruction for Payment Payee Details	
Payee Name	Doclin Clinical Research Services
PAN No	AZXPP8818R
GST No	29AZXPP8818R1ZP
Bank Account Number	919020049795418
Bank Name	Axis Bank
Bank Swift Code / IFSC Code	CHASUS33/UTIB0001690
Bank Branch Address	Nehru Nagar, Ratna Plaza, Cts. No. 10593 A& B, Kolhapur Circle, Belgaum 590010

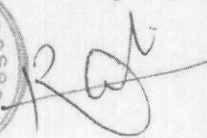
ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



Page 1 of 2



APPENDIX-B

Given below is the suggested financial break-up of total trial grant allocated to each center. You are requested to go through the same & revert as soon as possible regarding approval of this budget, following which the final financial agreement will be sent for your signature.

Payment Head	Amount (INR)
Total amount	INR. 19125/Subject.

Protocol ID: APL/CT/18/03	
Site Name	KLES Dr. P.B. Kore Hospital & Research Center, Neharu Nagar Belgaum-590010, Karnataka, India
Investigator Name	Dr. Smitha K. S.
Target of enrolment of subject	25
Note: This is a competitive recruitment trial having 210 subjects.	

Visit Description (Per Patient/ Visit)		
Visit Details	Day wise Visit	Cost (INR)
Screening (V1)	Day -3	2,000/-
Baseline/ Randomization (V2)	Day 0	1,500/-
Visit 3 (V3)	Day 14 ± 2 days	2,000/-
Visit 4 (V4)	Day 28 ± 2 days	1,500/-
Visit 5 (V5)	Day 56 ± 2 days	2,000/-
Visit 6 (V6)	Day 84 ± 2 days	2,000/-
Screening to End of Treatment Total		11000/-
Laboratory Investigations and ECG (at Visit-1 and Visit-6) Inclusive of all IOH @ 25%		3,500/-
Subject travel reimbursement		1000/-
Grand Total		19125/-
Note:		
1. Maximum cost per subject should not be more than INR.19125/-.		

EC fees as per actual.

After monitoring visit, Monitor will assure the subject data as per regulatory requirements and will release the payments within 15 working days.

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



Page 2 of 2

600

INVESTIGATOR CLINICAL STUDY AGREEMENT

This Clinical Study Agreement (the "Agreement"), effective as of the later of the dates appearing on the signature page, is entered into by and among Dr. Jyothi Hattitholi, Consultant Chest Physician ("Principal Investigator") at KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi-590010 Karnataka India ("INSTITUTION"), SIRO Clinpharm Pvt Ltd., a company incorporated under the laws of India whose principal place of business is located at Kaipatāru Prime, 1st Floor, Unit nos 3 and 4, Plot no D-3, Road no 16, Wagle Industrial Estate, Thane (West) – 400604, Maharashtra, INDIA (hereinafter referred to as "SIRO")

WHEREAS, the Principal Investigator is engaged in the treatment of subjects with potential exposure to the COPD; and is associated with the Institution in her capacity as *Consultant Chest*

WHEREAS, the INSTITUTION is a Private Multispecialty Hospital

WHEREAS, the SMO is engaged in management of the trial at the Institute and assisting the Principal Investigator; and;

WHEREAS, SPONSOR is engaged in the research and development of human pharmaceutical products;

WHEREAS, SPONSOR is the Sponsor of the clinical study CLR_18_09 Titled Pharmacodynamic Bioequivalence of two formulations of Ipratropium Bromide (21 mcg) HFA in Subjects with Chronic Obstructive Pulmonary Disease: A Randomized, Observer Blind, Three Treatment, Three Period, Six Sequence, Single Dose, Crossover, Placebo and Active Controlled Comparative Study (the "Clinical Study");

WHEREAS, SIRO is the Clinical Research Organization acting on behalf of SPONSOR to administer the clinical study;

WHEREAS, the Principal Investigator is engaged in the treatment of subjects with potential exposure to Chronic Obstructive Pulmonary Disease and

WHEREAS, the Principal Investigator wishes to participate in the Clinical Study and SPONSOR wishes to have the participation of the Principal Investigator.

NOW THEREFORE, the parties agree as follows:

1. Protocol

1.1. Title. The Clinical Research protocol CLR_18_09, titled a "Pharmacodynamic Bioequivalence of two formulations of Ipratropium Bromide (21 mcg) HFA in Subjects with Chronic Obstructive Pulmonary Disease: A Randomized, Observer Blind, Three Treatment, Three Period, Six Sequence, Single Dose, Crossover, Placebo and Active Controlled Comparative Study" which will guide the performance of the Clinical Study, has been prepared by SPONSOR and accepted by the Principal Investigator (the protocol, together with any of its subsequent amendments) shall be referred to in this Agreement as the "Protocol".

Clinical Study Agreement version 01 dated 03 Feb 2020
Dr. Jyothi Hattitholi
CLR_18_09

Confidential

Page 1



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Authorised Signatory
Dr. Thane Bharat Sahakar Bank Ltd.
Main Branch Thane

Thane Bharat Sahakar Bank Ltd.
Main Branch, Naupada, Thane.
SIRO/CLP/CLC/R/105/1104/1905-0
704

69126
135209
000600/PB5151
15:30
FEB 03 2020
Special
Adhesive
MAHARASHTRA

- 1.2. Conflicts. In the event of a conflict between the terms and conditions set forth in this Agreement and the Protocol, this Agreement will govern.
- 1.3. GCP. If generally accepted standards of Good Clinical Practice ("GCP") relating to the safety of subjects participating in the Clinical Study require a deviation from the Protocol, these standards will be followed. Any party who becomes aware of the need for a deviation from the Protocol will immediately inform the other parties to this Agreement of the facts causing the deviation as soon as the facts are known to the party. In addition, the Principal Investigator will promptly inform the Institution's institutional review board ("IRB") of the deviation.
- 1.4. Amendments. SIRO, on behalf of SPONSOR, may also, from time to time, make changes to the Protocol. Changes in the Protocol must take the form of written amendments and shall be approved by all signatories of the final version of the Protocol. Any amendments to the Protocol which affect the patient (e.g. changes in procedures/assessments or matters relating to patient safety) require approval of the relevant ethics committee as well as further informed consent from each concerned patient prior to implementation. The Principal Investigator shall obtain such approval. Changes of purely administrative nature shall be notified to the committee by the Principal Investigator, but do not require formal approval.

2. Principal Investigator and SMO

- 2.1. 2.1 The Principal Investigator and SMO shall carry out the Clinical Study in a professional, competent manner in accordance with the Protocol and the terms of this Agreement. The Principal Investigator and SMO will also be responsible for the direction of the Clinical Study in accordance with any applicable Institution policies. The Principal Investigator and SMO shall ensure that all staff are bound by and comply with the terms of the Protocol and this Agreement. The Principal Investigator, SMO or the INSTITUTION should inform SIRO and SPONSOR in the event of a discrepancy between the terms of the Protocol, this Agreement and its own INSTITUTION policies within twenty-one (21) working days of the Effective Date of this Agreement. In the absence of any such intimation by the Principal Investigator, SMO or the INSTITUTION, the terms of the Protocol and this Agreement shall prevail. The Principal Investigator and SMO shall ensure that all staff are bound by and comply with the terms of the Protocol and this Agreement.

3. Study Initiation and Subjects

- 3.1. It is anticipated that the Clinical Study will commence upon execution of this Agreement, that subject enrollment will be completed on or about June 2020, and that the Clinical Study will be completed on or about December 2020, unless otherwise terminated in accordance with the provisions of Para 17 of this Agreement.
- 3.2. If however, the Clinical Study obligations have not been completed by Dec 2020, the Principal Investigator and / or SMO shall continue with, and complete all obligations under this Agreement. All payments shall correspond with the appropriate milestone, as listed in Schedule A.
- 3.3. The Clinical Study will involve the enrollment of a maximum of 07 subjects (provided there may be an increase in enrollment upon SIRO request) meeting all Protocol eligibility requirements ("Subjects"). SIRO shall not be obligated to pay any sums for tests performed on subjects who do



Dr. V.A. Kothiwale
Registrar

not meet all Protocol eligibility criteria or for additional subjects who are enrolled in the Clinical Study without SIRO's prior written approval.

4. Patient Information and Consent

- 4.1. It is the Principal Investigator's responsibility to explain the Study to each potential patient (parent and/or legal guardian of the infant) and obtain written informed consent before any Study procedures are performed. This is an unconditional prerequisite for participation of a patient in the Study. The Investigator shall inform the subject or his/her nominee(s) for their rights to contact the sponsor or SIRO (whosoever has obtained permission from the licensing authority for the conduct of clinical trial) for the purpose of lodging claims in case of any trial related injury/death. The explanation shall at least include all points listed in the International Council on Harmonisation ("ICH") Guideline for Good Clinical Practice, section 4.8.10 including but not limited to applicable regulations, and it must be given both verbally and in writing in compliance with ICH-GCP, ethical principles based on the Declaration of Helsinki in its current version and national requirements. Patients shall be given sufficient time to consider their participation in the Study. Consent must be documented by the patient's dated signature on the trial informed consent form. A copy of the signed and dated information and consent form must be provided to the patient. In the event the Patient is not able to give informed consent, the same may be obtained from a legally acceptable representative. For the purpose of this section, a legally acceptable representative is a person who is able to give consent for or authorize an intervention in the Patient as provided by the applicable law(s) of India. In the event the Patient and where required his/her legally acceptable representative is unable to read/write, an impartial witness will remain present during the entire informed consent process and who must append his/her signatures to the trial informed consent form. The Principal Investigator will obtain prior approval from the relevant ethics committee in the event of any amendments to the trial informed consent form.
- 4.2. Provision of consent will be confirmed in the CRF as well as by the Principal Investigator's signature on the consent form. The signed and dated declaration of informed consent will remain at the INSTITUTION and must be safely archived by the Principal Investigator, so that the forms can be retrieved at any time for monitoring, auditing and inspection purposes.

5. Representations And Warranties

- 5.1. **No Inconsistent Obligations or Constraints.** Institution and Principal Investigator each represents and warrants that it is qualified and permitted to enter into this Agreement and that the terms of this Agreement are not inconsistent with its other contractual arrangements. Institution and Principal Investigator each warrants that it is not constrained by any existing agreement in performing its obligations under this Agreement.
- 5.2. **Legal and Binding Agreement.** Institution and Principal Investigator each represents and warrants that this Agreement is a legal and valid obligation binding upon it and enforceable in accordance with its terms.
- 5.3. **No Impairment; No Conflict.** During the term of this Agreement, Institution and Principal Investigator each warrants that it shall not enter into any agreement to provide services which would in any way (a) materially impair his, her or its ability to complete participation in the Study or (b) constitute a conflict of interest with Sponsor's development of Study Product.

Clinical Study Agreement version 01 dated 03 Feb 2020
Dr. Jyothi Hattitholi
CLR_18_09

Confidential

Page 3 of 22



Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

5.4. **No Pending Litigation; No Action by FDA.** Institution and Principal Investigator each represents and warrants that (a) it is not currently involved in any litigation, and is unaware of any pending litigation proceedings, relating to Institution's and/or Principal Investigator's role in the conduct of a clinical trial for any third party; and (b) it has not received any warnings from the FDA or other Regulatory Authority relating to services it has provided to third parties during the conduct of a clinical trial.

6. Insurance Coverage

6.1. SPONSOR shall adequately insure each and every Participating patient covering any injury or illness suffered as a direct result of their participation in this Clinical Study. Provided that the SPONSOR shall not be responsible to provide for insurance coverage with respect to any injury (including death) or illness arising as a result of (i) negligent acts of Principal Investigator, and/or INSTITUTION and/ or SMO with respect to activities or services undertaken pursuant to this Agreement; (ii) improper or negligent administration or use of the Clinical Study Drug during the course of the Clinical Study by the Principal Investigator,; or (iii) in violation of any and all applicable Central, State or Local laws rules and regulations in India by Principal Investigator, INSTITUTION, SMO and SIRO. All participating patients will be informed by the Principal Investigator about the existence of the insurance policy and the extent of the coverage.

6.2. INSTITUTION, SMO and the Principal Investigator, shall have adequate insurance coverage for any claims arising from their negligence, willful misconduct and other actions or omissions. The Institution and the Investigator will provide a copy of their insurance certificate to SIRO and the SPONSOR upon signature of this Agreement.

7. Ethics Committee Approval

7.1. The Study will only be started, when full written approval of/ favorable opinion on the Protocol has been obtained from the concerned local or regional Ethics Committees (EC) / Investigational Review Board (IRB). It is the Principal Investigator's responsibility to obtain EC/IRB approval/opinion for the Protocol and all subsequent amendments, in compliance with the national regulatory requirements and laws.

8. Study Management

8.1. Case Report Form Handling. The Principal Investigator and/ or SMO shall be responsible for providing correct Case Report Forms ("CRF") according to the following:

8.1.1. The main objective of the CRF is to obtain those data required by the Protocol in a complete, accurate, legible and timely fashion. The data in the CRF must be consistent with the relevant source documents, and they must be suitable for submission to authorities.

8.1.2. The data recorded in the course of the Study shall be documented in the CRFs and, as necessary, on the SAE report. They will then be forwarded to SIRO/SPONSOR for data management and biometric analysis.

8.1.3. The data in the CRF shall be recorded, evaluated, and stored in anonymous form in accordance with data-protection regulations. The Principal Investigator and/ or SMO shall

Clinical Study Agreement version 01 dated 03 Feb 2020

Dr. Jyothi Hattitholi

CLR_18_09

Confidential

Page 4 of 22



ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

ensure that patient names are not mentioned on any document, neither CRFs nor other documents that will be forwarded to SIRO/SPONSOR.

8.1.4 Wherever possible, all data obtained in the course of the Study must be recorded in the original patient files. Data to be recorded directly on the CRFs and considered as source data will be identified as such. All data in the CRFs must correspond exactly with data recorded in the source documents.

8.1.5 If CRFs are not complete the Principal Investigator and/ or SMO shall be obliged to complete them on request of SIRO/SPONSOR.

8.2. Source Data. The Principal Investigator and/ or SMO shall be responsible for providing the Source Data according to the following regulations.

Source data are the original patient records of all variables collected for the trial as well as the patient's medical history. Specifically they comprise:

- Signed informed consent form.
- Patient hospital file and individual clinical notes.
- Laboratory reports.
- Pharmacy records.
- Study specific source documents (e.g. x rays, ECG tracings).
- Appropriate sections of the CRF, where data are recorded directly onto specific forms.
- Other reports and records of any procedure performed in accordance with the Protocol.

The Principal Investigator shall safely maintain the original Study documentation together with all source data for the maximum period of time permitted by the hospital, research institute or practice in question, but not less than 15 years after the clinical part of the trial has been completed. If archiving can no longer be maintained at site, the Principal Investigator will notify SIRO/SPONSOR.

8.3. Investigator Study File and Archiving. The INVESTIGATOR and/ or SMO shall prepare and maintain complete and accurate study documentation in compliance with ICH-GCP standards and local regulations. Therefore, an investigator study file shall be prepared which contains all relevant documents necessary for the conduct of the study:

- Signed protocol and amendments.
- Investigator's Brochure and updates.
- EC composition, approval(s)/opinion correspondence/reporting.
- Notifications of regulatory authorities.
- CVs and signature sheet for key study personnel (e.g. investigators, study nurses).
- Signed study agreements including financial agreement.
- Trial initiation report.
- Approved and signed informed consent forms.
- Patient insurance certificate.
- CRFs (investigator's copy).
- Data correction forms (copies).
- SAE documentation and related correspondence/reporting.
- Shipping/accountability/destruction records for investigational product and material.
- Certificate of analysis.
- Instructions for handling of investigational product and material.

Clinical Study Agreement version 01 dated 03 Feb 2020
Dr. Jyothi Hattitholi
CLR_18_09

Confidential

Page 5 of 22



ATTESTED
Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- Laboratory accreditation/certification and up-to-date reference ranges of normal values.
- Screening, enrollment, and monitoring logs and subject identification code list
- Appointment diaries.
- Study related correspondence with SPONSOR or SIRO.

8.4. **Documentation and Material (Supplies).** All supplies provided to the Principal Investigator and/or SMO for the purpose of carrying out the Study are supplied only for the purpose of the Study and must not be used for any other purpose whatsoever. The Principal Investigator, or a person(s) delegated by him, are responsible for the security and accountability of all supplies.

The inventory must be available for monitoring, auditing and inspection. When the study is completed, or if it is prematurely terminated, any supplies of Investigational Product and any other material for the Study, supplied by SIRO/SPONSOR (except documentation required to be retained by the Principal Investigator), must be returned to SIRO/SPONSOR or destroyed at site, alternatively. In the latter case the identification and quantity of each unit of study medication, the method of destruction, and the person in charge must be documented.

8.5. **Monitoring, Quality Assurance, and Inspection by Authorities.** The Study will be monitored by SIRO. Its representatives (alone or together with representatives from SPONSOR) will be allowed access to all information resulting from this Study and SPONSOR will have an unrestricted right to use such information.

SIRO (alone or together with representatives from SPONSOR) will perform regular on-site monitoring visits throughout the Study. The tasks of the monitor comprise the following:

- to ensure protocol adherence,
- to verify the data in the CRFs against source documents (SDV),
- to check progress of the study and to motivate, if necessary,
- to review the CRFs for complete and accurate capture of data, including laboratory test reports and other patient records
- to check all data for possible SAEs and AEs,
- to review signed informed consent forms for signatures and date of consent,
- to ensure accurate record of drug accountability,
- to ensure adequate storage of study supplies,
- to collect completed CRFs,
- to discuss and help resolve any problems,
- to verify adequate insurance coverage undertaken by PI,
- to verify the ICF(s) as per the applicable regulatory guidelines.

Source Data Verification (SDV) shall be performed on 100% of key data such as informed consent, demographics, inclusion/exclusion criteria, parameters for the evaluation of the main endpoints, safety evaluation, and drug accountability.

The visits shall involve the Principal Investigator or his appointed representative(s) and any other staff, as required. The Principal Investigator shall ensure that sufficient time will be allowed for monitoring visits. Follow-up correspondence between the site and SIRO relating to apparent inconsistencies or clarification of CRF entries will be kept on file at both SIRO and the site.

ATTESTED
 Dr. V.A Kothiwale
 Registrar

Study protocol, patient information leaflet/consent forms, CRF and trial report as well as each step of data recording, monitoring and processing shall be subject to the independent Quality Assurance at SIRO.

This Study shall be audited on behalf of SPONSOR to assure GCP compliance as well as validity of the study data according to a study specific audit plan. The audits will be conducted in accordance with the SOPs of a contract organization selected by SPONSOR.

For monitoring visits and in case of audits and inspections by authorities the Principal Investigator and/ or SMO must provide direct access to the complete study records including CRFs, original source data, study documentation, and, if necessary, any additionally required background data. Furthermore, access to Study related facilities must be ensured.

- 8.6. **Confidentiality of Patient Records.** The INSTITUTION, SMO and the Principal Investigator must assure that study patients' anonymity will be maintained, and that their identities are protected from unauthorized parties. Documents stating patients' names must be kept in strict confidence by the Principal Investigator. On CRFs or other documents removed from the INSTITUTION patients must not be identified by their names, but by initials and patient identification number. The Principal Investigator and SMO is obliged to maintain a subject identification code list showing the patients' full names and dates of birth together with the corresponding patient identification numbers to allow revealing identity of any subject.

The Principal Investigator and SMO agrees that representatives of SPONSOR, SIRO, of the responsible EC/IRB and of national or international regulatory authorities may inspect the patient records at the site for source data verification. SPONSOR and SIRO guarantee for their representatives that patient data will be treated confidentially. Monitors and auditors are bound to secrecy.

- 8.7. Principal Investigator and SMO agrees for a period of ten (10) years after the expiration or termination of the Study not to use and disclose SIRO and Sponsor Confidential Information to any third party. Institution and Principal Investigator agrees not to disclose SIRO and Sponsor Confidential Information to third parties or use except as necessary to conduct a Study and under an agreement by the third party to be bound by the obligations of this Section. Institution and Principal Investigator shall safeguard SIRO and Sponsor Confidential Information with the same standard of care that is used with own Confidential Information, but in no event less than reasonable care. The parties understand and agree that information communicated to EC is "Confidential and Privileged"

- 8.8. The Parties agree to abide by applicable Law relating to the protection of Clinical Trial Subject Personal Information and where Confidential Information is also Personal Information, the obligations under this Section shall remain in force for the period required under such law. The Party that received Personal Information hereunder shall only use or disclose the Personal Information as set out in the Clinical Trial Subject's consent form or as required by applicable Law. Each Party shall give prompt notice to the other Parties of any privacy or security breach it has experienced that affects Clinical Trial Subject Personal Information.

9. Budget

Clinical Study Agreement version 01 dated 03 Feb 2020
Dr. Jyothi Hattitholi
CLR_18_09

Confidential



Page 7 of 22

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Cost and payment terms with all the Payee details(along with the GSTIN of all the Parties) are set forth in Schedule "A" attached to this Agreement and incorporated by reference. All the payment obligations of the Sponsor shall be routed through SIRO.

All payments payable by SIRO are subject to deduction of taxes at source ("TDS") as per applicable law unless relevant exemption certificate is produced by the Site. GST will be paid, if applicable, on generation of valid invoice showing the amount of GST to be charged before any payment is made under this Agreement.

All invoices should have GSTIN (Goods and Service Tax Identification Number) along with HSN code for services as mandated by GST provisions. This is mandatory to ensure compliance with GST.

In case the site defaults in making timely GST payments then SIRO shall retain 18% of each payment of the contract price payable to the Institution for a period of 45 days from the release of payment. However, such retention shall not be applicable in case the Institution discharges the applicable GST and files the GST Returns in relation to such payments, and the same is being reflected in SIRO's Returns.

In case of any non-compliance of any provisions under the GST Legislations by Institution, such Institution alone shall be liable to compensate SIRO for any losses arising to SIRO due to such non-compliances as well as shall also be liable to pay interest and/or penalty imposed by the Statutory Authorities and/or other legal fee or expenses incurred by the SIRO in this regard.

10. Data and Information

10.1. **Confidential Information.** During the term of this Agreement, and for a period of ten (10) years after termination of this Agreement, the Principal Investigator and SMO shall not disclose or use for any purpose other than performance of the Clinical Study, information including but not limited to any and all trade secrets, know-how, privileged records or other confidential or proprietary information and data, both technical and non-technical, disclosed to the Principal Investigator by SIRO or SPONSOR ("Information"). The obligation of non-disclosure shall not apply to the following:

10.1.1. Information at or after such time that it is or becomes publicly available through no fault of the Principal Investigator; and/ or SMO;

10.1.2. Information that is already independently known to the Principal Investigator and/ or SMO as evidenced by their prior written records;

10.1.3. Information at or after such time that it is disclosed to the Principal Investigator and/ or SMO on a non-confidential basis by a third party with the legal right to do so;

10.1.4. Information developed by the Principal Investigator and/ or SMO without the use of SIRO's or SPONSOR's Information as evidenced by their written records; or

10.1.5. Information required to be disclosed by law.

10.2. **Medical Records** In the event that either SIRO or SPONSOR come into contact with Subjects' medical records, such party shall hold in confidence the identity of the Subject and shall comply with the Information Technology (Reasonable security practices and procedures and



ATTESTED

Dr. V.A. Kothiwale
Registrar

sensitive personal data or information) Rules, 2011 made under the Information Technology Act, 2000 (and all other applicable law(s) with respect to the confidentiality of such records.

10.3. **Trading in Securities.** Securities and Exchange Board of India (SEBI) interalia, prohibits any person either on his own behalf or on behalf of any other person, deal in securities of a company listed on any stock exchange when in possession of or is likely to have access to or has received any unpublished price sensitive information. The Principal Investigator, by virtue of their participation in the Clinical Study, has access to data and information arising out of the conduct of the Clinical Study, which is material non-public information that belongs to SPONSOR. The Principal Investigator and SMO agrees not to use, or cause any other person to use, the data and information arising out of the Clinical Study to purchase or sell securities in SPONSOR Company.

10.4. **Proprietary Rights.** All information resulting from the Clinical Study conducted under this Agreement, including all data, results, conclusions, observations, discoveries, inventions, ideas, know-how, procedures, advancements and the like, whether patentable or not ("Data") shall be fully disclosed by the Principal Investigator and SMO to SPONSOR. All Data shall be the sole property of SPONSOR and SPONSOR shall have the unrestricted right to freely utilize all such Data in whatever manner it desires.

Principal Investigator, SMO and/or the INSTITUTION agree to undertake such actions reasonably requested by SPONSOR to give effect to such ownership and agrees to sign, execute, affirm all documents, including, without limitation, all applications, forms, instruments of assignment and supporting documentation and perform all other acts as may be required for this purpose.

10.5. **Resignation etc.** of the Principal Investigator: The INSTITUTION shall inform SIRO in case the Principal Investigator ceases to be associated with the INSTITUTION for any reason during the course of the Study. They shall also replace the Principal Investigator in case SIRO so desires and render all assistance to safeguard patient safety and Study data.

11. Drug Safety

11.1. The recording of adverse events (AEs) is an important aspect of study documentation. It is the Principal Investigator's responsibility to document all AEs according to the detailed guidelines of the Protocol. The Principal Investigator agrees to answer any questions of SPONSOR/SIRO's medical monitor concerning any AEs.

11.2. According to the Protocol, the Principal Investigator will assess at each visit whether any adverse event (AE) including abnormal laboratory values has occurred. The details of all AEs, whether reported by the patient or observed by the Principal Investigator /Study personnel during the entire Study, will be recorded onto the appropriate source document. Each adverse event must be recorded in the AE section of the case report form (CRF), regardless of the causal relationship.

11.3. The Principal Investigator must immediately report all serious adverse events (as defined in protocol)(within 24 hrs of occurrence of SAE), which occur during the course of the Study and up to the date of the patient's last visit, to the following addressee given below. The SAE Report form will be used for documentation and reporting.

24 hrs SAE Reporting

Clinical Study Agreement version 01 dated 03 Feb 2020

Dr. Jyothi Hattitholi

CLR_18_09

Confidential



Page 9 of 22

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Licensing authority: All SAE forms are to be e-mailed or faxed at Email ID: dci@nb.nic.in and Fax no.:011-23236973

Sponsor: All Initial and follow up SAE reports are to be sent on the following email ID: CT.SAE@sunpharma.com and Mahesh.kumbhar@sunpharma.com and clinical.safety@sparcmail.com /of the Sponsor

Ethics Committee: All Initial and follow up SAE reports are to be sent viae- mail – kleclinicalresearch@gmail.com

A Due Analysis report has to be submitted to the following addressee within 14 calendar days of occurrence to the DCGI (Licensing Authority), Ethics Committee Chairman and Head of the Institution for all the Initial and Follow-up information until stabilization/ resolution of the event.

- **Licensing authority:** For all SAEs as hard copy via courier at DCGI address

The Drugs Controller General (India)

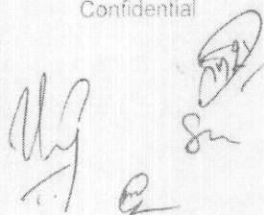
CDSCO Extn Office,
3rd Floor, CGHS Dispensary Sector-3
Sadiq Nagar, New-Delhi-110049
Fax: 011-23236973

- Chairman of Ethics Committee: For all SAEs as hard copy via courier at
Dr Subarna Roy- Chairman
Institutional Ethics Committee, KAHER
JNMC Campus Nehrunagar Belagavi-590010 Karnataka India
Email: kleclinicalresearch@gmail.com
- Head of the Institution: For all SAEs as hard copy via courier
Dr. M.V.Jali – MD & CEO
KLES Dr Prabhakar Kore Hospital & Medical Research Centre
Nehrunagar Belagavi-590010 Karnataka India
medicaldirector@klehospital.org

11.4. If the event is unexpected and fatal or life threatening and is considered by the Principal Investigator possibly related to the study medication, the Drug Safety Department of SIRO shall be informed by telephone and followed immediately by fax but not later than within 24 hours of occurrence of SAE.

11.5. SIRO undertakes to notify the Principal Investigator of all Suspected Unexpected Serious Adverse Reactions (SUSARs), which occur during the course of the Study in any other location and Periodic SAE listings, which are reported by SPONSOR to health authorities, at an interval of every 3 months. The Principal Investigator will inform the local ethics committee of SAEs reportable according to its national requirements and timelines, SUSARs, Periodic SAE listings and of findings that could adversely affect the patients' safety, could have an impact on the conduct of the study, or could alter the ECs / IRBs approval to continue the study.

11.6. SIRO will be responsible to notify on time the health authorities in India.





ATTESTED
Dr. V.A. Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

12. Study Drug and Study Materials

12.1. **Study Drug.** SIRO, on behalf of SPONSOR, will provide Clinical Study Drug for the Clinical Study. The use of the Clinical Study Drug for any purpose outside of the Clinical Study is prohibited by this Agreement. While SIRO in no way condones the use of the Clinical Study Drug for any purpose outside of the Clinical Study, if such work is performed, all data, results, conclusions, observations, discoveries, inventions, ideas, know-how, procedures, advancements and the like, whether patentable or not, shall be treated in all respects as Data in accordance with this Agreement.

12.2. **Materials.** Access to Study Materials shall be limited to only those persons who under the Principal Investigator's direct control will be using Study Materials for the Clinical Study. The term "Study Materials" shall include the Clinical Study Drug, reagents and materials derived from Subjects enrolled in the Clinical Study, including, but not limited to, blood, bone marrow, sera, and other biological materials. At no time shall any Study Materials be used for any purpose other than as described in the Protocol or transferred to any third party without SPONSOR's prior written consent. Upon termination or completion of the Clinical Study, all unused Study Materials shall be returned to SPONSOR or at SPONSOR's sole option, destroyed.

13. Publications

13.1. The Principal Investigator shall not publish any article or paper nor make any presentations, nor assist any other person in publishing any articles or papers or in making any presentations, relating or referring to:

- (a) the Study or any results, data or insights therefrom;
- (b) the Services performed hereunder; or
- (c) any data, information or materials obtained or generated in the performance of its obligations hereunder, in whole or in part, without the prior written consent of SIRO and SPONSOR, which consent may be granted or withheld depending on the Study Sponsor's sole discretion.

13.2. Any publication or disclosure by the Principal Investigator, SMO and/or Institution contrary to the provisions of this section or without prior written consent of Sponsor shall be void-ab-initio. It is agreed and acknowledged by the Parties that in the event of any breach of this Section, Section (7), (12) & (13), in addition to other legal remedies that may be available, Sponsor shall have the right to seek specific performance and other injunctive and equitable relief, in any court having jurisdiction over the Parties and the subject matter hereof.

14. Use of Name and Advertising

14.1. **Use of Name.** The INSTITUTION / Principal Investigator / SMO and SIRO, on behalf of SPONSOR, shall each obtain prior written consent from the other before using the name, symbols or marks of the other in any form of publicity in connection with the Clinical Study. If the INSTITUTION or SIRO is legally required to make any disclosure that identifies the existence or terms of this Agreement, then either may do so with prior written consent from the other.

14.2. **Advertising.** In the event that the Principal Investigator elects to advertise to recruit Subjects for enrollment in the Clinical Study, Principal Investigator will provide a copy of any such

Clinical Study Agreement version 01 dated 03 Feb 2020
Dr. Jyothi Hattitholi
CLR_18_09

Confidential



Page 11 of 22

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

advertisement to SIRO / SPONSOR for prior approval. In addition, Principal Investigator will obtain Institutional Review Board and Ethics Committee approval of all advertisement prior to use. Any promotional representation or suggestion that an investigational drug is safe or effective for the purposes for which it is under investigation is not permissible / a violation of the United States Code of Federal Regulation 21 CFR 312.7(a). (Strike out if not applicable depending upon the country of the sponsor).

14.3. Any use of name and advertising or disclosure by the Principal Investigator and/or Institution contrary to the provisions of this section or without prior written consent of Sponsor shall be void-ab-initio. It is agreed and acknowledged by the Parties that in the event of any breach of this Section, Section (7), (12) & (13), in addition to other legal remedies that may be available, Sponsor shall have the right to seek specific performance and other injunctive and equitable relief, in any court having jurisdiction over the Parties and the subject matter hereof.

15. Intellectual Property Rights

15.1. All Intellectual Property Rights owned by or licensed to Sponsor prior to and after the date of this Agreement are and shall remain the exclusive property of Sponsor.

15.2. All Intellectual Property Rights owned by or licensed to the Institution or the Principal Investigator prior to and after the date of this Agreement, other than any Intellectual Property Rights arising from the clinical Study, are and shall remain the exclusive property of the Institution or the Principal Investigator, as applicable.

15.3. All Intellectual Property Rights owned by or licensed to SIRO prior to and after the date of this Agreement, other than any Intellectual Property Rights arising from the clinical Study, are and shall remain the exclusive property of SIRO, as applicable.

15.4. All Intellectual Property Rights (including Clinical trial data and clinical trial documentation) arising from and relating to the Clinical Study/trial, the Investigational drug or the Protocol (the "Clinical Trial Intellectual Property") shall be the exclusive property of Sponsor and for this purpose, the Institution and the Principal Investigator hereby assign and transfer, and shall cause the trial site team members to assign and transfer, without additional consideration, to Sponsor (or its nominate designee), all their rights and title in and to the Clinical Trial Intellectual Property throughout the world on perpetual basis. The Institution and the Principal Investigator shall execute and deliver, and shall cause the trial site team members to execute and deliver, all such documents and, at Sponsor's expense, do all such other acts as Sponsor may reasonably require in order to vest fully and effectively all Clinical Trial Intellectual Property in Sponsor or its nominate designee.

15.5. The Institution, SMO and the Principal Investigator shall promptly disclose to Sponsor any Clinical Trial Intellectual Property generated pursuant to this Agreement and shall treat the Clinical Trial Intellectual Property as Confidential Information.

16. Compliance with Law; Financial

16.1. The Principal Investigator and the INSTITUTION shall perform the Clinical Study in compliance with generally accepted standards of Good Clinical Practice as defined in U.S. Code of Federal Regulations, 21 C.F.R., the Protocol, instructions provided by SIRO and all applicable

Clinical Study Agreement version 01 dated 03 Feb 2020
Dr. Jyothi Hattholi
CLR_18_09

Confidential

Page 12 of 22

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

local, state and federal laws and regulations governing the performance of clinical investigations including but not limited to the International Conference on Harmonization ("ICH") Tripartite Guideline for Good Clinical Practice ("GCP"), the Indian Drugs and Cosmetics Act, 1940, the New Drugs and Clinical Trials Rules, 2019 of the Drugs and Cosmetics Rules, 1945 and any Rules and amendments thereunder, the CDSCO-GCP. The Principal Investigator shall provide SIRO with sufficient accurate financial information to allow SIRO to submit complete and accurate certification or disclosure statements as required under U.S. Code of Federal Regulations, 21 C.F.R. 54. The Principal Investigator shall also promptly update this information if any relevant changes occur during the course of the Clinical Study and for one year following the completion of the Clinical Study. The Principal Investigator shall retain any records mutually agreed to by SIRO, resulting from the Clinical Study for the time required by applicable local and federal regulations, and to allow for inspection of all such records including the Subjects' medical records. The informed consent form signed by the Subjects shall provide for access to the Subjects' medical records by SIRO and by agencies such as the FDA.

17. Debarment

- 17.1. The Principal Investigator certifies that neither the Principal Investigator nor any person employed by the Principal Investigator or any subcontractor to perform any services in connection with the Agreement has been subject to any legal or regulatory discipline, nor ever been suspended, debarred, or is under any medical license limitation or condition, or otherwise disqualified from providing medical services by any governmental, regulatory or administrative body or organization within their jurisdiction.

18. Indemnification

- 18.1. To the maximum extent permitted by applicable laws, SPONSOR warrants that they shall defend, indemnify and hold harmless SIRO, PRINCIPAL INVESTIGATOR, INSTITUTION, SMO and any of their agents and employees ("indemnitees of Sponsor") from any and all liabilities, claims, actions or suits for personal injury or death directly arising out of the use of the Clinical Study Drug during the course of the Clinical Study in accordance with the Study Protocol.
- 18.2. The indemnity granted in this Article 18.1 shall not apply in the event when such liability, damage, loss, or expense was caused by the failure of an Indemnitee to:
- 18.2.1. adhere materially to the terms of the Protocol;
 - 18.2.2. comply with government regulations or requirements; or
 - 18.2.3. conduct the Clinical Trial in accordance with generally accepted medical standards including avoidance of negligence and willful misconduct; or
 - 18.2.4. carryout its obligation without any error or omission.
 - 18.2.5. the reason of loss/ damage is not directly and solely attributable to the SPONSOR.
- 18.3. SIRO warrants that it shall indemnify, defend and hold harmless SPONSOR, INSTITUTION, SMO and Principal Investigator, including their agents and employees (the "Indemnitees of SIRO") from

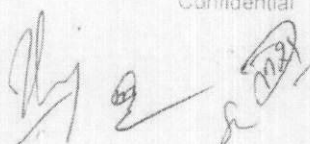
Clinical Study Agreement version 01 dated 03 Feb 2020

Dr. Jyothi Hattitholi

CLR_18_09

Confidential

Page 13 of 22



ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

any and all liabilities, claims, actions or suits for personal injury or death directly arising out of (i) negligent or deliberate wrongful acts of SIRO or its employees during the term of this Agreement; except to the extent that the same is caused as a result of the Project Materials provided by the Sponsor or adhering to the instructions of the Sponsor or Applicable Laws while rendering the Services or due to reasons attributable to the SPONSOR, INSTITUTION or Principal Investigator and their agents and employees; (ii) breach of confidentiality; (iii) non-compliance with the applicable laws; (iv) .

- 18.4. The indemnity granted in Article 18 shall apply separately to each Indemnitee in such manner and to the same extent as though a separate indemnity had been given to each. Said indemnity shall survive the completion or early termination of this Agreement.
- 18.5. Each party warrants that it shall provide a diligent defense against and/or settlement of, any claims brought or actions filed for the loss which is the subject of the indemnity, whether such claims or actions are rightfully or wrongfully brought or filed. The indemnifying Party shall have the right to settle claims at its sole expense.
- 18.6. The Principal Investigator/ INSTITUTION/ SMO shall promptly notify SIRO and SPONSOR of any claim for which indemnity may be sought. The Principal Investigator /SMO/ INSTITUTION shall fully cooperate with SPONSOR / SIRO and its legal representatives in the investigation and defense of any claim or suit covered under this Agreement. If the claim or action is asserted, the Principal Investigator shall have the right to select and obtain representation by separate legal counsel, as long as the Principal Investigator pays for all costs and expenses incurred by it for the separate counsel.
- 18.7. SPONSOR warrants that it maintains policies or programs of insurance or self insurance at levels sufficient or have SIRO to maintain such programs of insurance at the cost of SPONSOR to support the indemnification obligations assumed under this Agreement. Upon request, SPONSOR will provide evidence of their insurance or self-insurance.
- 18.8. The Principal Investigator and INSTITUTION each shall indemnify, defend and hold harmless the Sponsor, including its agents and employees, and SIRO, including its agents and employees, against any losses suffered and from all liabilities, claims, actions or suits for personal injury or death, directly arising out of the negligence, willful misconduct or any other act or omission by the Principal Investigator or the INSTITUTION, or by their agents and employees, during the course of the Clinical Study.
- 18.9. The Principal Investigator and the INSTITUTION each shall also indemnify, defend, and hold harmless the Sponsor and SIRO against:
- i. any and all loss, costs, claims, actions, liability and/or suits (including without limitation, interest, penalties and reasonable attorneys' fees) on the Sponsor or SIRO due to negligence, gross negligence or intentional misconduct of Principal Investigator and/or INSTITUTION in connection with its performance of the services, obligations, responsibilities and undertakings under this Agreement;
 - ii. Principal Investigator's and/or INSTITUTION's violation of any and all applicable Central, State or Local laws rules and regulations of India;

Clinical Study Agreement version 01 dated 03 Feb 2020
Dr. Jyothi Hattitholi
CLR_18_09

Confidential

Page 14 of 22




ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- iii. Principal Investigator's and/or INSTITUTION's breach or default in performance of its obligations in connection with a Study;
- iv. Principal Investigator's and/or INSTITUTION's material deviation from the Protocol or other written recommendation or instructions furnished by SPONSOR through SIRO to Principal Investigator and the INSTITUTION for the Study;
- v. Principal Investigator's and/or INSTITUTION's failure to complete the Study and any such delay attributable solely to Principal Investigator's and/ or INSTITUTION's willful misconduct, negligence or mistakes and/or or failure to comply with its obligations under this Agreement.

Without prejudice to any other Section, the reference to Principal Investigator and INSTITUTION above includes reference to its agents and employees.

19. Independent Contractor

19.1. The parties to this Agreement hereby agree that the Principal Investigator and Institution are independent contractors hereunder and are not employees or agents of the SPONSOR or SIRO. The Principal Investigator and INSTITUTION further agree that neither they nor their employees or agents shall make any claim against the SPONSOR or SIRO for compensation, vacation pay, sick leave, retirement benefits, social security benefits, workers' compensation, disability or unemployment benefits or employee benefits of any kind. Further, their agents and employee shall not be considered to be employees of the Sponsor or SIRO under any circumstance.

20. Termination

20.1. This Agreement may be terminated:

20.1.1. by the Principal Investigator upon thirty (30) days' prior written notice;

20.1.2. by SIRO on behalf of SPONSOR immediately upon thirty (30) days written notice,

20.1.3. by SIRO immediately if the Principal Investigator is unable to continue to serve and a successor acceptable to SIRO is not available; or

20.1.4. upon the occurrence of an event qualifying as a termination event as described in the Protocol

20.2. Upon the effective date of termination, the Principal investigator shall conduct an accounting review, which is subject to verification by SIRO. If SIRO objects to any charges, the parties shall use reasonable efforts to resolve expeditiously any disagreement within thirty (30) days upon receipt of adequate documentation therefor, SIRO will make payment to the Institution for:

20.2.1. all services properly rendered and monies properly expended by the Principal Investigator and/ or SMO prior to the date of termination and not yet paid for, and

20.2.2. reasonable non-cancelable obligations properly incurred for the Clinical Study by the Principal Investigator prior to the effective date of termination.

Clinical Study Agreement version 01 dated 03 Feb 2020
 Dr. Jyathi Hattitholi
 CLR_18_09

Confidential

Page 15 of 22

(Handwritten signatures)



(Handwritten signature)
ATTESTED
(Handwritten signature)

Dr. V.A.Kothiwale
 Registrar

KLE Academy of Higher Education and Research,
 (Deemed-to-be-University u/s 3 of the UGC Act,1956)
 Belagavi-590 010,Karnataka

- 20.3. The Principal Investigator and/ or SMO will credit or return to SIRO any funds not expended or obligated by the Principal Investigator in connection with the Clinical Study prior to the effective termination date.
- 20.4. Immediately upon receipt of a notice of termination, the Principal Investigator shall stop enrolling Subjects into the Clinical Study and shall cease conducting procedures on Subjects already enrolled in the Protocol as directed by SIRO to the extent medically permissible and appropriate.
- 20.5. Termination of this Agreement by either party shall not affect the rights and obligations of the parties accrued prior to the effective date of the termination. The rights and duties under Sections 4.2, 8.2, 9, 10, 12.2 and 18 survive the termination or expiration of this Agreement.

21. Miscellaneous

- 21.1. **Applicable Law and Arbitration.** This Agreement is entered into and will be deemed for all purposes to have been made in Mumbai, India and shall be governed and construed in accordance with the laws of India applicable to contracts and agreements. Notwithstanding the foregoing, SPONSOR may seek injunctive or equitable relief, in addition to damages, for a breach of any of the confidentiality provisions contained herein in any court of competent jurisdiction.
- 21.2. All disputes arising out or in connection with the present Agreement, which cannot be settled amicably, shall be referred to and settled by sole arbitrator. The proceedings will be governed by the Indian (Arbitration & Conciliation) Act, 1996. The place of the arbitration shall be Mumbai and the language of the arbitration proceedings shall be English. Any judgment, decision or award of the arbitrators shall be final and binding on both the Parties, and shall be enforceable in any court of competent jurisdiction.
- 21.3. Subject to 21.2 above the courts of Mumbai will have exclusive jurisdiction to try and entertain any dispute arising out of this Agreement.
- 21.4. The parties shall share equally the costs of the Board of Arbitration unless the Board determines otherwise.
- 21.5. **Amendments.** This Agreement may only be amended by the mutual written consent of the parties hereto.
- 21.6. **Entire Agreement.** This Agreement represents the entire understanding of the parties with respect to the subject matter of this Agreement and supercedes all prior agreements, undertakings, negotiations and discussions, whether oral or written between the parties and there are no warranties, condition, representations or other Agreements between the parties in connection with the subject matter of this Agreement. In the event of any inconsistency between this Agreement and the Protocol, the terms of this Agreement shall govern. This Agreement may be executed in any number of counterparts, each of which shall be an original and all of which together shall be one document binding on all the parties even though each of the parties may have signed different counterparts. This Agreement shall also be considered executed by the parties upon receipt by SIRO by facsimile transmission of the counterparts signed by all the parties.
- 21.7. **Severability.** Should one or more provisions in this Agreement be or become invalid or unenforceable, the Parties shall substitute such invalid provisions by valid provisions as close in meaning and effect as the original provisions. Should such substitution not be possible the invalidity or unenforceability of such provision shall not affect the validity of the Agreement as a whole.

Clinical Study Agreement version 01 dated 03 Feb 2020

Dr. Jyothi Hattitholi
CLR_18_09

Confidential

Page 16 of 22



ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- 21.8. **Assignment.** The Principal Investigator may not assign or transfer any of their rights or obligations under this Agreement without the prior written consent of SIRO. SIRO may assign this Agreement and all its rights and obligations hereunder to a successor or assignee of the business to which this Agreement relates.
- 21.9. **Waiver.** Any waiver by any Party of any breach of, or failure to comply with or failure to enforce at any time, any of the provisions of this Agreement shall not be construed as or constitute a continuing waiver of such provision, or a waiver of any other breach of or failure to comply with, any other provision of this Agreement, nor shall it in any way affect the validity of this Agreement or any part thereof or the right of any Party thereafter to enforce each and every provision of this Agreement.
- 21.10. **Notice.** Any notice required or permitted hereunder shall be in writing and shall be deemed given as of the date it is (A) delivered by hand or (B) received by Registered or Certified Mail, postage prepaid, return receipt requested, or received by facsimile and addressed to the party to receive such notice at the address set forth below, or such other address as is subsequently specified in writing:

If to Principal Investigator:

Dr. Jyothi Hattitholi
 Consultant Chest Physician
 KLES Dr Prabhakar Kore Hospital & MRC
 Nehrunagar Belagavi-590010 Karnataka India

If to INSTITUTION:

Dr. M.V. Jali
 Medical Director & CEO
 KLES Dr Prabhakar Kore Hospital &
 MRCNehrunagar Belagavi-590010
 Karnataka India

If to SIRO:

Dr Ganesh Divekar
 Head, Clinical Research & Medical Services
 SIRO Clinpharm Pvt. Ltd
 Kalpataru Prime, 1st Floor, Unit nos 3 and 4, Plot no
 D-3, Road no 16, Wagle Industrial Estate, Thane
 (West) - 400604, Maharashtra, INDIA

With a Copy to:

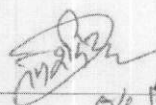
Maruti Patil
 Managing Director
 Doclin Clinical Research Services
 445, Maruti Galli, Main Road, Hangarge,
 Mandoli, Belagavi - Karnataka India 590008

IN WITNESS WHEREOF, the parties hereto have executed this Agreement in Quadripartite by proper persons thereunto duly authorized.

SIRO Clinpharm Pvt. Ltd

INSTITUTION

Signature: _____


 04 Feb 2020

Signature: _____



Name: Dr Ganesh Divekar

Name: Dr M.V. Jali

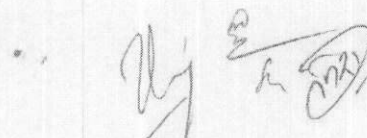
Designation: Head Clinical Research & Medical Services

Designation: MD & CEO

Clinical Study Agreement version 01 dated 03 Feb 2020
 Dr. Jyothi Hattitholi
 CLR_18_09

Confidential

Page 17 of 22





ATTESTED


 Dr. V.A. Kothiwale
 Registrar

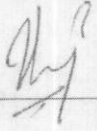
KLE Academy of Higher Education and Research,
 (Deemed-to-be-University u/s 3 of the UGC Act, 1956)
 Belagavi-590 010, Karnataka


Date: 04 Feb 2020

Date: 25 Feb 2020

PRINCIPAL INVESTIGATOR

SMO(Doclin Clinical Research Services)

Signature: 

Signature: 

Name: Dr Jyothi Hattiholi

Name: Maruti Patil

Designation: Principal Investigator

Designation: Managing Director

Date: 12 Feb 2020

Date: 12 Feb 2020

EXHIBIT A: PROTOCOL

As annexure 1

 **ATTESTED** 



Dr. V.A. Kothiwale
Registrar

EXHIBIT B: BUDGET AND PAYMENT SCHEDULE

BUDGET:

Principal Investigator : Dr. Jyothi Hattitholi

Site Address :KLES Dr. Prabhakar Kore Hospital & Medical Research Centre,
Belagavi- 590010 Karnatka India

PAYMENT SCHEDULE

Payment Schedule for the total study Grant for patients is as follows:

Overall Per Patient Budget

Amount in Indian rupees per patient	Reimbursement
INR 62,220 per patient.	Includes the following <ul style="list-style-type: none">PI and site team payment including Co- Investigator (s), Site coordinator(s)Local lab cost, Study related testsHospitalization cost (on basis of actual number of days of hospitalization per subject)Institutional overhead 25%Patient travel reimbursement as approved by the EC.

Budget Bifurcation

Visits	PI & CRC fees per Visit (INR)	IOH 25% (INR)	Lab + test charges (INR)	Hospitalization (per actual No of days)	Patient travel reimbursement (INR)	Total Payment Per Complete Patient (INR)
Screening / Placebo Run-in	6000	1500	5310	NA	NA	12,810
Period 1	6000	1500	NA	7000	500	15,000
Period 2	6000	1500	NA	7000	500	15,000
Period 3	6000	1500	4410	7000	500	19,410
Total	24,000	6,000	9,720	21,000	1500	62,220

Clinical Study Agreement version 01 dated 03 Feb 2020
Dr. Jyothi Hattitholi
CLR_18_09

Confidential

Page 19 of 22



Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

The Payee designated above will receive all compensation paid to the Institution in connection with the Investigator Agreement, if applicable. Payee will provide all applicable tax identification numbers and, upon reasonable request, will provide or assist CRO with forms related to applicable taxes.

Payment Schedule for the advance payment is as follows:

1] Study Study start up cost (**Advance/** pre payment) INR. 50,000/-

The advance payment (pre payment) provided to the PI **will be adjusted against first two invoices** raised by PI as per the PI grant.

The remaining payments will be provided on monthly basis as per the patients visit charges/ patient study completion.

2] CRO will pay only INR5000/- for 1 screen fail subject per site. Any Study subject who has been enrolled in the Study but does not meet eligibility requirements (as set forth in the Protocol) may be withdrawn from study without any payments. CRO reserves the right to withhold payment for any Study subject: (i) for whom a signed informed consent form has not been obtained prior to enrollment, (ii) for whom reasonably complete Case Report Forms have not been obtained, or (iii) for whom the Protocol has not been followed, absent reasonable explanation from Institution and/or Principal Investigator for the Protocol deviation(s).

3] Archival fees: CRO shall pay INR 90,000 per year towards archival of study documents for 15 years from time of site close out.

4] IP Management fees of 30,000 per year

Payee Details

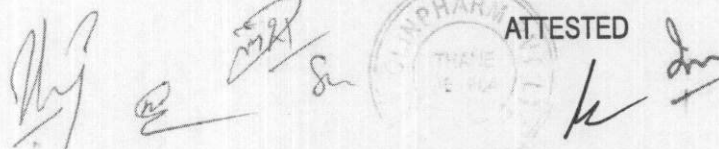
Payee Name (or institution)	Doclin Clinical Research Services
Payee Address	445,Maruti Galli, Main Road, Hangarge, Mandoli, Belagavi Karnataka,590008
Bank Name and Address	Axis Bank -Nehru Nagar, Ratna Plaza, Cts. No. 10593 A& B, Kolhapur Circle, Belgaum 590010
Cheque/Draft (in favor of)	Doclin Clinical Research Services
Account Number	919020049795418
PAN Card Number	AZXPP8818R

Clinical Study Agreement version 01dated 03 Feb 2020

Dr. Jyothi Hattitholi
CLR_18_09

Confidential

Page 20 of 22



Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

GST Number	29AZXPP8818R1ZP
IFSC Code	UTIB0001690
Contact person for payments	Mr Maruti Patil

Payment Adjustments

If Institution's/Principal Investigator's participation is terminated because no Study subjects have been enrolled, Institution/Principal Investigator / SMO will not be entitled to reimbursement or payment for any administrative costs that were incurred prior to such termination, except to the extent such costs are set forth expressly in this Investigator Agreement.

If, upon termination of this Investigator Agreement, CRO, on behalf of Sponsor, has prepaid funds that Institution/Principal Investigator has not earned in accordance with Exhibit A, Institution/Principal Investigator (or its designated payee) will return to CRO all such prepaid funds within thirty (30) days after the effective date of termination. Prepaid funds owed to CRO, if any, will be returned pursuant to instructions provided by the CRO accountant assigned to administer payments to the Payee.

In the event this Exhibit A sets forth a maximum number of subjects that may be enrolled by Institution in the Study or a maximum payment amount to Payee pursuant to the Study, Sponsor at its discretion may authorize increases in Study subjects and/or payments.

In the event the Protocol is amended, compensation paid to the Payee may be adjusted to give effect to the Protocol amendment.

During the course of the Study, Institution will have forty five (45) days after the receipt of final payment to dispute any reasonable payment discrepancies.

Invoices:

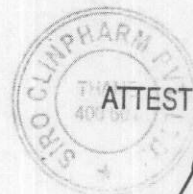
Send invoices to: Siro Clinpharm Pvt Ltd Contact Person: Study PM

Address : Siro Clinpharm Pvt Ltd
Kalpataru prime,
1st floor, Units 3 and 4, Plot D3, Road 16
Wagle industrial estate, Thane west 400604

Clinical Study Agreement version 01 dated 03 Feb 2020
Dr. Jyothi Hattitholi
CLR_18_09

Confidential

Page 21 of 22



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Failure to include Protocol number and Principal Investigator's name on all invoices may result in delayed payment.

Final Payment

The final payment will be made after the close-out visit by the CRO CRA, after all CRFs for all subjects have been received and accepted by a CRO project manager, and all data queries for Institution have been resolved satisfactorily.

Budget notes, payment schedule, conditions of payment and payment directions

1. All amounts above are in Indian Rupee (INR).
2. Lab Investigations: The study requires lab examination at specific visits. The local lab investigation charges if any will be reimbursed on actual, as per invoices.
3. Serious Adverse event related costs: Costs relating to SAE that arise due to study participation would be borne by the Sponsor on actual.
4. Please note that approx. 20 % of the total amount for one randomized patient only i.e. INR. 12424/- will be considered as retention amount and will be paid at the end of study/ study close out; once all the study related procedure and documentation would be over.
5. All payments are subject to withholding tax under all applicable laws including Income Tax Act, 1962.
6. A tax of 10% will be deducted in case a tax exemption certificate is not provided. This tax amount has been calculated and added to total grant amount. In case a tax exemption certificate is provided, then the tax amount (@ 10%) will not be applicable to be released to the site in the budget.
7. A GST (as applicable) will be considered on total grant subject to availability of GST registration number with service provider. GST will be paid and applicable to service provider, provided the GST registration number is reflected on Invoice / Bills."
8. In case recruitment is not initiated within a reasonable time period, unutilized amount (In keeping with the payment head above) would have to be returned to Sponsor.



Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



Clinical Trial Details (PDF Generation Date :- Tue, 26 Nov 2019 04:57:30 GMT)

CTRI Number	CTRI/2018/07/015021 [Registered on: 24/07/2018] - Trial Registered Prospectively	
Last Modified On	16/11/2019	
Post Graduate Thesis	No	
Type of Trial	Interventional	
Type of Study	Dentistry Other (Specify) [Nutritional]	
Study Design	Randomized, Crossover Trial	
Public Title of Study	Benefits of a form of food preservative in treating facial pain	
Scientific Title of Study	Effectiveness of Palmitoyl Ascorbate in Managing Trigeminal Neuralgia (TN):A Cross-over Phase II Randomised Controlled Clinical Trial	
Secondary IDs if Any	Secondary ID	Identifier
	NIL	NIL
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator	
	Name	Dr Shahnavaaz Khijmatgar
	Designation	Lecturer
	Affiliation	A.B.Shetty Memorial Institute of Dental Sciences
	Address	Floor 6 Department of Oral Biology and Genomic Studies A.B. Shetty Memorial Institute of Dental Sciences Nitte (Deemed to be University) Deralakatte-575018 Mangalore Karnataka India Dakshina Kannada KARNATAKA 575018 India
	Phone	8722186551
	Fax	
	Email	khijmatgar.s@gmail.com
Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
	Name	Dr Shahnavaaz Khijmatgar
	Designation	Lecturer
	Affiliation	A.B.Shetty Memorial Institute of Dental Sciences
	Address	Floor 6 Department of Oral Biology and Genomic Studies A.B. Shetty Memorial Institute of Dental Sciences, Nitte (Deemed to be University) Deralakatte-575018 Mangalore Karnataka India Dakshina Kannada KARNATAKA 575018 India
	Phone	8722186551
	Fax	
	Email	khijmatgar.s@gmail.com
Details Contact Person (Public Query)	Details Contact Person (Public Query)	
	Name	Dr Shahnavaaz Khijmatgar
	Designation	Lecturer
	Affiliation	A.B.Shetty Memorial Institute of Dental Sciences
	Address	Floor 6 Department of Oral Biology and Genomic Studies A.B. Shetty Memorial Institute of Dental Sciences Nitte (Deemed to be University) Deralakatte-575018 Mangalore Karnataka India Dakshina Kannada KARNATAKA

ATTESTED

page 1 / 8

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



	575018 India
Phone	8722186551
Fax	
Email	khijmatgar.s@gmail.com
Source of Monetary or Material Support	Source of Monetary or Material Support > Parkinsons Improvement Programme Registered Charity No:1137081 27,Newton Road Ashton, Preston PR2 1DY Email:andrew@brainhelp.info Contact: 00441772728820
Primary Sponsor	Primary Sponsor Details
	Name Parkinsons Improvement Programme
	Address 27, Newton Road Ashton Preston UK
	Type of Sponsor Other [Charity Organisation]
Details of Secondary Sponsor	Name Address
	NIL NIL
Countries of Recruitment	List of Countries
	India
Sites of Study	Name of Principal Investigator Name of Site Site Address Phone/Fax/Email
	Dr Shahnawaz Khijmatgar A.B.Shetty Memorial Institute of Dental Sciences Floor 6 Department of Oral Biology and Genomic Studies Nitte (Deemed to be University) A.B. Shetty Memorial Institute of Dental Sciences Deralakatte-575018 Mangalore Karnataka India Dakshina Kannada KARNATAKA 8722186551 khijmatgar.s@gmail.com
Details of Ethics Committee	Name of Committee Approval Status Date of Approval Is Independent Ethics Committee?
	Central Ethical Committee Approved 16/06/2018 No
	KAHERs VK Institute of Dental Sciences Belagavi No Objection Certificate 06/09/2018 No
	KAHERs VK Institute of Dental Sciences Belagavi Not Applicable No Date Specified No
Regulatory Clearance Status from DCGI	Status Date
	Not Applicable No Date Specified
Health Condition / Problems Studied	Health Type Condition
	Patients Trigeminal neuralgia
	Patients Trigeminal neuralgia
	Patients Trigeminal neuralgia
Intervention / Comparator Agent	Type Name Details
	Intervention Palmitoyl Ascorbate (PA) 2 g/twice daily (3 Months)
	Comparator Agent Cabamazepine 400mg/day (3 Months)
Inclusion Criteria	Inclusion Criteria

ATTESTED

Dr. V.A.Kothiwale
Registrar

page 2 / 8

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka



	Age From	20.00 Year(s)
	Age To	70.00 Year(s)
	Gender	Both
	Details	The TN cases included will be based according to the international headache classification: paroxymal unilateral pain triggered in the anatomical region of the trigeminal nerve without any sensory or motor focal symptoms in this region.
Exclusion Criteria	Exclusion Criteria	
	Details	Excluded from the study will be the patients with other neurological diseases, severe psychological diseases, serious chronic diseases, such as ischemic heart disease, pulmonary emphysema, and those with history of severe drug allergy. We also excluded patients treated with orally anaesthetics, allergy to vitamin C.
Method of Generating Random Sequence	Computer generated randomization	
Method of Concealment	On-site computer system	
Blinding/Masking	Outcome Assessor Blinded	
Primary Outcome	Outcome	
	Timepoints	
	1. Reduction in TN Symptoms 2. Clinicians Experience in Managing TN	30mins, 90mins, 24 hours
Secondary Outcome	Outcome	
	Timepoints	
	Patient reported outcome measures (PROM)	90 mins, 48 hrs, 1 week, one month, 3 months after post intervention
Target Sample Size	Total Sample Size=10 Sample Size from India=10 Final Enrollment numbers achieved (Total)=Applicable only for Completed/Terminated trials Final Enrollment numbers achieved (India)=Applicable only for Completed/Terminated trials	
Phase of Trial	Phase 2	
Date of First Enrollment (India)	01/08/2018	
Date of First Enrollment (Global)	No Date Specified	
Estimated Duration of Trial	Years=1 Months=6 Days=0	
Recruitment Status of Trial (Global)	Not Applicable	
Recruitment Status of Trial (India)	Open to Recruitment	
Publication Details	None	
Brief Summary	<p>The definition according to International Headache Society and Classification (HIS Classification ICHD-II) it is "A disorder characterized by recurrent unilateral brief electric shock-like pains, abrupt in onset and termination, limited to the distribution of one or more divisions of the trigeminal nerve and triggered by innocuous stimuli. It may develop without apparent cause or be a result of another diagnosed disorder. Additionally, there may be concomitant continuous pain of moderate intensity within the distribution(s) of the affected nerve division(s)". The reference number is Classical trigeminal neuralgia [G50.00] 13.1.1 G44.847.</p> <p>The prevalence of trigeminal neuralgia (TN) is between 0.03% and 0.3% worldwide (1). In</p>	

ATTESTED

Dr. V.A. Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



India, the prevalence and incidence rates are difficult to estimate due to few numbers of studies. But, the predominance of occurrence in rural areas to urban areas in India is estimated to be in the ratio of 1.7:1 (2). Females in the age range of 37-67 years old are most commonly affected. The Majority of patients suffer from pain on the unilateral side of the face affecting most commonly maxillary and mandibular branches of the trigeminal nerve (1). TN patients suffer from a lancinating, sharp shooting, radiating pain, with specific trigger pain zones, elicited upon chewing, cleaning teeth, speaking and applying cold water to face. There is strong empirical evidence for explanation of pathophysiology that TN is caused by vascular compression of the trigeminal nerve root in 95% of patients (3). But how vascular compression leads to trigeminal neuralgia is speculative. The possible explanation is that there is a combination of central demyelination of the nerve root entry zone and reinforcing electrical excitability. This demyelination then leads to an impairment of the nociceptive system (3).

TN is managed by single or combinational therapy. The most common therapy employed is the prescription of carbamazepine (Tegretol). Other therapies include administering gabapentin, alcohol injection, decompression, peripheral neurectomy and surgical procedures. But the effectiveness of these treatments was between 23% and 60% and these management strategies have a poor outcome and morbidity pain in trigeminal neuralgia recurs when the effect of the medication is subsided and elicited once touched to trigger zones.

Recently, a case review highlighted the benefits of palmitoyl ascorbate in combination with the in managing TN (3,11). **Palmitoyl Ascorbate (PA)** is a fat-soluble form of vitamin C. It is used as an antioxidant food additive (E number E304) (4-6). It is absorbed into the bloodstream after breaking down into ascorbic and palmitic acid (7). **Fish Oil** (Omega 3) is also used in managing migraines (8-9), owing to its platelet-stabilizing and antivasospastic actions. There is strong evidence that oral nutritional supplements have a good outcome in preventing and managing TN(10).

Aim 1: Palmitoyl ascorbate in managing trigeminal neuralgia.

1. To determine the effect of palmitoyl ascorbate on pain measurements in TN

We hypothesize that Palmitoyl ascorbate will help to reduce pain effectively in trigeminal neuralgia cases in comparison to gold standard treatment of care.

Aim 2: Cost-effectiveness of palmitoyl ascorbate in managing trigeminal neuralgia

1. To determine the cost-effectiveness of this treatment in managing TN

Patients have to be on long-term medication to overcome the trigeminal neuralgia. This adds cost burden and also financial mental stress. Palmitoyl ascorbate is used as food additives and is economical. We will try to investigate the following hypothesis:

Palmitoyl ascorbate is cost effective as compared to gold standard treatment in the same selected population.

In above context, we would like to outline innovative proposal for phase II cross-over double-blind clinical trial to investigate the effectiveness of palmitoyl ascorbate against a gold standard method of treating TN. Our investigative efforts will include the spectrum of trigeminal neuralgia cases that enables to test the effectiveness of innovative therapy and

ATTESTED

page 4 / 8

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka



also its cost-effectiveness in managing TN. Through this innovative way of management, we will hope to contribute to future TN management. Therefore, the purpose of this trial is to identify the effectiveness of palmitoyl ascorbate will help to manage TN.

Preliminary Data:

Feasibility: Nitte University is located in the coastal part of Karnataka state India. The university has dedicated dental hospital which attracts more than 500 patients a day for dental treatment.

Personal Experience and Department: The Department of Oral Biology conducts academic, clinical and research activities. It is mainly involved in conducting clinical studies and transferring research into clinical practice. I am currently working as a lecturer in this department. I am a qualified dentist with 8 years of clinical and research experience in dentistry. I am trained to conduct clinical trials and to understand the principles of good clinical practice (GCP).

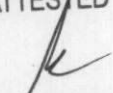
Expertise: The investigators involved in this particular trial are trained and specialised in managing orofacial pain. I have access to TN patients coming to the Department of Oral medicine. We have very good psychiatry centre where 10 cases of trigeminal neuralgia cases are seen every six months and diagnosed TN cases.

Alternative solution: Based on the sample size we calculated, it is feasible to conduct a trial at this center. If there are no sufficient cases met within the deadline, we will approach an orofacial pain center located in Mumbai India.

Previous Data: A recent clinical review by J C Carmichael et al (2016) tried to determine the benefits of palmitoyl ascorbate in managing TN (3). They found that, in first 90 mins, the pain started to recede. The patients reported with better outcomes in terms of pain and quality of life with PA as compared to the carbamazepine (12).

Experimental design Trial design: The designed study will be a single centre double-blind phase II randomized cross-over clinical trial in patients suffering from trigeminal neuralgia (N=10). The samples will be randomised in i.e, Carbamazepine and palmitoyl ascorbate with no carbamazepine (n=10). Any previous medication will be stopped before 24hr of the study to avoid any analgesic effect but will be resumed if pain recurs or failed to relieve the pain. After screening and informed consent, subjects will be evaluated at the clinical unit at Nitte University. A Gold Standard Carbamazepine dose (300 mg) will be administered. The samples will be crossed in other arms after minimum days of washout period (20 days). The dose of palmitoyl ascorbate (PA) 2 g/twice daily will be administered. The pain will be measured by using numerical rating scale (NRS; scale 0–10; 0 = no pain, 10 = worst pain) a tool for measuring severity of pain. In addition, McGill Pain Questionnaire and Brief Pain Questionnaire will also be used. The pain scores are recorded pre-intervention and post-intervention over a period of 30mins, 90mins and 48 hours. The patients are asked to mark the descriptive scale i.e. markedly better; moderately better, unchanged, or worse to grade the outcome. The primary endpoint will be to assess the change in numerical rating scale (NRS), pain scores at various time intervals and McGill Pain Questionnaire and Brief Pain Questionnaire following the initiation of therapy. The patients will be monitored for 3 months. The ethical approval will be sought from the local institutional ethical and scientific committee. **Baseline Information:** 1) Patient-reported outcomes measures (PROM's) questionnaire used for assessing the impact on oral health has on day to day life and quality of life. PROM's are scores of tools to measure outcomes that matters to the patient for example; cost, symptoms relieve, quality of care, improvement of oral health and general health. It is collected after the each intervention 2) Numerical rating scale (NRS) used for measurement of pain in adults before and after the intervention.

ATTESTED


Dr. V.A. Kothiwale
Registrar

page 5 / 8



Inclusion Criteria: The inclusion criteria for the selection of classic TN will be based on the definition of the International Headache Classification: paroxysmal unilateral pain triggered in the anatomical region of the trigeminal nerve, without any sensory or motor focal symptoms in this region. Patients will be eligible for inclusion if they had the most severe TN pain in the oral cavity or pain on toughing trigger zones, aged 20 years or older, are capable of proper assessment of the severity of pain and their condition, and had experienced multiple episodes of intraoral pain for at least 3 months with a pain intensity of more than 4 points on the numerical rating scale (NRS; scale 0–10; 0 = no pain, 10 = worst pain). The McGill Pain Questionnaire and Brief Pain Questionnaire will be used. **Exclusion Criteria:** Excluded from the study will be the patients with other neurological diseases, severe psychological diseases, serious chronic diseases, such as ischemic heart disease, pulmonary emphysema, and those with a history of severe drug allergy. We also excluded patients treated with oral anesthetics, allergy to vitamin C.

Statistical Analysis: A difference of at least 3 points of NRS score was considered clinically significant. For a power of 0.8 and significance level $\alpha=0.05$, an allocation ratio of 1, a sample size for each group is determined to be 10 patients. Therefore, the estimated total sample size will be 10 patients in this study, as these patients will be studied under phase II crossover design.

The assessment of pre-NRS score and post-NRS score difference will be calculated by using Wilcoxon signed-rank test. The difference in scores between the standard of care arm and palmitoyl ascorbate group will be assessed by Mann–Whitney *U*-test. To compare the differences between the two arms outcome, the outcome will be divided into three groups; responded excellent, moderately better outcome and the patients with no or worse outcomes will be calculated using chi-square and fishers exact t-test will be evaluated. The significance between the effective group (Pain-free), less pain and not-effective (No change or worse pain) will be done by using chi-square and fishers exact t-test.

Safety measurements and adverse events: Ascorbyl palmitate used as a chemical preservative in food for human consumption is generally recognized as safe when used in accordance with good manufacturing practice. 21 CFR 182.3149; U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of August 4, 2010: <http://www.ecfr.gov>

All patients will be monitored for general health and for serious adverse events related to the drug intervention. General and oral assessment including weight, blood pressure, pulse rate, skin, lymph node size, and thyroid palpation will be recorded. There will be no compensation for any adverse events or withdrawal from the study.

Challenges:

1. **Selection of TN cases with true positives:** Since the TN is rare disease and has chances of the wrong diagnosis, it makes a challenging task to have true positive cases that need to include in the trial. This will be overcome by using standard criteria of diagnosis as mentioned in the inclusion criteria.

2. **Followup:** There may be chances that the patient may fail to follow-up for 3 months.

Funding: The funding for the project was neutrally funded project. The project is funded by the Parkinsons Improvement Programme (PIP). There is no conflict of interest with the

ATTESTED

Dr. V.A.Kothiwale

Registrar

page 6 / 8



product used in the trial. The funding is not by any interested parties. Therefore, there is no conflict of interest to declare.

Clinical Trial Registry: The protocol will be the registered on clinical trial registry India.

References

1. De Toledo IP, Réus JC, Fernandes M, Porporatti AL, Peres MA, Takaschima A, Linhares MN, Guerra E, Canto GD. Prevalence of trigeminal neuralgia: a systematic review. *The Journal of the American Dental Association*. 2016 Jul 31; 147(7):570-6.
2. Yadav S, Mittal HC, Sachdeva A, Verma A, Dhupar V, Dhupar A. A retrospective study of 72 cases diagnosed with idiopathic trigeminal neuralgia in indian populace. *Journal of clinical and experimental dentistry*. 2015 Feb; 7(1):e40.
3. Zakrzewska JM, Linskey ME. Trigeminal neuralgia. *Bmj*. 2014 Feb 17;348(9):g474.
4. UK Food Standards Agency: "Current EU approved additives and their E Numbers".
5. US Food and Drug Administration: "Listing of Food Additives Status Part I". Archived from [the original](#) on 2012-01-17.
6. Health Canada: "Chemical Substance - Ascorbyl palmitate". Retrieved 2016-08-13. Australia New Zealand Food Standards Code "Standard 1.2.4 - Labelling of ingredients".
7. DeRitter E.; Cohen, N; Rubin, SH (1951). "Physiologic availability of dehydro-L-ascorbic acid and palmitoyl-L-ascorbic acid". *Science*. **113** (2944): 628–631.
8. Cleland LG, James MJ, Proudman SM. Fish oil: what the prescriber needs to know. *Arthritis research & therapy*. 2005 Dec 21;8(1):202.
9. McCarty MF. Magnesium taurate and fish oil for prevention of migraine. *Medical hypotheses*. 1996 Dec 31;47(6):461-6.
10. Stratton RJ, Elia M. A review of reviews: A new look at the evidence for oral nutritional supplements in clinical practice. *Clinical Nutrition Supplements*. 2007 Dec 31;2(1):5-23.
11. Carmichael A. PA and fish oil. *British dental journal*. 2012 Apr 27;112(8):356.

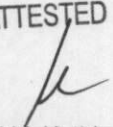
ATTESTED

Dr. V.A.Kothiwale
Registrar



12. Trigeminal Neuralgia | BrainHelp.info [Internet]. Brainhelp.info. 2017 [cited 14 September 2017]. Available from: <http://www.brainhelp.info/2016/01/01/trigeminal-neuralgia/>

ATTESTED


Dr. V.A. Kothiwale
Registrar

page 8 / 8

PARKINSON'S IMPROVEMENT PROGRAMME

Registered Charity no: 1137081

27, Newton Road,

Ashton,

PRESTON PR2 1DY

andrew@brainhelp.info

01772728820

28th May 2018

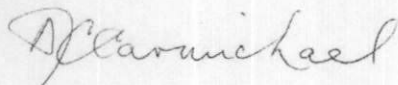
FAO Dr Shahnawaz Khijmatgar

Re grant no: 01/2018

This is to confirm:

1. The grant no: 01/2018 awarded to Dr Shahnawaz Khijmatgar (Chief Principal Investigator) for the project titled "Effectiveness of Palmitoyl Ascorbate (PA) in Managing trigeminal Neuralgia" A Randomised Cross-over Clinical Trial
2. The total of the grant to be £4000 sterling not including the provision of 2000 sachets of PA (aka E-304 as labelled) already received by Dr Khijmatgar as a gift from this charity.
3. We are delighted to be associated with this study and hope for relief of pain for all patients treated with PA in line with our experience in the UK and Ireland.

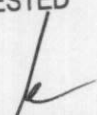
With our best wishes



Andrew Carmichael (Chair)

For Parkinson's Improvement Programme

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

To,

The Principal and Dean
A B Shetty Memorial Institute of Dental Sciences
Nitte (Deemed to be University)
Deralakatte-575018
Mangalore Karnataka India

Through,

Professor Chitta Chowdhury
Head
Department of Oral Biology and Genomic Studies
A B Shetty Memorial Institute of Dental Sciences
Nitte (Deemed to be University)
Deralakatte-575018
Mangalore Karnataka India

Sub: Application for the permission to include the site in Trial

Dear Sir,

Recently, we have registered clinical trial on "Effectiveness of Palmitoyl Ascorbate in Managing Trigeminal Neuralgia" A Cross over Trial. The registration number on Clinical trial registry is CTRI/2018/07/015021. The ethical approval from Central Ethical Committee has been taken. We would like to include external site into the clinical trial to meet the sample numbers in the clinical trial.

I would like to seek your permission to include K.L.E's Institute of Dental Sciences, Belgaum Karnataka and Adesh Dental College, Punjab as sites for collecting the samples.

Please may kindly request your permission to proceed.

Thanking you,

Yours Sincerely,

Dr Shahnawaz Khijmatgar

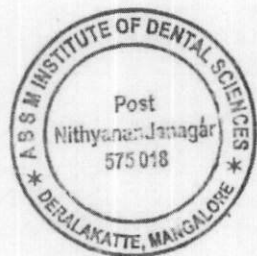
A.B. Shetty Memorial Institute of Dental Sciences,

Nitte (Deemed to be University)

Deralakatte-575018

Mangalore Karnataka India.

Date: 13/10/2018



ATTESTED

Pl Proceed.
Kindly oblige.
13/10/2018
Krishna
15/10/18.

Prof. (Dr.) Krishna Nayak U.S.

Principal & Dean

A.B. Shetty Memorial Institute of Dental Sciences

Mangalore

Dr. V.A.Kothiwale

Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Head and Neck CBCT Imaging Centre

First floor, Mujawar Arcade, Nehru Nagar, Belagavi - 590010

Tel.no.0831-4263479, Mob.no.9901884401,9902801989

Date: 2nd January 2020

This is to confirm:

The Project titled "A Retrospective Study on Incidental Findings of Maxillary Sinus Pathology by Cone Beam Computed Tomography: A cross sectional observational study" conducted at KLE VK Institute of Dental Sciences by Dr. Ansari Sulem Riyaz Ahmed (Chief Principal Investigator) under guidance of Dr. Shivayogi Charantimath will be sponsored by Head & Neck CBCT Imaging Centre, Belagavi.

50 CBCT scans required for the project costing Rs.2,25,000/- will be sponsored by this CBCT Imaging Centre, Belagavi.

We are delighted to be associated with this study and hope for success.

With our best wishes.



Dr. Vishwanath Pattar,

Head and Neck CBCT Imaging Centre

Belagavi

Dr. VISHWANATH PATTAR
Reg. No.27103-A B.D.S.,M.D.S.
Head & Neck CBCT Imaging Centre
First Floor, Mujawar Arcade, Nehru Nagar,
BELAGAVI- 590010

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

HC Haitech Medical Solutions Pvt. Ltd.

17-12-2019

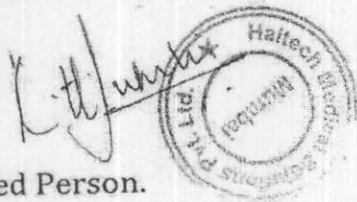
To whom so ever it may concern

Dear Sir/Madam,

We have given Dr. Minal Manolkar Ossix Volumax 25*30 – 4 qty (3+1) in
Rs 39,000/-

Invoice No - 99/19-20/1304 dated 17-12-2019 for the research purpose.

For Haitech Medical Solutions Pvt Ltd




Authorized Person.

Plot No26, Anandan Building, NS Road No -7, Juu Scheme, (POB No 28254) , Mumbai-49; India
Ph: +91-22-3297-4416; Fax: +91-26707566; Mobile: +91-98192-13933, email:info@haitech-group.com,

www.haitech-group.com

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

YASHODHA DENTAL CLINIC

No. 1154, 4th Main, 11th Cross, West of Chord Road, 2nd Stage, Mahalingapuram, Bangalore-560080

Dr. ULHAS AMASI

B.Sc., M.D.S., NDB (U.S.A.)
Professor, Dental Surgeon & Prosthodontist

KSDC Reg No: 1518-A

Phone: 23491581

Mob: 9611887313

Email: uamasi@gmail.com

Ref:

Date: 10th May, 2019

To
Dr. Hogepatil Sayali Pralhad
III year Postgraduate student
KLE VK Institute of Dental Sciences
Belagavi

Respected Madam,

We are happy to inform you that we have sponsored the material required for your research "To evaluate and compare the effect of nanoparticles of titanium dioxide, Silicon dioxide on tensile strength, tear strength, shore hardness of maxillofacial silicone elastomers: An In-vitro study from 'YASHODHA DENTAL CLINIC. We are eagerly waiting for the results whenever your study is completed.

YASHODHA DENTAL CLINIC grant to help out with your research proposal is worth the amount Rs 55000. We are always there to support your endeavors.

Thanking you.

With Regards

Ulhas Amasi

Dr. Ulhas N. Amasi

B.Sc., M.D.S., NDB

Dental Surgeon & Prosthodontist

Reg. No. 1518-A.

Dr. V.A. Kothiwale

Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

HP LaserJet Pro

M402/M403 Series



Optimize your day-to-day workflow with this reliable, high-performance black and white printer designed for work teams of 3 to 10 people. Share printing resources on a network¹ and take advantage of fast printing speeds. Be productive and save paper using automatic two-sided printing.² Embedded PIN printing helps keep confidential documents safe.³ The easy-to-use two-line control panel lets you start printing right away.



2-sided printing²



Auto On/Off Technology



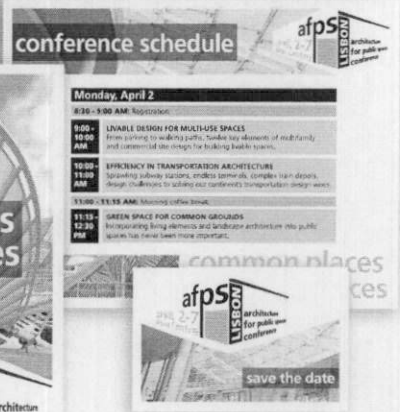
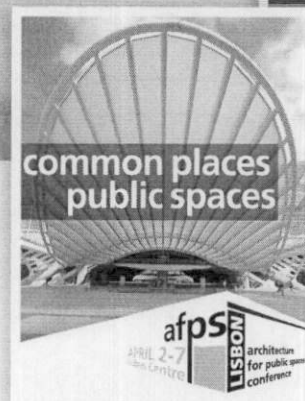
Wireless direct printing⁴



PIN printing³



NFC touch-to print⁵



¹ Available only on HP LaserJet Pro M402 and M403 n/dn/dw. ² Available only on HP LaserJet Pro M402 and M403 d/dn/dw. ³ Requires purchase and installation of separate USB drive and available only on HP LaserJet Pro M402 and M403 n/dn/dw. ⁴ Print without a router and available only on HP LaserJet Pro M402 and M403 dw. ⁵ Available only on HP LaserJet Pro M402 and M403 dw.

Original HP Toner Cartridges with
JETINTELLIGENCE
More. Pages, performance and protection.

www.hp.com
Dr. V.A. Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



polyhydron foundation

Plot No 4, R.S.No 680/2, Udyambag,
Belgaum - 590008
Phone: +91-8105207771
Email:polyhydronfoundation@gmail.com

Date: 06 -09 -19

To,

Dr Aarti Sethia,
Department of Orthodontics
KLE VK institute of Dental Sciences,
Belagavi - 590010

We are happy to inform you that, we have sponsored your research "Comparison of rate of tooth movement during individual canine retraction using flapless micro osteoperporation and piezocision assisted by low level laser therapy - a randomised control trial" by giving you the following material

S.No	Material Name	Total Nos	Total Amount
1	Implants (SK Surgicals ,Pune)	12 Nos	2400=00 INR

We are eagerly awaiting the results, whenever you're study is completed.

We are always there to support your endeavours.

Best regards,

For, Polyhydron Foundation

Authorised Signatory

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



polyhydron foundation

Plot No 4, R.S.No 680/2, Udyambag,
Belgaum - 590008
Phone: +91-8105207771
Email: polyhydronfoundation@gmail.com

Date: 07-10-19

To,

Dr Sumedh Deshpande,
Department of Orthodontics
KLE VK institute of Dental Sciences,
Belagavi - 590010

We are happy to inform you that, we have sponsored your research "Evaluation of Bicortical Vs Monocortical Miniscrews- a Comparative Clinical Study", by giving you the following material

S.No	Material Name	Total Nos	Total Amount
1	Implants (SK Surgicals ,Pune)	30 Nos	6000=00 INR

We are eagerly awaiting the results, whenever you're study is completed.

We are always there to support your endeavours.

Best regards,

For, Polyhydron Foundation

Authorised Signatory

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



hyloc hydrotechnic pvt. ltd.

An ISO 9001, ISO 14001 & ISO 45001 Certified Company
DNV Certified Type Approved Supplier for Marine
ISO/TS 22163 (BRS) Certified Company
CIN - U85110KA1991PTC011924

88, Machhe Industrial Estate, Machhe, Belgaum 500014 - INDIA
Tel : +91 831 241 2777 • E-mail: sales@hyloc.co.in • Web: www.hyloc.co.in

Date: 10-12-19

To,

Dr Ann Benzy,
Department of Orthodontics
KLE VK Institute of Dental Sciences,
Belagavi - 590010

We are happy to inform you that, we have sponsored your research "Effects of a fluoride containing casein phosphopeptide-amorphous calcium phosphate complex on shear bond strength and adhesive remnant index of teeth eroded by different beverages: An In-Vitro Study", by giving you the following material

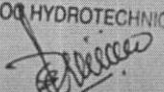
S.No	Material Name	Total Nos	Total Amount
1	3M Transbond XT (3M Unitek ,USA)	2 Kits	9776=00 INR

We are eagerly awaiting the results, whenever you're study is completed.

We are always there to support your endeavours.

Best regards,


For HYLOC HYDROTECHNIC PVT. LTD.


Authorised Signatory

Branch Office:

39/1, West Park Road, 13th Cross, Malleswaram, BANGALORE- 560 003 - INDIA Tel: +91 80 2334 4992

ATTESTED


Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010, Karnataka

MEMORANDUM OF UNDERSTANDING

BETWEEN

**RASAYU CANCER CLINIC, B-1, AMRUT KUMBHA, LAKSHMI
PARK SOCIETY, NAVIPETH PUNE**

AND

**KLE UNIVERSITY'S
SHRI B.M. KANKANAWADI AYURVEDA MAHAVIDYALAYA
SHAHAPUR, BELAGAVI, KARNATAKA.**

For

**Establishment of Cancer OPD at KLE Ayurveda Hospital
And Research Activities**

MEMORANDUM OF UNDERSTANDING

ATTESTED



**Dr. V.A. Kothiwale
Registrar**

**KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka**

This Memorandum of Understanding ("MoU") dated this 11th day of July 2017

by and between:

KLEU's Shri B M Kankanawadi Ayurveda Mahavidyalaya & KLE Ayurveda hospital, Belagavi is a leading institute in offering super speciality quality health care in field of Ayurveda in India., having its office at Nathpai circle, Shahapur, Belagavi (here in after referred to as '**KLE Ayurveda hospital**') which expression shall unless it be repugnant to the context or meaning there of shall be deemed to mean and include its successors and permitted assigns) of the **One Part**

AND

Rasayu cancer clinic having its place of business at B-1 Amrut kumbha, Lakshmipark society, Navipeth Pune .(here in after referred to as '**RCC**') which expression shall unless it be repugnant to the context or meaning thereof shall be deemed to mean and include its successors and permitted assigns) of the **Other Part**

KLE Ayurveda hospital and RCC shall be individually here in after referred to as '**Party**' and collectively as '**Parties**'.

Where as

A. 'KLE Ayurveda hospital' is a Teaching Ayurveda hospital providing wide range of super-specialty healthcare facilities to Patients.

B. 'RCC' is engaged in specialised Ayurveda based cancer therapies to cancer patients and cancer survivors. These facilities include but are not limited to offering Ayurveda consultation, preparing Ayurveda medicines and dietary supplements for these patients, Panchakarma therapies, offering diet, yoga and psychology consultation.

C. The parties are interested in exploring possible opportunities of establishing a mutually cooperative and beneficial relationship, including the carrying out of Projects relevant to their respective capabilities in India.

D. KLE Ayurveda hospital and RCC, confirm and understand that this MOU is not intended to provide and set out any contractual terms binding or otherwise

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

governing the terms and conditions or the manner of conduct of any Projects and that may necessarily require the Parties to:

- share relevant information on a confidential basis with the aim and objective of identifying their requirements, needs and capabilities;
- establish a working relationship between themselves (which is targeted to the parties' specific needs);
- establish Projects which may be of mutual benefits and interest;
- Determine the details of Projects, their scope and purview, Project work plan, funding of the Project, their rights, duties and obligations in relation to the Project and its outcome.

For the purposes of each Project, the Parties shall enter into separate Agreements.

For the purposes of this MOU, "**Project**" shall mean a collaboration relating to Establishing specialty cancer OPD for development of Standard Treatment Protocol's in Cancer Management through specialized Ayurveda consultation and therapies for cancer patient at the premise of KLE Ayurveda hospital, Shahapur, Belagavi.


1. SCOPE OF THE MOU

1.1 The Parties will co-operate to:

- (a) Establish facilities for offering specialized Ayurveda consultation to cancer patients which includes offering Ayurveda, yoga, diet and psychological consultation; preparing personalized medicines and dietary supplements for cancer Patients.
- (b) Conduct cancer awareness drives, campaigns and lectures for common public and patients.
- (c) Conducting various oncology based training programs for Medical students and professionals.
- (d) Conduct an annual review of current and future Projects approximately one (1) week prior to the anniversary of the execution of this MOU.

1.2 Subject to the terms and conditions of any Collaboration Agreement agreed to and executed, each Party will have the right, in any field related to the Project or otherwise, to:

ATTESTED


Dr. V.A. Kothiwale
Registrar


KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- (a) conduct business or research independently, whether or not with third parties;
- (b) continue existing commitments, or make new ones;
- (c) Exploit or otherwise take advantage of its intellectual property.

2. COLLABORATION AGREEMENT

- 2.1 The Parties acknowledge and confirm their intention to negotiate and settle the terms and conditions of a Collaboration Agreement in respect of each Project.
- 2.2 The parties agree that the ownership of the intellectual property rights arising out collaboration will be jointly shared between RCC & KLE. Publications, Authorship rights of involved Doctors/Consultants will be protected. Freedom for conducting individual OPD and Research & Developing new protocols on their own.
- 2.3 Each Collaboration Agreement will include provisions relating amongst other things to:
 - (a) A Project plan pursuant to which the Project will be carried out which will include information pertaining to technical objectives, statement of work, deliverables, schedule, decision gates, resource requirements and costs;
 - (b) Funding arrangements for the Project;
 - (c) Holding by the Parties of periodic Project review meetings to assess the management and the progress of the Project and the status of any expenditure;
 - (d) Exploitation of Intellectual property and rights arising from the same including their protection, enforcement and commercialization.
 - (e) Commercial arrangements between the KLE Ayurveda hospital and RCC.
- 2.4 The Parties agree, acknowledge and confirm that for any agreement to be binding on them, it must be in writing and shall be executed by a duly authorized representative of each of the KLE Ayurveda hospital and RCC.


ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- 2.5 KLE Ayurveda hospital will provide basic infrastructure/facilities required for offering patient care which include consultation, treatment procedure, inpatient hospitalisation, investigations, dispensing medicines and dietary supplements and collecting treatment charges. KLE will establish speciality Cancer OPD for Ayurveda management. KLE will provide OPD facility in it to RCC for their expert consultancy as per mutual understanding and permit to prescribe the proprietary/ Research formulations of RCC and protect the confidentiality of RCC.
- 2.6 KLE Ayurveda hospital will make necessary arrangements for offering medical care and consultation by qualified Ayurveda physician trained in RCC Treatment protocol, to patients approaching for treatment in the collaborative RCC and KLE cancer OPD. Consultant from KLEU in Speciality Cancer OPD will have freedom to plan for different protocols and medications based on the clinical case otherwise RCC standard protocol will be used.
- 2.7 KLE Ayurveda hospital will make necessary arrangements to avail expert medical opinion or to refer the patient to appropriate medical facilities in case of any emergencies.
- 2.8 KLE Ayurveda hospital will make arrangements to procure medicines manufactured by Ayurved Rasayani, as required for the collaborative RCC and KLE cancer OPD.
- 2.9 RCC will offer appropriate training in Ayurveda oncology to doctors deputed by KLE Ayurveda hospital. The number of doctors at a given point of time will not exceed two (2).
- 2.9 RCC will periodically depute a trained qualified Ayurveda physician so as to provide direct consultation to patients approaching the collaborative RCC and KLE cancer OPD. This doctor will visit KLE Ayurveda hospital at least once in a month. The travel expenses for this visit will be totally beared by RCC.
- 2.10 KLE Ayurveda hospital will be conducting regular awareness activities about the collaborative RCC and KLE cancer OPD. These activities includes Awareness programs, lectures, pamphlets, banners, newspaper articles and Radio broadcast. KLE Ayurveda hospital will bear all the expenses of such activities.

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

2.11 If required for the betterment of patient, RCC will make necessary arrangement to provide online/skype consultation to these patients in Belgaum.

2.12 The responsibility for providing best possible treatment for patient and ensuring his wellbeing lies entirely with the treating physician.

3. REPRESENTATIVE

3.1 For the term and purposes of this MOU, each party shall appoint a designated representative ("the **Representative**").

3.2 The Representative of the appointing Party will be responsible for:

- a) managing, overseeing or coordinating that Party's relationship with the other Party;
- b) identifying any commercial issues that arise between the Parties and refer them to the **Competent Authority** within the Representative's organization;
- c) discussing any issues arising out of this MOU or a Collaboration Agreement with the Representative of the other party; and
- d) Co-coordinating the exchange of information between the Parties.

3.3 The Representatives designated at the time of signing this MOU by the parties are:

(a) for KLE Ayurveda hospital:

Name: Dr B S Prasad.

Designation: Medical Director

Email: kleayurvedahospital@gmail.com

Mob. 9448569289.

(b) for RCC

Name: Dr. Avinash Kadam

Designation: Administrator.

Email: avinashk@rbpl.co.in

Mob. 9970259583

4. CONFIDENTIAL INFORMATION

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- 4.1 Definition:** As used herein **Confidential Information** shall mean and include all information and data which has been provided/disclosed/shared by RCC to KLE Ayurveda hospital prior and post the execution of this MOU and/or the Collaboration Agreement either written or oral or in any other form or manner of communication or which has been acquired or will be acquired by either Party such as designs, drawings, specifications, technical information, documents and know-how, designs, manufacturing processes, ideas, data, financial information and other technologies, whether patentable, copyrightable or susceptible to any other form of protection. The terms and existence of this MOU, the fact that Confidential Information has been shared and/or made available, that discussions or negotiations pertaining to the technology are taking place between the Parties shall also be considered Confidential Information for the purposes of this MOU.
- 4.2 Purpose:** The Parties shall use the Confidential Information strictly and solely for the purposes the Confidential Information is provided under this MOU and none other.
- 4.3 Ownership:** The Parties hereby understand, acknowledge, and confirm that the Confidential Information is a valuable trade secret owned by each Party and which retains all right, title, and interest in and unto the same. Neither Party shall have any right, title and interest in the Confidential Information of the other Party. By virtue of either Party disclosing the Confidential Information, no license to such Confidential information or any Intellectual Property rights owned by that Party is or are granted to the other Party. Neither Party shall directly or indirectly, through its directors, employees or agents, at any point of time, do any acts, things or deeds that may prejudicially affect the proprietary right, title and interests of either Party in and unto the Confidential Information.
- 4.4 No Warranties:** At no point of time shall either Party be responsible for any loss or damages which may be suffered by the Party receiving the Confidential Information or for that matter by its customers or any third parties on account of or arising from the use of the Confidential Information. Neither Party makes any representations or warranties of any kind, whether expressed or implied as to the accuracy or completeness of the Confidential Information.

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- 4.5 Use of Confidential Information:** Each Party may use the Confidential Information for the purposes stated in Clause 4.2 above only. Each Party recognizes that this MOU imposes an affirmative duty on the other Party to hold such information in confidence and to protect it from dissemination to and use by any and all unauthorized parties. In the absence of any prior written consent neither Party shall copy, reproduce or disclose the Confidential Information to any third party in any manner whatsoever.
- 4.6 Further Responsibility:** The Parties agree and undertake to use the same degree of care to protect the confidentiality of the Confidential Information as it would exercise to protect its own trade secrets and information but in no case less than a reasonable degree of care. Each Party may grant access to the Confidential Information to its directors, officers, employees, advisors and consultants (“**related parties**”) who have a clear need to know, for purposes of this MOU and shall advise such related parties of the existence and terms of this MOU and of its obligations of confidentiality herein. MoU shall lead to standard clinical protocols in management of cancer which will be asset of both the institutions. Each organisation will have the right to continuc or utilize the products, protocols developed during the collaboration even after termination of MoU.
- 4.7 Return of Confidential Information** Promptly following the request of either Party the receiving Party will return to the disclosing Party or certify in writing to the disclosing Party as to the destruction of (without retaining any copy in any form or manner) all Confidential Information including copies and extracts thereof as may have been or will be furnished as by the disclosing Party to the receiving Party. But the Hospital records/ data and pharmacy data will be archived to oblige hospital/ pharmacy regulations.
- 4.8 Remedies:** The Parties acknowledge, understand and confirm that the disclosing Party is the proprietor of the Confidential Information and that any unauthorized disclosure, misappropriation or unauthorized use of such Confidential Information by the receiving Party in any manner whatsoever will cause serious irreparable loss and harm to disclosing Party. The receiving Party expressly agrees that the disclosing Party shall be entitled to seek injunctive and other

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

equitable relief against it to prevent the breach or further breaches of any of its confidentiality obligations under this MOU and which it will not dispute by challenging the jurisdiction of the competent Courts where injunctive or equitable relief is being sought at by the disclosing Party.

5. TERMINATION AND AMENDMENT

The term of this MOU is a period of one (1) year from the date of execution. The MOU will be automatically renewed for a further period of one (1) year unless one Party notifies the other Party in writing 30 days in advance that they do not wish to renew the MOU at the completion of the annual review of current and future projects.

- 5.1 This MOU may be terminated by mutual consent of the parties. Either party may terminate this MOU upon one (1) month written notice to the other.
- 5.2 A Collaboration Agreement made pursuant to clause 2 of this MOU shall survive termination or expiration of this MOU.
- 5.3 This MOU may be amended only by an agreement in writing between the Parties and not otherwise.

6. GENERAL

- 6.1 KLE Ayurveda hospital and RCC agree that each of them is free to undertake R&D and business projects on their own or in conjunction with third party, and that the Parties will co-operate only in circumstances where each of them agrees if co-operation is for their mutual benefit and each is satisfied that the specific provisions covering their co-operation are appropriate and will not adversely or prejudicially affect their interests.
 - 6.2 With the exception of Clause 4 herein, this MOU is not binding and the Parties do not intend that it or any part of it be binding. It serves only as a record of the understanding between the Parties' intentions pending possible execution of a Collaboration Agreement as contemplated by Clause 2 herein.
 - 6.3 Nothing in this MOU will oblige or cast any obligation upon either Party to enter into a Collaboration Agreement with the other Party or to conduct any Project.
7. This MOU constitutes the entire understanding between the Parties regarding the subject matters contained herein. Any prior agreements,

ATTESTED




Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

commitments or negotiations concerning the subject matters herein are superseded.

8. The headings contained herein are for the purposes of convenience only and are not intended to define or limit the contents of the provisions contained therein.
9. If one or more provisions of this MOU are held to be illegal or unenforceable, such provisions will be limited or excluded to the minimum extent required so that this MOU will otherwise remain enforceable in accordance with the remaining terms.
10. The rights of the Parties hereto shall not be prejudiced or restricted by any indulgence or forbearance extended to the other party and no waiver by the parties hereto of any breach of the other party of any of the terms hereunder shall operate as a waiver in respect of any subsequent breach. No variation of this MOU shall be effective unless it is in writing and duly signed by both parties.
11. **FORCE MAJEURE:** Neither party shall be liable for any delay in or failure of discharging respective obligations under this MOU caused by occurrence beyond the control of KLE Ayurveda hospital or RCC as the case may be, including but not limited to fires, floods, explosions, power shortage, failure/breakdown of UPS/DG set/computer, acts of GOD, hostility, acts of public enemy wars, insurrections, riots, strikes, lockouts, sabotage. Either parties shall promptly but not later than 10 days of the commencement there of notify the other in writing of such contingency and prove that such is beyond the control and affects the implementation of this MOU adversely and materially. If such contingency continues beyond 30 days both the parties, agree to discuss and agree upon an equitable solution.
12. **ARBITRATION:** For any interpretation of clauses in this MOU or in case of any dispute during implementation, such matter will be jointly discussed by representative of KLE Ayurveda hospital and RCC. In case of disagreement, the matter would be referred to the International Centre for Alternative Dispute Resolution (ICADR, an autonomous organization

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

working under the aegis of the Ministry of Law and Justice, Govt. of India)
New Delhi-110 070. ICADR decision would be binding on both parties.

IN WITNESS, WHERE OF, the parties have executed this MOU as of the
date first above written

SIGNED AND DELIVERED BY

SIGNED AND DELIVERED BY


Registrar KLE University

RCC

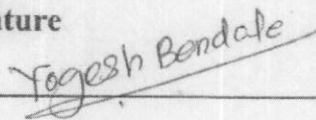
through its Authorized Signatory

through its Authorized Signatory

Signature



Signature



Name of person signing MOU

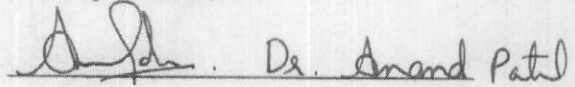
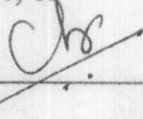
Dr Yogesh Bendale

Designation

Chairman and MD (RBPL)

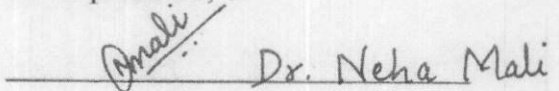
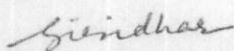
in the presence, of

in the presence, of



in the presence, of

in the presence, of



(Dr. Vedantam Giridhar)

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



INSTITUTIONAL ETHICS COMMITTEE

KLE University's Shri B. M. Kankanawadi Ayurved Mahavidyalaya &
KLE Ayurveda Hospital, Shahapur, Belgaum

COMMUNICATION OF DECISION OF THE INSTITUTIONAL ETHICS COMMITTEE (IEC)

Protocol No: BMK/17/BSP /01

Protocol Title: "A prospective, open labelled, pilot, group study to evaluate efficacy, safety and bio availability of oral Arsenic Trioxide prepared by Ayurvedic method (Somal) in patients of solid tumours "			
Principal Investigators/Co-investigators: Dr. B. S Prasad, Dr Santosh Patil			
Name & Address of Institution: KLE University's Shri B. M. Kankanawadi Ayurveda Mahavidyalaya & KLE Ayurveda Hospital, Shahapur, Belgaum			
<input type="checkbox"/> New Review	<input checked="" type="checkbox"/> Revised Review	<input type="checkbox"/> Expedited Review	
Date of Review (DD/MM/YY): 5.4.2018			
Date of previous review, if revised application: 21.07.2017			
Name of the Reviewers who attended the meeting: Dr. Supriya Bhalerao, Dr. Rajashree Kamat, Dr. Pradeep Shinde, Dr Aziz Arbar, Mrs. Arati S Balikai, Mrs. Sarita S. Shirodkar, Dr. Basavaraj R Tubaki,			
Decision of the the Ethics Committee:			
Recommended	<input type="checkbox"/>	Recommended with suggestions	<input checked="" type="checkbox"/>
Revision	<input type="checkbox"/>	Rejected	<input type="checkbox"/>

ATTESTED

↓

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka


Suggestions/ Clarifications / Reasons/ Remarks:

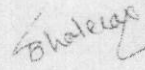
1. Minor revisions to the protocol have been approved by IEC

Recommended for a period of :One Year

Please note *


- Inform EC immediately in case of any Adverse Events and Serious Adverse Events
- Inform EC in case of any change of study procedure, site and investigator
- This permission is only for period mentioned above
- Annual report to be submitted to EC
- The study has to be conducted as per approved protocol. Any amendments in the Protocol/ICF/CRF has to be approved from IEC before implementation
- Members of EC have right to monitor the trial with prior intimation
- The status of the study (Completed/Ongoing/Terminated) should be reported annually
- It is mandatory to obtain renewal of approval and apply for the same at the end of 11 months
- The renewal of approval is subjected to submission of annual report. If the above application is not received within specified period then the permission to renew the project may lapse


Dr. Basavaraj R Tubaki
(Member Secretary)


Dr. Supriya Bhalerao
(Chairperson)

Page 2 of 2

Page 2 of 2


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

SHRI BM KANKANAWADI AYURVED MAHAVIDYALAYA

Post Graduate Studies & Research Centre

(Approved by Central Council of Indian Medicine, New Delhi & M/o AYUSH, GoI)

A Constituent Unit of

KLE ACADEMY OF HIGHER EDUCATION & RESEARCH

(DEEMED-TO-BE-UNIVERSITY)

(Re-Accredited 'A' Grade by NAAC (2nd Cycle) || Placed under Category 'A' by MHRD GoI)

First AYUSH Institution having NAAC & NABH Accreditation



IMPARTING AYURVEDA EDUCATION SINCE 1933

Certificate

Our institute had made an agreement with sponsor Timer for conducting clinical trial on title "A Clinical Evaluation of Efficacy and Safety of AyuAsmo Capsules in Patients Suffering From Bronchial Asthma"

Name of the Investigator: Dr. Kiran M

Details of released Grant in rupees year wise

Details	2018-2019	2019-2020
A Clinical Evaluation of Efficacy and Safety of AyuAsmo Capsules in Patients Suffering From Bronchial Asthma	Rs.100000/-	Rs.145530/-

This is as per institutional audited financial reports

ATTESTED

k
Dr. V.A.Kothiwale
Registrar

ch
PRINCIPAL

Shri B.M. Kankanwadi
Ayurved Mahavidyalaya
A Constituent Unit of KAHER
Shahapur, BELAGAVI-03.

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Shahapur, Belagavi – 590 003, Karnataka, India

Phone: +91 831 2486286 Fax: +91 831 2424157

Website: www.kleayurworld.edu.in Email: bmkprincipal.kaher@kleayurworld.edu.in

Clinical Study Report

Version: 1.0, Dated: 22nd Jul 2019

“A Clinical Evaluation of Efficacy and Safety of AyuAsmo Capsules in Patients Suffering From Bronchial Asthma.”

Protocol No. AYUASMO/BA/WELX/2017, Version 1.0, 20th Nov 2017

CTRI Registration Number: CTRI/2018/04/012980,
Registered on 3rd Apr 2018.


Sponsor



Welex Laboratories Pvt Ltd

1002, Marathon Innova Nextgen,
Off Ganpatrao kadam marg, Lower Parel,
Mumbai -400013

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Table of Content

Sr. No	Topics	Page No.
1.	Statement of Compliance	5
2.	Executive Summary	6
2.1	Protocol Title	6
2.2	Protocol ID Version and Date	6
2.3	Study Design	6
2.4	Study Duration	6
2.5	Total no of visits	6
2.6	Sample size	6
2.7	Investigational product and Dosage	6
2.8	Study Objectives	6
2.9	Tools used for evaluation	7
2.10	Inclusion Criteria	7
2.11	Exclusion Criteria	8
2.12	Methodology	8
2.13	Statistical Methods of Assessment	11
2.14	Result	11
2.15	Conclusion	16
3.	Ethics	18
3.1	Ethics Committee Approval	18
3.2	Ethical Conduct of the Study	18
3.3	Subject Information and Consent	18
4	CTRI Registration	19
5	Study Events	19
6	Study Administrative Structure and Investigators	20
7	Introduction of the Study	21
8	Study Objectives and Purpose	23
8.1	Primary Objectives	23


ATTESTED


 Dr. V.A. Kothiwale
 Registrar

KLE Academy of Higher Education and Research,
 (Deemed-to-be-University u/s 3 of the UGC Act, 1956)
 Belagavi-590 010, Karnataka

8.2	Secondary Objectives	23
9	Test product details	24
9.1	Test Products	24
9.2	Ingredients of the test products	24
9.3	Dosage and administration	24
10	Study Methodology	25
10.1	Study Design and duration	25
10.2	Study End Points (Primary and Secondary)	25
10.3	Inclusion Criteria	26
10.4	Exclusion Criteria	26
11	Assessment Parameters	27
11.1	Assessment of Efficacy parameters	27
11.2	Assessment of Safety parameters	29
12	Study Visit Details	32
12.1	Study population and pre study screening evaluation	32
12.2	Procedures performed during the study period	33
13	Study Population	36
14.	Observations and results	37
15	Conclusion	53
16.	References	54
17.	Annexure	55

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE/BMK/MRC/454/18



INSTITUTIONAL ETHICS COMMITTEE
KAHER's Shri B. M. Kankanawadi Ayurveda Mahavidyalaya &
KLE Ayurveda Hospital, Shahapur, Belagavi

COMMUNICATION OF DECISION OF THE INSTITUTIONAL ETHICS COMMITTEE (IEC)

Protocol No: BMK/17/ASMO/KM/1			
Protocol Title: "A Clinical Evaluation of Efficacy and Safety of AyuAsmo Capsules in Patients Suffering From Bronchial Asthma"			
Principal Investigators/Co-investigators: Dr. Kiran Mutnali			
Name & Address of Institution: KAHER's Shri B. M. Kankanawadi Ayurveda Mahavidyalaya & KLE Ayurveda Hospital, Shahapur, Belagavi			
<input checked="" type="checkbox"/> New Review	<input type="checkbox"/> Revised Review	<input type="checkbox"/> Expedited Review	
Date of Review (DD/MM/YY): 20.03.2018			
Date of previous review, if revised application:			
Name of the Reviewers who attended the meeting: Dr. SupriyaBhalerao, Dr. RajashreeKamat, Dr. PradeepShinde, Mr.Sudheer Kulkarni, Mrs. Arati S Balikai, Mrs. Sarita S. Shirodkar, Dr. Basavaraj R Tubaki, Dr.Aziz, Dr.Giridhar V, Col.Ishwar Hurkadli			
Decision of the the Ethics Committee:			
Recommended	<input checked="" type="checkbox"/>	Recommended with suggestions	<input type="checkbox"/>
Revision	<input type="checkbox"/>	Rejected	<input type="checkbox"/>

Received.
[Signature]
Dr. Kiran Mutnali

ATTESTED

Page 1 of 2

[Signature]
Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

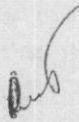
Suggestions/ Clarifications / Reasons/ Remarks:

1. Subjects to FDA license submission

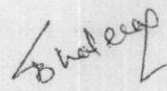
Recommended for a period of :One Year

Please note *

- Inform EC immediately in case of any Adverse Events and Serious Adverse Events
- Inform EC in case of any change of study procedure, site and investigator
- This permission is only for period mentioned above
- Annual report to be submitted to EC
- The study has to be conducted as per approved protocol. Any amendments in the Protocol/ICF/CRF has to be approved from IEC before implementation
- Members of EC have right to monitor the trial with prior intimation
- The status of the study (Completed/Ongoing/Terminated) should be reported annually
- It is mandatory to obtain renewal of approval and apply for the same at the end of 11 months
- The renewal of approval is subjected to submission of annual report. If the above application is not received within specified period then the permission to renew the project may lapse




Dr. Basavaraj R Tubaki
(Member Secretary)



Dr. Supriya Bhalerao
(Chairperson)

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

KLE/BMK/MRC/454/18



INSTITUTIONAL ETHICS COMMITTEE
KAHER's Shri B. M. Kankanawadi Ayurveda Mahavidyalaya &
KLE Ayurveda Hospital, Shahapur, Belagavi

COMMUNICATION OF DECISION OF THE INSTITUTIONAL ETHICS COMMITTEE (IEC)

Protocol No: BMK/17/ASMO/KM/1			
Protocol Title: "A Clinical Evaluation of Efficacy and Safety of AyuAsmo Capsules in Patients Suffering From Bronchial Asthma"			
Principal Investigators/Co-investigators: Dr. Kiran Mutnali			
Name & Address of Institution: KAHER's Shri B. M. Kankanawadi Ayurveda Mahavidyalaya & KLE Ayurveda Hospital, Shahapur, Belagavi			
<input checked="" type="checkbox"/> New Review	<input type="checkbox"/> Revised Review	<input type="checkbox"/> Expedited Review	
Date of Review (DD/MM/YY): 20.03.2018			
Date of previous review, if revised application:			
Name of the Reviewers who attended the meeting: Dr. SupriyaBhalerao, Dr. RajashreeKamat, Dr. PradeepShinde, Mr.Sudheer Kulkarni, Mrs. Arati S Balikai, Mrs. Sarita S. Shirodkar, Dr. Basavaraj R Tubaki, Dr.Aziz, Dr.Giridhar V, Col.Ishwar Hurkadli			
Decision of the the Ethics Committee:			
Recommended	<input checked="" type="checkbox"/>	Recommended with suggestions	<input type="checkbox"/>
Revision	<input type="checkbox"/>	Rejected	<input type="checkbox"/>

Received.

Dr. Kiran Mutnali

ATTESTED

Dr. V.A. Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

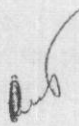
Suggestions/ Clarifications / Reasons/ Remarks:

1. Subjects to FDA license submission

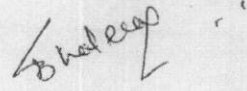
Recommended for a period of :One Year

Please note *

- Inform EC immediately in case of any Adverse Events and Serious Adverse Events
- Inform EC in case of any change of study procedure, site and investigator
- This permission is only for period mentioned above
- Annual report to be submitted to EC
- The study has to be conducted as per approved protocol. Any amendments in the Protocol/ICF/CRF has to be approved from IEC before implementation
- Members of EC have right to monitor the trial with prior intimation
- The status of the study (Completed/Ongoing/Terminated) should be reported annually
- It is mandatory to obtain renewal of approval and apply for the same at the end of 11 months
- The renewal of approval is subjected to submission of annual report. If the above application is not received within specified period then the permission to renew the project may lapse



Dr. Basavaraj R Tubaki
(Member Secretary)



Dr. Supriya Bhalerao
(Chairperson)

ATTESTED

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

MEMORANDUM OF UNDERSTANDING

BETWEEN

**RASAYU CANCER CLINIC, B-1, AMRUT KUMBHA, LAKSHMI
PARK SOCIETY, NAVIPETH PUNE**


AND

**KLE UNIVERSITY'S
SHRI B.M. KANKANAWADI AYURVEDA MAHAVIDYALAYA
SHAHAPUR, BELAGAVI, KARNATAKA.**

**For
Establishment of Cancer OPD at KLE Ayurveda Hospital
And Research Activities**

MEMORANDUM OF UNDERSTANDING

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

This Memorandum of Understanding ("MoU") dated this 11th day of July 2017

by and between:

KLEU's Shri B M Kankanawadi Ayurveda Mahavidyalaya & KLE Ayurveda hospital, Belagavi is a leading institute in offering super speciality quality health care in field of Ayurveda in India., having its office at Nathpai circle, Shahapur, Belagavi (here in after referred to as '**KLE Ayurveda hospital**') which expression shall unless it be repugnant to the context or meaning there of shall be deemed to mean and include its successors and permitted assigns) of the **One Part**

AND

Rasayu cancer clinic having its place of business at B-1 Amrut kumbha, Lakshmipark society, Navipeth Pune (here in after referred to as '**RCC**') which expression shall unless it be repugnant to the context or meaning thereof shall be deemed to mean and include its successors and permitted assigns) of the **Other Part**

KLE Ayurveda hospital and RCC shall be individually here in after referred to as '**Party**' and collectively as '**Parties**'.

Where as


A. 'KLE Ayurveda hospital' is a Teaching Ayurveda hospital providing wide range of super-specialty healthcare facilities to Patients.

B. 'RCC' is engaged in specialised Ayurveda based cancer therapies to cancer patients and cancer survivors. These facilities include but are not limited to offering Ayurveda consultation, preparing Ayurveda medicines and dietary supplements for these patients, Panchakarma therapies, offering diet, yoga and psychology consultation.

C. The parties are interested in exploring possible opportunities of establishing a mutually cooperative and beneficial relationship, including the carrying out of Projects relevant to their respective capabilities in India.

D. KLE Ayurveda hospital and RCC, confirm and understand that this MOU is not intended to provide and set out any contractual terms binding or otherwise

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

governing the terms and conditions or the manner of conduct of any Projects and that may necessarily require the Parties to:

- share relevant information on a confidential basis with the aim and objective of identifying their requirements, needs and capabilities;
- establish a working relationship between themselves (which is targeted to the parties' specific needs);
- establish Projects which may be of mutual benefits and interest;
- Determine the details of Projects, their scope and purview, Project work plan, funding of the Project, their rights, duties and obligations in relation to the Project and its outcome.

For the purposes of each Project, the Parties shall enter into separate Agreements.

For the purposes of this MOU, "**Project**" shall mean a collaboration relating to Establishing specialty cancer OPD for development of Standard Treatment Protocol's in Cancer Management through specialized Ayurveda consultation and therapies for cancer patient at the premise of KLE Ayurveda hospital, Shahapur, Belagavi.


1. SCOPE OF THE MOU

1.1 The Parties will co-operate to:

- (a) Establish facilities for offering specialized Ayurveda consultation to cancer patients which includes offering Ayurveda, yoga, diet and psychological consultation; preparing personalized medicines and dietary supplements for cancer Patients.
- (b) Conduct cancer awareness drives, campaigns and lectures for common public and patients.
- (c) Conducting various oncology based training programs for Medical students and professionals.
- (d) Conduct an annual review of current and future Projects approximately one (1) week prior to the anniversary of the execution of this MOU.

1.2 Subject to the terms and conditions of any Collaboration Agreement agreed to and executed, each Party will have the right, in any field related to the Project or otherwise, to:

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- (a) conduct business or research independently, whether or not with third parties;
- (b) continue existing commitments, or make new ones;
- (c) Exploit or otherwise take advantage of its intellectual property.

2. COLLABORATION AGREEMENT

- 2.1 The Parties acknowledge and confirm their intention to negotiate and settle the terms and conditions of a Collaboration Agreement in respect of each Project.
- 2.2 The parties agree that the ownership of the intellectual property rights arising out collaboration will be jointly shared between RCC & KLE. Publications, Authorship rights of involved Doctors/Consultants will be protected. Freedom for conducting individual OPD and Research & Developing new protocols on their own.
- 2.3 Each Collaboration Agreement will include provisions relating amongst other things to:
 - (a) A Project plan pursuant to which the Project will be carried out which will include information pertaining to technical objectives, statement of work, deliverables, schedule, decision gates, resource requirements and costs;
 - (b) Funding arrangements for the Project;
 - (c) Holding by the Parties of periodic Project review meetings to assess the management and the progress of the Project and the status of any expenditure;
 - (d) Exploitation of Intellectual property and rights arising from the same including their protection, enforcement and commercialization.
 - (e) Commercial arrangements between the KLE Ayurveda hospital and RCC.
- 2.4 The Parties agree, acknowledge and confirm that for any agreement to be binding on them, it must be in writing and shall be executed by a duly authorized representative of each of the KLE Ayurveda hospital and RCC.

ATTESTED




Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- 2.5 KLE Ayurveda hospital will provide basic infrastructure/facilities required for offering patient care which include consultation, treatment procedure, inpatient hospitalisation, investigations, dispensing medicines and dietary supplements and collecting treatment charges. KLE will establish speciality Cancer OPD for Ayurveda management. KLE will provide OPD facility in it to RCC for their expert consultancy as per mutual understanding and permit to prescribe the proprietary/ Research formulations of RCC and protect the confidentiality of RCC.
- 2.6 KLE Ayurveda hospital will make necessary arrangements for offering medical care and consultation by qualified Ayurveda physician trained in RCC Treatment protocol, to patients approaching for treatment in the collaborative RCC and KLE cancer OPD. Consultant from KLEU in Speciality Cancer OPD will have freedom to plan for different protocols and medications based on the clinical case otherwise RCC standard protocol will be used.
- 2.7 KLE Ayurveda hospital will make necessary arrangements to avail expert medical opinion or to refer the patient to appropriate medical facilities in case of any emergencies.
- 2.8 KLE Ayurveda hospital will make arrangements to procure medicines manufactured by Ayurved Rasayani, as required for the collaborative RCC and KLE cancer OPD.
- 2.9 RCC will offer appropriate training in Ayurveda oncology to doctors deputed by KLE Ayurveda hospital. The number of doctors at a given point of time will not exceed two (2).
- 2.9 RCC will periodically depute a trained qualified Ayurveda physician so as to provide direct consultation to patients approaching the collaborative RCC and KLE cancer OPD. This doctor will visit KLE Ayurveda hospital at least once in a month. The travel expenses for this visit will be totally beared by RCC.
- 2.10 KLE Ayurveda hospital will be conducting regular awareness activities about the collaborative RCC and KLE cancer OPD. These activities includes Awareness programs, lectures, pamphlets, banners, newspaper articles and Radio broadcast. KLE Ayurveda hospital will bear all the expenses of such activities.

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

2.11 If required for the betterment of patient, RCC will make necessary arrangement to provide online/skype consultation to these patients in Belgaum.

2.12 The responsibility for providing best possible treatment for patient and ensuring his wellbeing lies entirely with the treating physician.

3. REPRESENTATIVE

3.1 For the term and purposes of this MOU, each party shall appoint a designated representative ("the **Representative**").

3.2 The Representative of the appointing Party will be responsible for:

- a) managing, overseeing or coordinating that Party's relationship with the other Party;
- b) identifying any commercial issues that arise between the Parties and refer them to the **Competent Authority** within the Representative's organization;
- c) discussing any issues arising out of this MOU or a Collaboration Agreement with the Representative of the other party; and
- d) Co-coordinating the exchange of information between the Parties.

3.3 The Representatives designated at the time of signing this MOU by the parties are:

(a) for KLE Ayurveda hospital:

Name: Dr B S Prasad.

Designation: Medical Director

Email: kleayurvedahospital@gmail.com

Mob. 9448569289.

(b) for RCC

Name: Dr. Avinash Kadam

Designation: Administrator.

Email: avinashk@rbpl.co.in

Mob. 9970259583

4. CONFIDENTIAL INFORMATION


ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- 4.1 Definition:** As used herein "Confidential Information" shall mean and include all information and data which has been provided/disclosed/shared by RCC to KLE Ayurveda hospital prior and post the execution of this MOU and/or the Collaboration Agreement either written or oral or in any other form or manner of communication or which has been acquired or will be acquired by either Party such as designs, drawings, specifications, technical information, documents and know-how, designs, manufacturing processes, ideas, data, financial information and other technologies, whether patentable, copyrightable or susceptible to any other form of protection. The terms and existence of this MOU, the fact that Confidential Information has been shared and/or made available, that discussions or negotiations pertaining to the technology are taking place between the Parties shall also be considered Confidential Information for the purposes of this MOU.
- 4.2 Purpose:** The Parties shall use the Confidential Information strictly and solely for the purposes the Confidential Information is provided under this MOU and none other.
- 4.3 Ownership:** The Parties hereby understand, acknowledge, and confirm that the Confidential Information is a valuable trade secret owned by each Party and which retains all right, title, and interest in and unto the same. Neither Party shall have any right, title and interest in the Confidential Information of the other Party. By virtue of either Party disclosing the Confidential Information, no license to such Confidential information or any Intellectual Property rights owned by that Party is or are granted to the other Party. Neither Party shall directly or indirectly, through its directors, employees or agents, at any point of time, do any acts, things or deeds that may prejudicially affect the proprietary right, title and interests of either Party in and unto the Confidential Information.
- 4.4 No Warranties:** At no point of time shall either Party be responsible for any loss or damages which may be suffered by the Party receiving the Confidential Information or for that matter by its customers or any third parties on account of or arising from the use of the Confidential Information. Neither Party makes any representations or warranties of any kind, whether expressed or implied as to the accuracy or completeness of the Confidential Information.

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- 4.5 Use of Confidential Information:** Each Party may use the Confidential Information for the purposes stated in Clause 4.2 above only. Each Party recognizes that this MOU imposes an affirmative duty on the other Party to hold such information in confidence and to protect it from dissemination to and use by any and all unauthorized parties. In the absence of any prior written consent neither Party shall copy, reproduce or disclose the Confidential Information to any third party in any manner whatsoever.
- 4.6 Further Responsibility:** The Parties agree and undertake to use the same degree of care to protect the confidentiality of the Confidential Information as it would exercise to protect its own trade secrets and information but in no case less than a reasonable degree of care. Each Party may grant access to the Confidential Information to its directors, officers, employees, advisors and consultants ("**related parties**") who have a clear need to know, for purposes of this MOU and shall advise such related parties of the existence and terms of this MOU and of its obligations of confidentiality herein. MoU shall lead to standard clinical protocols in management of cancer which will be asset of both the institutions. Each organisation will have the right to continuc or utilize the products, protocols developed during the collaboration even after termination of MoU.
- 4.7 Return of Confidential Information** Promptly following the request of either Party the receiving Party will return to the disclosing Party or certify in writing to the disclosing Party as to the destruction of (without retaining any copy in any form or manner) all Confidential Information including copies and extracts thereof as may have been or will be furnished as by the disclosing Party to the receiving Party. But the Hospital records/ data and pharmacy data will be archived to oblige hospital/ pharmacy regulations.
- 4.8 Remedies:** The Parties acknowledge, understand and confirm that the disclosing Party is the proprietor of the Confidential Information and that any unauthorized disclosure, misappropriation or unauthorized use of such Confidential Information by the receiving Party in any manner whatsoever will cause serious irreparable loss and harm to disclosing Party. The receiving Party expressly agrees that the disclosing Party shall be entitled to seek injunctive and other

ATTESTED



Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

equitable relief against it to prevent the breach or further breaches of any of its confidentiality obligations under this MOU and which it will not dispute by challenging the jurisdiction of the competent Courts where injunctive or equitable relief is being sought at by the disclosing Party.

5. TERMINATION AND AMENDMENT


The term of this MOU is a period of one (1) year from the date of execution. The MOU will be automatically renewed for a further period of one (1) year unless one Party notifies the other Party in writing 30 days in advance that they do not wish to renew the MOU at the completion of the annual review of current and future projects.

- 5.1 This MOU may be terminated by mutual consent of the parties. Either party may terminate this MOU upon one (1) month written notice to the other.
- 5.2 A Collaboration Agreement made pursuant to clause 2 of this MOU shall survive termination or expiration of this MOU.
- 5.3 This MOU may be amended only by an agreement in writing between the Parties and not otherwise.

6. GENERAL

- 6.1 KLE Ayurveda hospital and RCC agree that each of them is free to undertake R&D and business projects on their own or in conjunction with third party, and that the Parties will co-operate only in circumstances where each of them agrees if co-operation is for their mutual benefit and each is satisfied that the specific provisions covering their co-operation are appropriate and will not adversely or prejudicially affect their interests.
 - 6.2 With the exception of Clause 4 herein, this MOU is not binding and the Parties do not intend that it or any part of it be binding. It serves only as a record of the understanding between the Parties' intentions pending possible execution of a Collaboration Agreement as contemplated by Clause 2 herein.
 - 6.3 Nothing in this MOU will oblige or cast any obligation upon either Party to enter into a Collaboration Agreement with the other Party or to conduct any Project.
7. This MOU constitutes the entire understanding between the Parties regarding the subject matters contained herein. Any prior agreements,

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

commitments or negotiations concerning the subject matters herein are superseded.

8. The headings contained herein are for the purposes of convenience only and are not intended to define or limit the contents of the provisions contained therein.
9. If one or more provisions of this MOU are held to be illegal or unenforceable, such provisions will be limited or excluded to the minimum extent required so that this MOU will otherwise remain enforceable in accordance with the remaining terms.
10. The rights of the Parties hereto shall not be prejudiced or restricted by any indulgence or forbearance extended to the other party and no waiver by the parties hereto of any breach of the other party of any of the terms hereunder shall operate as a waiver in respect of any subsequent breach. No variation of this MOU shall be effective unless it is in writing and duly signed by both parties.
11. **FORCE MAJEURE:** Neither party shall be liable for any delay in or failure of discharging respective obligations under this MOU caused by occurrence beyond the control of KLE Ayurveda hospital or RCC as the case may be, including but not limited to fires, floods, explosions, power shortage, failure/breakdown of UPS/DG set/computer, acts of GOD, hostility, acts of public enemy wars, insurrections, riots, strikes, lockouts, sabotage. Either parties shall promptly but not later than 10 days of the commencement thereof notify the other in writing of such contingency and prove that such is beyond the control and affects the implementation of this MOU adversely and materially. If such contingency continues beyond 30 days both the parties, agree to discuss and agree upon an equitable solution.
12. **ARBITRATION:** For any interpretation of clauses in this MOU or in case of any dispute during implementation, such matter will be jointly discussed by representative of KLE Ayurveda hospital and RCC. In case of disagreement, the matter would be referred to the International Centre for Alternative Dispute Resolution (ICADR, an autonomous organization

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

working under the aegis of the Ministry of Law and Justice, Govt. of India)
New Delhi-110 070. ICADR decision would be binding on both parties.

IN WITNESS, WHERE OF, the parties have executed this MOU as of the
date first above written

SIGNED AND DELIVERED BY

SIGNED AND DELIVERED BY

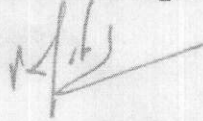
Registrar KLE University

RCC

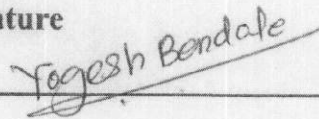
through its Authorized Signatory

through its Authorized Signatory

Signature



Signature



Name of person signing MOU


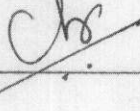
Dr Yogesh Bendale

Designation

Chairman and MD (RBPL)

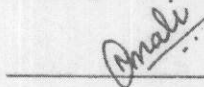
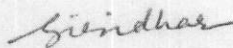
in the presence, of

in the presence, of

 Dr. Anand Patel

in the presence, of

in the presence, of

 Dr. Neha Mali

(Dr. Vedantam Giridhar)

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

CONFIDENTIAL

STUDY PROTOCOL

STUDY TITLE

A multicentric open labelled single arm clinical study to evaluate the effect of NTGX-10 in the treatment of patients with Diabetic Retinopathy.

STUDY PROTOCOL NO: RB/CTD/NTGX-10/001/0.1

SPONSOR

RASAYANI BIOLOGICS PRIVATE LIMITED

B-1, Amrutkumbh, Lakshmi Park

Society, Navi Peth., Pune- 411030.

Contact No: +91-020-24537149

MASTER COPY

CONTROLLED COPY

ATTESTED

Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Title Page

Full title of the clinical study: A multicentric open labelled single arm clinical study to evaluate the effect of NTGX-10 in the treatment of patients with Diabetic Retinopathy.

Study number: RB/CTD/NTGX-10/001/00.

Protocol number: RB/CTD/NTGX-10/001/0.1

Protocol version number with date: Version 0.1 Dated 10 May 2019.

Name of Investigational Drug: NTGX -10.

Complete Name and Address of the Sponsor: Rasayani Biologics Pvt. Ltd., B-1, Amrutkumbh, Lakshmi Park Society, Navi Peth., Pune- 411030.

List of the Investigator's who are conducting the Study, Their Respective Institutional Affiliations and Site Locations.

Site Number	Site name and Address	Principal Investigator	Co-Investigator
1.	Dept. of Shalakyta Tantra SDM collage of Ayurved and Hospital Hassan, Karnataka (India) - 573201.	Dr.Ashwini M. J.	Dr.Amarnath.
2.	Rasayu Ayurved Clinic Karvenagar, Pune. Maharashtra (India) - 411052.	Dr.Ketaki Jagtap	Dr.Rajesh Pawar.
3.	Dept. of Shalakyta Tantra KAHERs Ayurved Hospital and Research Centre. Shahapur, Belgaum, Karnataka (India) - 590003.	Dr. Arun Biradar	

MASTER COPY

CONTROLLED COPY

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- Name(s) of Clinical Laboratories' and other departments and or facilities participating in the study.

Laboratory-1(Pune site)
Golwilkar Metropolis Health Services India Private Limited., Construction House, 796/189-B, Bhandarkar Rd, Shreeman Society, Deccan Gymkhana, Pune, Maharashtra (India) - 411004.
Laboratory-2 (Belgaum Site)
KLE's, P B Kore Hospital and MRC, KLE University's BMK Ayurved college Hospital and Research Centre, Shahapur, Belgaum, Karnataka (India) – 590003.
Laboratory-3 (Hassan Site)
Chanre Diagnostics, 121/1, 3rd Main Road, Between 10 th & 11 th Cross, Margosa Road, Malleshwaram, Bengaluru, Karnataka (India) - 560003.

	Name and Address	Sign and Designation
Person authorised to sign protocol or protocol amendments	Dr. Avinash Kadam. Rasayani Biologics Pvt. Ltd. B1-Amrut kumbha, Navi peth. Pune-411030. avinashk@rbpl.co.in	
Sponsors medical expert	Dr. Avinash Kadam. Rasayani Biologics Pvt. Ltd. B1-Amrut kumbha, Navi peth. Pune-411030. avinashk@rbpl.co.in	
Qualified physician responsible for trial site related medical decision	Principal Investigator of the site	

MASTER COPY

CONTROLLED COPY

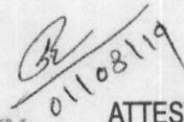

01108119
ATTESTED


Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

CONFIDENTIAL

This investigational protocol is the property of Rasayani Biologics Pvt. Ltd. Pune, and contains confidential information for use by the principal investigators and their designated representatives participating in this clinical investigation. It should be held confidential and maintained in a secure location. It should not be copied or made available for review by any unauthorized person or firm.

MASTER COPY
CONTROLLED COPY


01108119

ATTESTED



Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

2. Table of Contents

SR. No.	Topic	Page No
1.	Background and Introduction	5
2.	Study Rationale	12
3.	Study Objective(s)	13
4.	Study Design	13
5.	Study Population	17
6.	Patient Eligibility	18
7.	Study Assessments	19
8.	Study Conduct	20
9.	Study Treatment	23
10.	Adverse Events	24
11.	Ethical Considerations	24
12.	Study Monitoring and Supervision	25
13.	Investigational Product Management	26
14.	Data Analysis	27
15.	Financing	27
16.	References	28
17.	Principal Investigator's Undertaking	29
18.	Protocol signature page	32

MASTER COPY

CONTROLLED COPY

ATTESTED

Dr. V.A.Kothiwale

Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

MEMORANDUM OF UNDERSTANDING

BETWEEN

**RASAYU CANCER CLINIC, B-1, AMRUT KUMBHA, LAKSHMI
PARK SOCIETY, NAVIPETH PUNE**

AND


**KLE UNIVERSITY'S
SHRI B.M. KANKANAWADI AYURVEDA MAHAVIDYALAYA
SHAHAPUR, BELAGAVI, KARNATAKA.**

For

**Establishment of Cancer OPD at KLE Ayurveda Hospital
And Research Activities**

MEMORANDUM OF UNDERSTANDING

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

This Memorandum of Understanding ("MoU") dated this 11th day of July 2017

by and between:

KLEU's Shri B M Kankanawadi Ayurveda Mahavidyalaya & KLE Ayurveda hospital, Belagavi is a leading institute in offering super speciality quality health care in field of Ayurveda in India., having its office at Nathpai circle, Shahapur, Belagavi (here in after referred to as '**KLE Ayurveda hospital**') which expression shall unless it be repugnant to the context or meaning there of shall be deemed to mean and include its successors and permitted assigns) of the **One Part**

AND

Rasayu cancer clinic having its place of business at B-1 Amrut kumbha, Lakshmipark society, Navipeth Pune (here in after referred to as '**RCC**') which expression shall unless it be repugnant to the context or meaning thereof shall be deemed to mean and include its successors and permitted assigns) of the **Other Part**

KLE Ayurveda hospital and RCC shall be individually here in after referred to as '**Party**' and collectively as '**Parties**'.

Where as

- A. 'KLE Ayurveda hospital'** is a Teaching Ayurveda hospital providing wide range of super-specialty healthcare facilities to Patients.
- B. 'RCC'** is engaged in specialised Ayurveda based cancer therapies to cancer patients and cancer survivors. These facilities include but are not limited to offering Ayurveda consultation, preparing Ayurveda medicines and dietary supplements for these patients, Panchakarma therapies, offering diet, yoga and psychology consultation.
- C.** The parties are interested in exploring possible opportunities of establishing a mutually cooperative and beneficial relationship, including the carrying out of Projects relevant to their respective capabilities in India.
- D.** KLE Ayurveda hospital and RCC, confirm and understand that this MOU is not intended to provide and set out any contractual terms binding or otherwise

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

governing the terms and conditions or the manner of conduct of any Projects and that may necessarily require the Parties to:

- share relevant information on a confidential basis with the aim and objective of identifying their requirements, needs and capabilities;
- establish a working relationship between themselves (which is targeted to the parties' specific needs);
- establish Projects which may be of mutual benefits and interest;
- Determine the details of Projects, their scope and purview, Project work plan, funding of the Project, their rights, duties and obligations in relation to the Project and its outcome.

For the purposes of each Project, the Parties shall enter into separate Agreements.

For the purposes of this MOU, "Project" shall mean a collaboration relating to Establishing specialty cancer OPD for development of Standard Treatment Protocol's in Cancer Management through specialized Ayurveda consultation and therapies for cancer patient at the premise of KLE Ayurveda hospital, Shahapur, Belagavi.


1. SCOPE OF THE MOU

1.1 The Parties will co-operate to:

- (a) Establish facilities for offering specialized Ayurveda consultation to cancer patients which includes offering Ayurveda, yoga, diet and psychological consultation; preparing personalized medicines and dietary supplements for cancer Patients.
- (b) Conduct cancer awareness drives, campaigns and lectures for common public and patients.
- (c) Conducting various oncology based training programs for Medical students and professionals.
- (d) Conduct an annual review of current and future Projects approximately one (1) week prior to the anniversary of the execution of this MOU.

1.2 Subject to the terms and conditions of any Collaboration Agreement agreed to and executed, each Party will have the right, in any field related to the Project or otherwise, to:

ATTESTED


Dr. V.A. Kothiwale
Registrar


KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- (a) conduct business or research independently, whether or not with third parties;
- (b) continue existing commitments, or make new ones;
- (c) Exploit or otherwise take advantage of its intellectual property.

2. COLLABORATION AGREEMENT

- 2.1 The Parties acknowledge and confirm their intention to negotiate and settle the terms and conditions of a Collaboration Agreement in respect of each Project.
- 2.2 The parties agree that the ownership of the intellectual property rights arising out collaboration will be jointly shared between RCC & KLE. Publications, Authorship rights of involved Doctors/Consultants will be protected. Freedom for conducting individual OPD and Research & Developing new protocols on their own.
- 2.3 Each Collaboration Agreement will include provisions relating amongst other things to:
 - (a) A Project plan pursuant to which the Project will be carried out which will include information pertaining to technical objectives, statement of work, deliverables, schedule, decision gates, resource requirements and costs;
 - (b) Funding arrangements for the Project;
 - (c) Holding by the Parties of periodic Project review meetings to assess the management and the progress of the Project and the status of any expenditure;
 - (d) Exploitation of Intellectual property and rights arising from the same including their protection, enforcement and commercialization.
 - (e) Commercial arrangements between the KLE Ayurveda hospital and RCC.
- 2.4 The Parties agree, acknowledge and confirm that for any agreement to be binding on them, it must be in writing and shall be executed by a duly authorized representative of each of the KLE Ayurveda hospital and RCC.


ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- 2.5 KLE Ayurveda hospital will provide basic infrastructure/facilities required for offering patient care which include consultation, treatment procedure, inpatient hospitalisation, investigations, dispensing medicines and dietary supplements and collecting treatment charges. KLE will establish speciality Cancer OPD for Ayurveda management. KLE will provide OPD facility in it to RCC for their expert consultancy as per mutual understanding and permit to prescribe the proprietary/ Research formulations of RCC and protect the confidentiality of RCC.
- 2.6 KLE Ayurveda hospital will make necessary arrangements for offering medical care and consultation by qualified Ayurveda physician trained in RCC Treatment protocol, to patients approaching for treatment in the collaborative RCC and KLE cancer OPD. Consultant from KLEU in Speciality Cancer OPD will have freedom to plan for different protocols and medications based on the clinical case otherwise RCC standard protocol will be used.
- 2.7 KLE Ayurveda hospital will make necessary arrangements to avail expert medical opinion or to refer the patient to appropriate medical facilities in case of any emergencies.
- 2.8 KLE Ayurveda hospital will make arrangements to procure medicines manufactured by Ayurved Rasayani, as required for the collaborative RCC and KLE cancer OPD.
- 2.9 RCC will offer appropriate training in Ayurveda oncology to doctors deputed by KLE Ayurveda hospital. The number of doctors at a given point of time will not exceed two (2).
- 2.9 RCC will periodically depute a trained qualified Ayurveda physician so as to provide direct consultation to patients approaching the collaborative RCC and KLE cancer OPD. This doctor will visit KLE Ayurveda hospital at least once in a month. The travel expenses for this visit will be totally beared by RCC.
- 2.10 KLE Ayurveda hospital will be conducting regular awareness activities about the collaborative RCC and KLE cancer OPD. These activities includes Awareness programs, lectures, pamphlets, banners, newspaper articles and Radio broadcast. KLE Ayurveda hospital will bear all the expenses of such activities.

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

2.11 If required for the betterment of patient, RCC will make necessary arrangement to provide online/skype consultation to these patients in Belgaum.

2.12 The responsibility for providing best possible treatment for patient and ensuring his wellbeing lies entirely with the treating physician.

3. REPRESENTATIVE

3.1 For the term and purposes of this MOU, each party shall appoint a designated representative ("the **Representative**").

3.2 The Representative of the appointing Party will be responsible for:

- a) managing, overseeing or coordinating that Party's relationship with the other Party;
- b) identifying any commercial issues that arise between the Parties and refer them to the **Competent Authority** within the Representative's organization;
- c) discussing any issues arising out of this MOU or a Collaboration Agreement with the Representative of the other party; and
- d) Co-coordinating the exchange of information between the Parties.

3.3 The Representatives designated at the time of signing this MOU by the parties are:

(a) for KLE Ayurveda hospital:

Name: Dr B S Prasad.

Designation: Medical Director

Email: kleayurvedahospital@gmail.com

Mob. 9448569289.

(b) for RCC

Name: Dr. Avinash Kadam

Designation: Administrator.

Email: avinashk@rbpl.co.in

Mob. 9970259583

4. CONFIDENTIAL INFORMATION

ATTESTED



Dr. V.A. Kothiwale

Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- 4.1 Definition:** As used herein "Confidential Information" shall mean and include all information and data which has been provided/disclosed/shared by RCC to KLE Ayurveda hospital prior and post the execution of this MOU and/or the Collaboration Agreement either written or oral or in any other form or manner of communication or which has been acquired or will be acquired by either Party such as designs, drawings, specifications, technical information, documents and know-how, designs, manufacturing processes, ideas, data, financial information and other technologies, whether patentable, copyrightable or susceptible to any other form of protection. The terms and existence of this MOU, the fact that Confidential Information has been shared and/or made available, that discussions or negotiations pertaining to the technology are taking place between the Parties shall also be considered Confidential Information for the purposes of this MOU.
- 4.2 Purpose:** The Parties shall use the Confidential Information strictly and solely for the purposes the Confidential Information is provided under this MOU and none other.
- 4.3 Ownership:** The Parties hereby understand, acknowledge, and confirm that the Confidential Information is a valuable trade secret owned by each Party and which retains all right, title, and interest in and unto the same. Neither Party shall have any right, title and interest in the Confidential Information of the other Party. By virtue of either Party disclosing the Confidential Information, no license to such Confidential information or any Intellectual Property rights owned by that Party is or are granted to the other Party. Neither Party shall directly or indirectly, through its directors, employees or agents, at any point of time, do any acts, things or deeds that may prejudicially affect the proprietary right, title and interests of either Party in and unto the Confidential Information.
- 4.4 No Warranties:** At no point of time shall either Party be responsible for any loss or damages which may be suffered by the Party receiving the Confidential Information or for that matter by its customers or any third parties on account of or arising from the use of the Confidential Information. Neither Party makes any representations or warranties of any kind, whether expressed or implied as to the accuracy or completeness of the Confidential Information.


ATTESTED



Dr. V.A. Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

- 4.5 Use of Confidential Information:** Each Party may use the Confidential Information for the purposes stated in Clause 4.2 above only. Each Party recognizes that this MOU imposes an affirmative duty on the other Party to hold such information in confidence and to protect it from dissemination to and use by any and all unauthorized parties. In the absence of any prior written consent neither Party shall copy, reproduce or disclose the Confidential Information to any third party in any manner whatsoever.
- 4.6 Further Responsibility:** The Parties agree and undertake to use the same degree of care to protect the confidentiality of the Confidential Information as it would exercise to protect its own trade secrets and information but in no case less than a reasonable degree of care. Each Party may grant access to the Confidential Information to its directors, officers, employees, advisors and consultants (“**related parties**”) who have a clear need to know, for purposes of this MOU and shall advise such related parties of the existence and terms of this MOU and of its obligations of confidentiality herein. MoU shall lead to standard clinical protocols in management of cancer which will be asset of both the institutions. Each organisation will have the right to continuc or utilize the products, protocols developed during the collaboration even after termination of MoU.
- 4.7 Return of Confidential Information** Promptly following the request of either Party the receiving Party will return to the disclosing Party or certify in writing to the disclosing Party as to the destruction of (without retaining any copy in any form or manner) all Confidential Information including copies and extracts thereof as may have been or will be furnished as by the disclosing Party to the receiving Party. But the Hospital records/ data and pharmacy data will be archived to oblige hospital/ pharmacy regulations.
- 4.8 Remedies:** The Parties acknowledge, understand and confirm that the disclosing Party is the proprietor of the Confidential Information and that any unauthorized disclosure, misappropriation or unauthorized use of such Confidential Information by the receiving Party in any manner whatsoever will cause serious irreparable loss and harm to disclosing Party. The receiving Party expressly agrees that the disclosing Party shall be entitled to seek injunctive and other

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

equitable relief against it to prevent the breach or further breaches of any of its confidentiality obligations under this MOU and which it will not dispute by challenging the jurisdiction of the competent Courts where injunctive or equitable relief is being sought at by the disclosing Party.

5. TERMINATION AND AMENDMENT

The term of this MOU is a period of one (1) year from the date of execution. The MOU will be automatically renewed for a further period of one (1) year unless one Party notifies the other Party in writing 30 days in advance that they do not wish to renew the MOU at the completion of the annual review of current and future projects.

- 5.1 This MOU may be terminated by mutual consent of the parties. Either party may terminate this MOU upon one (1) month written notice to the other.
- 5.2 A Collaboration Agreement made pursuant to clause 2 of this MOU shall survive termination or expiration of this MOU.
- 5.3 This MOU may be amended only by an agreement in writing between the Parties and not otherwise.

6. GENERAL

- 6.1 KLE Ayurveda hospital and RCC agree that each of them is free to undertake R&D and business projects on their own or in conjunction with third party, and that the Parties will co-operate only in circumstances where each of them agrees if co-operation is for their mutual benefit and each is satisfied that the specific provisions covering their co-operation are appropriate and will not adversely or prejudicially affect their interests.
 - 6.2 With the exception of Clause 4 herein, this MOU is not binding and the Parties do not intend that it or any part of it be binding. It serves only as a record of the understanding between the Parties' intentions pending possible execution of a Collaboration Agreement as contemplated by Clause 2 herein.
 - 6.3 Nothing in this MOU will oblige or cast any obligation upon either Party to enter into a Collaboration Agreement with the other Party or to conduct any Project.
7. This MOU constitutes the entire understanding between the Parties regarding the subject matters contained herein. Any prior agreements,

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

commitments or negotiations concerning the subject matters herein are superseded.

8. The headings contained herein are for the purposes of convenience only and are not intended to define or limit the contents of the provisions contained therein.
9. If one or more provisions of this MOU are held to be illegal or unenforceable, such provisions will be limited or excluded to the minimum extent required so that this MOU will otherwise remain enforceable in accordance with the remaining terms.
10. The rights of the Parties hereto shall not be prejudiced or restricted by any indulgence or forbearance extended to the other party and no waiver by the parties hereto of any breach of the other party of any of the terms hereunder shall operate as a waiver in respect of any subsequent breach. No variation of this MOU shall be effective unless it is in writing and duly signed by both parties.
11. **FORCE MAJEURE:** Neither party shall be liable for any delay in or failure of discharging respective obligations under this MOU caused by occurrence beyond the control of KLE Ayurveda hospital or RCC as the case may be, including but not limited to fires, floods, explosions, power shortage, failure/breakdown of UPS/DG set/computer, acts of GOD, hostility, acts of public enemy wars, insurrections, riots, strikes, lockouts, sabotage. Either parties shall promptly but not later than 10 days of the commencement there of notify the other in writing of such contingency and prove that such is beyond the control and affects the implementation of this MOU adversely and materially. If such contingency continues beyond 30 days both the parties, agree to discuss and agree upon an equitable solution.
12. **ARBITRATION:** For any interpretation of clauses in this MOU or in case of any dispute during implementation, such matter will be jointly discussed by representative of KLE Ayurveda hospital and RCC. In case of disagreement, the matter would be referred to the International Centre for Alternative Dispute Resolution (ICADR, an autonomous organization

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

working under the aegis of the Ministry of Law and Justice, Govt. of India)
New Delhi-110 070. ICADR decision would be binding on both parties.

**IN WITNESS, WHERE OF, the parties have executed this MOU as of the
date first above written**

SIGNED AND DELIVERED BY

SIGNED AND DELIVERED BY

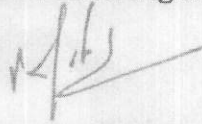
Registrar KLE University

RCC

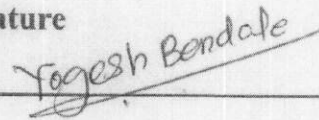
through its Authorized Signatory

through its Authorized Signatory

Signature



Signature



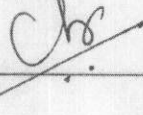
Name of person signing MOU

Dr Yogesh Bendale


Designation

Chairman and MD (RBPL)

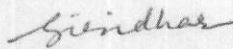
in the presence, of



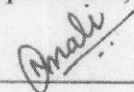
in the presence, of

 **Dr. Anand Patil**

in the presence, of

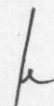


in the presence, of

 **Dr. Neha Mali**

(Dr. Vedantam Giridhar)

ATTESTED



**Dr. V.A. Kothiwale
Registrar**

**KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka**

Dr. B.S. Prasad
Chairman/ Biological Scientist
Shri B.M.K.Ayurved Mahavidyalaya
Shahapur- Belagavi

Mr. Mallikarjun Kolhar
Nominee of CPCSEA
H.S.K College of Pharmacy,
Bagalkot

Dr. Rudramma R. Hiremath
Member Secretary
Scientist In charge of Animal House Facility
Shri B.M.K.Ayurved Mahavidyalaya Shahapur Belagavi

File No.25/369/2010-AWD Government of India Ministry of Environment & Forests (Animal Welfare Division) Dated: 24/11/2016

Dr. Giridhar Vedantam
Scientist-Biological Discipline
Shri B.M.K. Ayurved
Mahavidyalaya Shahapur
Belagavi

CERTIFICATE

This is to certify that the P.G./Ph.D/Research project entitled:

“Effect of NTPX, NTAX, pinzar and Dasma on N-nitrosodiethylamine and carbon tetrachloride induced hepatocarcinogenesis in Wistar rats”

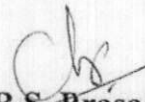
Dr. Santosh Patil
Scientist-Biological Discipline
Shri B.M.K. Ayurved
Mahavidyalaya Shahapur
Belagavi

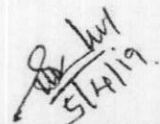
Submitted by: **Dr Giridhar Vedantham**

Dr. Vinaykumar S
Veterinarian
Vadgaon, Belagavi

Has been approved by the Institutional Animal Ethical Committee meeting held on **05th April 2019** vide Resolution No. **BMK/IAEC/Res.No.-19/2019- 02**

Shri. Sunil Patil
Goshala Secretary
Socially Aware Nominee
Nidasoshi, Belagavi



Dr. B.S. Prasad
Chairman
IAEC, Shri B.M.K.A.M Belagavi


Mr. Mallikarjun Kolhar
CPCSEA Nominee
IAEC, Shri B.M.K.A.M. Belagavi

Mr. Prakash Geriyol
Scientist from outside the
institute Honnali, Davangere

Shahapur, Belagavi – 590 003, Karnataka, India
Phone: +91 831 2486286 Fax: +91 831 2424157
Website: www.kleayurworld.edu.in, Email: bmkiprincipal@gmail.com

ATTESTED


Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

MEMORANDUM OF UNDERSTANDING

The memorandum understanding is concurred into this
BETWEEN

M/s Med Manor Organics PVT. Ltd., D. no 16-11-477/45, Dilsukhnagar, Hyderabad-500036, Telangana State, through its Director, here in after referred to as the **company**, which expression shall unless repugnant to the context and meaning thereof include its heirs, successors of the one part.

AND

KAHER's Shri.B.M.KankanawadiAyurvedMahavidyalaya – Medical Research Centre Shahapur, Belagavi, Karnataka-590003, India.A constituent unit of KAHER Deemed to be University through its Principal here in after referred to as the **institute** which expression shall unless repugnant to the context and meaning thereof include its heirs, successors and assignees of the Second Part.

Both parties decided in principle on 31-08-2019 to make an agreement for conducting clinical trial on TRUIAIR OIL in KAHER's BMK with 80 subjects of two groups for 90 day administration. Study will be conducted as per protocol approved by IEC and as per AYUSH GCP. Terms of MoU, protocol and budget will be approved after mutual agreement.

In witness whereof the parties hereof have signed in this agreement on 31st August 2019 mentioned herein below.

PARTIES

For and on behalf of M/S. Med Manor is a pharmaceutical company	For and on behalf of KAHER's Shri.B.M.Kankanawadi Ayurveda Mahavidyalaya,
M/s Med Manor Organics PVT. Ltd D. no 16-11-477/45, Dilsukhnagar, Hyderabad- 500036, Telangana	KAHER's Shri.B.M.Kankanawadi Ayurveda Mahavidyalaya, Shahapur-Belagavi-590003,Karnataka, India Fax:0831-2424157, Tel: 0831- 2486286 Website: www.klebmkgmail.edu.in . Email:mrcklebmkgmail.com
Signature with date <i>A. Padmasekhar</i> Name: A. PADMASEKHAR. Designation DIRECTOR	Signature with date <i>Prashant G Jadar</i> Name: Dr. Prashant G Jadar Designation Vice - Principal

Witness:

- 1) B. LAKSHMAIAH. *Chemist.*
- 2) T. RAJESH *Partner*
- 3) Dr. Vedantam Giridhar Srinidhar
- 4)

ATTESTED

L
Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

PRINCIPAL
Shri B. M. Kankanawadi
Ayurved Mahavidyalaya
A Constituent Unit of KAHER
Shahapur, Belagavi-590003.

MEMORANDUM OF UNDERSTANDING

The memorandum understanding is concurred on Date 16/12/2019 into this

BETWEEN

M/s Bhagyalaxmi Industries, 51 EC Extn, Kushaiguda, Kapra, Hyderabad, 500062 Telangana State, **India** through its **Proprietor**, Mr Balakrishna, hereinafter referred to as the **company**, which expression shall unless repugnant to the context and meaning thereof include its heirs, successors of the one part.

AND

KAHER's Shri.B.M.Kankanawadi Ayurved Mahavidyalaya – Medical Research Centre, Shahapur, Belagavi, Karnataka-590003, India through its Principal, Dr.B.Sreenivas Prasad hereinafter referred to as the **institute** which expression shall unless repugnant to the context and meaning thereof include its heirs, successors and assignees of the Second Part.

WHERE AS the company is engaged, inter alia, in research and development of various Ayurveda Drugs.


AND WHERE AS the institute has fully established good research facilities and hospital facility for the clinical studies in the field of Ayurveda and Ayurvedic Drugs.

WHERE AS the company has developed Proprietary Ayurveda Preparations in its laboratory for the management of HERBHAIR OIL and want to study clinically for assessment for its efficacy in Hair Regrowth in Diffuse hair or Hair fall subjects, to be done in hospital of the Institute, to which the Institute has agreed.

NOW, THEREFORE, in consideration of the representations, warranties, covenants and agreements set forth herein and other valuable consideration and subject to the terms and conditions set forth herein, the Lessor and the Lessee hereby agree as follows.

1. That the Institute has agreed to conduct a clinical assessment of HERBHAIR oil, development by the company.

Page 1 of 5



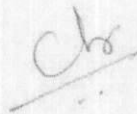
ATTESTED



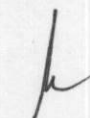
Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

2. That the company has agreed to provide to the Institute detail ingredients of the drugs, type of investigation required in the clinical trial, brief details of the products, copy of certificate of analysis of used raw materials and ingredient pharmacology of used raw materials.
3. That the company has also agreed to utilize the result of the clinical study for the benefit of patients and undertakes that the company shall only be responsible /liable for any legal or other requirement arising out of the application of the project.
4. That the clinical study would require certain amount of expenditure as per details attached herewith in the project proposal (including financial) to which both the parties have agreed. Total amount of project is Rs. 5,74,350/-Only(Five Lakh Seventy Four Thousand Three Hundred and Fifty Rupees only)in words exclusive of any taxes or insurance or study related injury compensation which has to bared by the company.
Put of the above proposed fixed expenditure of Rs.574350/- the company has agreed to make 10% non- refundable amount (Rs. 57435/-) along with application which will be adjustable in total project cost. 50%(Rs.287175/-) of payment will be made after ethical clearance as part of project institution, and 30%(Rs.1,72,305/-) payment will be made once the 50% of sample size is reached. Remaining 10% (Rs.57435/-) of project cost should be paid after the completion of the project during submission of study report.
5. That the said trial shall be completed in the period of 12 months from the day of study initiation after due IEC permission and CTRI Registration.
6. The clinical study will be Single group Pre-Post assessment study on maximum 50 subjects recruited as per inclusion and exclusion criteria mentioned in the protocol.
7. The Clinical study will be conducted as per accepted Protocol as approved by IEC.
8. The company is responsible for payment of study related injury, if any, for clinical management charges as well as compensation as per law, if any.
9. The Institute has agreed to provide periodical progress report of the clinical trial.
10. The company has agreed to provide all detail of work, and all other necessary co-operation in order to complete the research activities of the drugs.
11. It has agreed between the parties that all rights arising and of research and clinical activities of the said drugs, including patent right shall vest with the company and the Institute shall never claim any right over the drugs time in future.



ATTESTED



Dr. V.A.Kothiwale
Registrar

12. Important research findings arising out of the activities covered under this MOU will be published or presented at National/International Journals, Conferences with joint authorship of both of parties.
13. All notes and other communication required to be served on parties under the terms of the agreement shall be considered duly served if the same have been delivered to or posted by registered mail to:

In case of Bhagyalaxmi Industries, **Hyderabad.**

Mr Balakrishna,
Proprietor,
Bhagyalaxmi Industries,
51 EC Extn, Kushaiguda,
Kapra, Hyderabad, 500062

In case of KLEU's Shri.B.M.Kankanawadi Ayurveda Mahavidyalaya:

Coordinator, Medical Research Centre,

KAHER's Shri.B.M.Kankanawadi Ayurveda Mahavidyalaya,

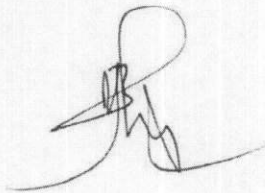
Shahapur-Belagavi-590003, Karnataka, India

Fax:0831-2424157, Tel: 0831- 2486286

Website: www.klebmkgmail.edu.in,

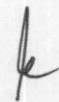
Email:mrcklebmkgmail.com.

14. That the company shall provide various trade secrets and proprietary information of the company to the Institute. The Institute acknowledges that the company's information is valuable, special and unique to its business and the company has exclusive right to the



ATTESTED
ATTESTED

Page 3 of 5

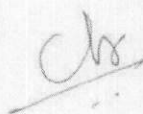


Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

use the same as per the law. Hence in order to save the proprietary information/trade secret, both the parties has agreed as follows:

- I. All rights to the proprietary information to the development product shall remain the sole property of the company.
 - II. The Institute undertakes to keep confidential all information provided by the company in the Institute whether in the drugs under trial of otherwise.
 - III. The Institute undertakes do not disclose to any third party about the present Agreement understanding.
15. None of the parties to this MOD shall make any public discloses in any form relating to this MOU without the prior written consent of the other party: provided, the party shall be permitted to make such disclosures to the Public or to Government agencies as the party shall deem necessary to comply with any applicable law, rule or regulation or to Government Reviews or approvals of the proposed business agreement disclosed on this MOU.
16. This MOU can be terminated by either of the party by giving 30 days of notice to the other party for the reasons stated below:
- I. Any material breach of terms of the agreement.
 - II. The termination shall not affect the parties liability for its unperformed obligations which have accrued prior to the date of termination and hence the parties shall fulfill its obligation under the agreement till the date termination.
17. The parties to the MOU agree that the present MOU can be modified, varied, changed or otherwise in whole or in part only with mutual consent, in writing and executed by or on behalf of the parties.
18. This is the essence of this agreement.
19. Any dispute, difference or claim arising out of or in connection with the Agreement including the construction, validity, execution, performance, termination or breach hereof (a "Dispute") that is not settled within fifteen (15 business days of the date on which such dispute, difference or claim is raised, shall be referred to final and binding arbitration under the Indian Arbitration and Conciliation. All proceedings of such arbitration shall be in the English Language.



ATTESTED Page 4 of 5



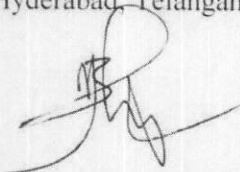
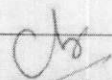
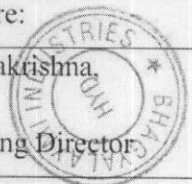
Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

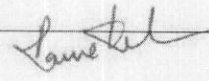
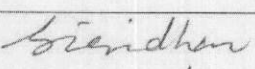
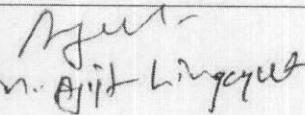

20. The courts of shall have the sole and exclusive jurisdiction to resolve any dispute if not solved amicably between the parties.

In witness whereof the parties hereof have signed in this agreement and the day month and year mentioned herein above:


PARTIES

For and on behalf of	For and on behalf of
Bhagyalaxmi Industries, 51 EC exon, Kushaiguda, Kapra, Hyderabad, Telangana 500062	KAHER's Shri B. M. Kankanawadi Ayurveda Mahavidyalaya, Shahpur, BELAGAVI, Karnataka 590003
Seal 	Seal 
signature: Mr Balakrishna Managing Director	signature: Dr. B. Sreenivas Prasad Principal
	PRINCIPAL Shri B. M. Kankanawadi Ayurved Mahavidyalaya A Constituent Unit of KAHER Shahapur, BELAGAVI-03.

Witness:

1	Signature:  Name: Dr. Rame Krishna V	1	Signature:  Name: Dr. Vedantam Anandhan
2	Signature:  Name: M. Ajit Lingappa	2	Signature:  Name: Dr. Maheshw. B. Anandakalle

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Page 5 of 5

New Tab x Captive Portal x Welcome to UGC, N x (3) WhatsApp x Fw: Results of SIP 20 x ROMANTIC MA x

mail.google.com/mail/u/0/#inbox/FMfcgxwHNqKNQpwBpwSxnrMMmGgBLVkB

Apps Gmail YouTube Maps Captive Portal KLE Management and T...

Gmail Search mail G Suite

3 of 177

Fw: Results of SIP 2019-2020 Research Grant Award - Senior Category Inbox x

deepa metgud <drdeepa_metgud@yahoo.com> to me Tue, Jun 16, 4:34 PM (2 days ago)

Sent from Yahoo Mail on Android

— Forwarded Message —

From: "Sundar Kumar" <sundark94@gmail.com>
To: "drdeepa_metgud@yahoo.com" <drdeepa_metgud@yahoo.com>, "narasimman swaminathan" <naraswamin2001@gmail.com>, "researchgrant@sip-physio.org" <researchgrant@sip-physio.org>
Sent: Tue, Jan 21, 2020 at 10:16 AM
Subject: Results of SIP 2019-2020 Research Grant Award - Senior Category

Dear Dr Deepa,

Thank for choosing to apply for SIP research grant. Your grant application reference number is SIPSR02_2019.

The application was reviewed by the committee and three blinded subject experts. We are happy to inform you that your application has been shortlisted for funding under the senior researcher category.

CamScanner 06-18...pdf
CamScanner 06-18...pdf
onco 4.tif
onco 2.tif
onco 2.tif
Show all x

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

New Tab x Captive Portal x Welcome to UGC, N... x (3) WhatsApp x Fw: Results of SIP 20... x ROMANTIC MA... x

mail.google.com/mail/u/0/#inbox/FMfcgqxwHNqKNQpwBpwSXnrMMmGgBLVkB

Apps Gmail YouTube Maps Captive Portal KLE Management and T...

Gmail Search mail G Suite

3 of 177

The application was reviewed by the committee and three blinded subject experts. We are happy to inform you that your application has been shortlisted for funding under the senior researcher category.

The peer reviewers had a few suggestions for your proposal. Please consider incorporating the suggestions and mail us an updated proposal incorporating the changes as deemed necessary. Kindly note that ethical approval letter is mandatory for the release of funds and to start the research. In addition, since your research is proposed as a randomised controlled trial, it is mandatory for registration of the protocol in CTRI before initiation of the study and enrollment on first participant. In addition, update your proposal using the CONSORT recommendations including information of participant election, allocation to intervention group, blinding and the like

Peer Review Comments:

Overall the study is well planned. There are a few concerns as specified below. The Introduction implies that the study aims at assessing the long term effects of the intervention on long term neurodevelopmental outcomes in preterm and low birth weight infants. The outcomes will be assessed at baseline i.e. when the baby is 5.5. to 6.5 months old and at 12 months of age. How is this classified as long term outcome? Since the child will be followed up for 6 months, the time-line for data collection in the time chart may need to be modified. There is lack of clarity with regard to the total sample size i.e. how many participants will be recruited in each group? The intervention details may need to be elaborated i.e. is it a home based program? I understand that information regarding demonstration of intervention is provided. But after demonstration is the intervention provided daily by the mother? Will it be provided only once a day or several times a day? The control group is provided some information at 6 months, however the subsequent 2 visits there is no information provided to the parents. This is a concern as the parents will visit the same follow-up clinic with one set of participants receiving toys along with demonstration and the other set of parents not even receiving any information. This can lead to ethical concerns and there is a high possibility of contamination between the groups.

The inclusion criteria mentions Preterm low birth weight infants but objectives mention these are two separate groups. It needs to be clearly defined

CamScanner 06-18...pdf removed CamScanner 06-18...pdf onco 4.jfit onco 3.jfit onco 2.jfit Show all X

ATTESTED

Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

New Tab x Captive Portal x Welcome to UGC N x (3) WhatsApp x Fw: Results of SIP 20 x ROMANTIC MA x

mail.google.com/mail/u/0/#inbox/FMfcgxwHNqKNQpwBpwSXnrMMmGgBLvkB

Gmail Search mail G Suite

contamination between the groups.


The inclusion criteria mentions Preterm low birth weight infants but objectives mention these are two separate groups. It needs to be clearly defined whether the participants are Preterm infants with low birth weight or whether there will be Preterm infants and Low birth weight term infants. Extreme PT and extreme LBW infants have worse outcome than those who are late preterm or moderately LBW. Therefore the Inclusion criteria needs to be more clearly defined. How will the PI/CI ascertain whether the intervention is being carried out by the parent at home? Additional information on the benefits of SDP on the neurodevelopmental outcomes in typically growing term born infants will be helpful. The outcome measure used to exclude infants with neurodevelopmental disabilities is unclear.

V. Sundeel Kumar, Ph. D
Assistant Professor
Department of Physiotherapy
Ramalah Medical College,
MSR Nagar, MSRIT Post,
Bangalore - 560054

Congratulations! Hearty congratulations. Very nice!

CamScanner 06-18...pdf removed CamScanner 06-18...pdf onco 4.tif onco 3.tif onco 2.tif Show all

ATTESTED


Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka



Current & Saving Account Statement

THE PRINCIPAL KLE U INS OF PHYSIOTHERAP
KLES INSTITUTE OF PHYSIOTHERAPY
JNMC COMPOUND
BELGAUM
BELGAUM
KARNATAKA
590010
IN

Account Statement as of 07-01-2021 16:04:01 +0530

Customer Name	THE PRINCIPAL KLE U INS OF PHYSIOTHERAP
Branch	NEHRU NAGAR, BELGAUM
Searched By	From 05 Jan 2021 To 05 Jan 2021
Account No	05042010105520
Account Currency	INR
Opening Balance	Rs. 6,600.00
Closing Balance	Rs. 6,600.00

Transaction Date	Value Date	Cheque No.	Description	Debit	Credit	Balance
05 Jan 2021	05 Jan 2021		B/F...			6,600.00
05 Jan 2021	05 Jan 2021	550206404229	To Clg :CHEQUE PAID IN CLEARING - SERVBR-BANGA- FOR PAYEE SUJATA PAI - BZC	6,600.00		6,600.00
05 Jan 2021	05 Jan 2021		NEFT:N005211362428014:SOCIETY OF INDIAN PHYSIOTHERAPISTS		25,000.00	6,600.00


*This is a Computer generated Statement and does not require signature. Any discrepancies in this statement may kindly be brought to the Bank's notice within seven days.

**Never Share Internet Banking password, OTP, ATM PIN, Credit/Debit Card Numbers, Expiry date, CVV, MPIN, MMID, and Aadhar Number over Phone/E-mail/SMS/ with anyone. Bank or its employees never ask for this information.




SUPERINTENDENT

ATTESTED


Dr. V.A.Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

Date: 21st January 2020

To,

Dr. Deepa C Metgud.

Professor
Department of Pediatric Physiotherapy
KLE University's Institute of Physiotherapy,
Nehru Nagar, Belgaum
Karnataka 590010.

Subject: Award of SIP Research Grant for the year 2019

Dear Dr. Deepa C Metgud

On behalf of the Governing Body of the Society of Indian Physiotherapists, it is my pleasure to inform you that your Research Proposal titled "Sit Down and Play Intervention on Neuromotor Outcome and Parenting Behavior In Preterm Low Birth Weight Infants- Randomized Controlled Trial" has been selected for funding by the SIP Research Grant Committee for the year 2019 under the Senior Physiotherapist Category. Congratulations!

The application was reviewed by the committee and three blinded subject experts. The peer reviewers had a few suggestions for your proposal. You are requested to respond to the peer review comments and incorporate changes in your proposal as deemed necessary and submit the revised proposal to committee. While revising your proposal, please use CONSORT Guidelines to provide relevant information on study methods.

Kindly note that ethical approval letter is mandatory for the release of funds and to start the research. In addition, since your proposed research is a randomized controlled trial, as per DGCI mandate, the recruitment and enrollment of participants can happen only after your protocol is registered with CTRI. Please intimate us in writing once you receive the CTRI registration number.

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Registered Address:

Society of Indian Physiotherapists
Amar Jyoti Institute of Physiotherapy
Vikas Marg, Karkardooma,
New Delhi 110092 INDIA
www.sip-physio.org | mail@sip-physio.org

Upon completion of these requirements, as a condition to receive the research grant, you are required to submit an affidavit (in a Stamp Paper of value INR 100/, prepared using the attached template) and provide the official bank account details for transferring the research grant. The first installment of INR 25,000 will be released by the treasurer after receipt of the affidavit and bank account details. The bank account should be institutional account and the institution should be able to certify the expenditure as per the required format.

All expenditure should be paid by cheque or online transfer and original bills should be obtained. Expenditure towards items not approved by the grants committee will not be accepted. Submission of an interim report, bills and expenditure statement are mandatory requirements for release of the next installment.

It is expected to complete the project within one year from the date of the grant sanction order. The mid-term report should be submitted by email within six months about the progress made in the execution of the project along with all bills in original and an expenditure statement (attested by the head of the institution). At the end of the research project, a final report of the project in the prescribed format, statement of expenditure (attested by the head of the institution) and all bills in original should be submitted to the grants committee within one month of the project completion deadline. Project extensions may be provided only under rare circumstances and will be decided on a case to case basis by the grants committee.

You are strongly encouraged to publish the results in good quality peer reviewed indexed journals. The support of SIP grant with details should be acknowledged in all such publications arising out of the funded project.

Congratulations once again and good luck with your research!

Sincerely,



Dr V Sundar Kumar
Coordinator
SIP Research Grants Committee

ATTESTED



Dr. V.A. Kothiwale
Registrar

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

Registered Address:

Society of Indian Physiotherapists
Amar Jyoti Institute of Physiotherapy
Vikas Marg, Karkardooma,
New Delhi 110092 INDIA
www.sip-physio.org | mail@sip-physio.org