Subaward Agreement

Organization ("Organization")	Institution ("Collaborator")
Name: Christiana Care Health Services, Inc. (CCHS) Address: Office of Sponsored Programs, Suite 2400 200 Hygeia Drive, Newark, DE 19713	Name: Jawaharlal Nehru Medical College (JNMC), KLE Organization Address: Nehru Nagar, Belgaum – 590010 Karnataka, India TIN.: BLRK04603E
Prime Award No. Thrasher Award #: 10326 Matthew Hoffman	Subaward No. 601465
Awarding Agency Thrasher Research Fund	CFDA No. NA
Subaward Period of Performance June 22, 2013 – June 21, 2014	Amount Funded this Action $155,873 / Est. Total (if incrementally funded) $298,541
Project Title Clindamycin to reduce preterm birth in a low resource setting: a randomized placebo-controlled trial	
Reporting Requirements/Payment Schedule [Check here if applicable: ☒ See Attachment 4]	

Terms and Conditions

1) Organization hereby awards a (*choose one*): ☒ cost reimbursable ☐ firm-fixed-price subaward, as described above, to Collaborator. The statement of work and budget for this subaward are shown in Attachment 5. In its performance of subaward work, Collaborator shall be an independent entity and not an employee or agent of Organization.

2) Organization shall (*choose one*):
☒ issue an advance payment of $53,717 U.S dollars upon execution of this Agreement. Organization shall thereafter reimburse Collaborator on a monthly basis for allowable costs based on invoices submitted in accordance with sample invoice shown in Attachment 6.
☐ pay Collaborator according to the payment schedule in Attachment 4.

Expenditures of Collaborator shall conform to budget in Attachment 5. All payments will be in U.S. dollars. Questions concerning payments should be directed to the appropriate party's Financial Contact, as shown in Attachment 3.

3) A final statement of cumulative costs incurred, including cost sharing, marked "FINAL," must be submitted to the Organization's Financial Contact NOT LATER THAN forty-five (45) days after subaward end date. The final statement of costs shall constitute Collaborator'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 Collaborator.

5) Matters concerning the technical performance of this subaward should be directed to the Organization Principal Investigator,, as shown in Attachment 3. 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 Attachment 3. Any such changes made to this subaward agreement require the written approval of each party's Authorized Official, as shown in Attachment 3.

7) 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.

8) Either party may terminate this agreement with thirty days written notice to the appropriate party's Administrative Contact, as shown in Attachment 3.

9) No-cost extensions require the approval of Organization and the Awarding Agency. Any requests for a no-cost extension should be addressed to and received by the Administrative Contact, as shown in Attachment 3, not less than thirty days prior to the desired effective date of the requested change.

10) The Subaward is subject to the terms and conditions of the Award Letter (Attachment 1) and other special terms and conditions, as identified in Attachment 2.

11) By signing below Collaborator makes the certifications and assurances shown in Attachment 2.

By an Authorized Official of ORGANIZATION:		By an Authorized Official of COLLABORATOR:	
Thomas L Corrigan	Date: 8/21/13	Dr. Ashok S. Godhi, Principal	Date: 8/26/13

APPROVED BY LEGAL

ATTESTED

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

01

Thrasher Research Fund
Medical Research for Children
68 S. Main Street, Suite 400
Salt Lake City, UT 84101
Phone: 801-240-4753
Fax: 801-240-1625
ThrasherResearch.org

November 7, 2012

Matthew K. Hoffman, M.D., MPH
Director, Division of Education & Research
Dept. of Obstetrics & Gynecology
Christiana Care Health Services, Inc.
4755 Ogletown-Stanton Rd.
Newark, DE 19718

Dear Dr. Hoffman:

This Award Letter is to advise you that the Thrasher Research Fund ("Fund") has approved your application for a grant (the "Grant") described below, to be made upon the following terms and conditions:

1. The Principal Investigator is **Matthew K. Hoffman, M.D., MPH.** The project name is **"Clindamycin to reduce preterm birth in a low resource setting: A randomized placebo-controlled trial."** The total project grant award for the period of **April 1, 2013** to **March 31, 2016** is **$418,262.** The Supervising Institution is **Christiana Care Health Services, Inc.**

2. This Grant is awarded on the condition that proof of IRB approval is received, proof of registration as a clinical trial at https://register.clinicaltrials.gov, or equivalent, is provided and the enclosed budget supersedes any previous requests. These requirements must be met and the project must begin by **June 22, 2013.**

3. By acceptance of the Grant, the Principal Investigator and the Supervising Institution expressly acknowledge and accept all of the conditions in this Award Letter as well as the conditions stated in the document entitled Conditions of Grant, a copy of which is enclosed and made part of this Grant by this reference. Please pay particular attention to the details stated in this Award Letter as well as in the Conditions of Grant, and retain them for future reference. Unauthorized reallocation of funds or failure to submit semiannual reports as required will give the Fund the right, but not the obligation, to suspend the Grant. If suspended, the Grant can only be reinstated upon written authorization from the Fund. Unless otherwise specifically stated in this Award Letter, this Grant shall be paid to the Supervising Institution under whose supervision the Principal Investigator shall be responsible for the research and other activities required to complete the project.

4. The Principal Investigator and Supervising Institution agree to adhere to this Award Letter and the Conditions of Grant, the violation of any provision of which shall be reason for suspension of the Grant for which reinstatement shall require written appeal from the Principal Investigator and Supervising Institution.

ATTESTED

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KLE Academy of Higher Education and Research,
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Belagavi-590 010,Karnataka

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5. The Supervising Institution agrees to disclose promptly and in confidence to the Fund any patentable inventions conceived and reduced to practice in the performance of research funded in whole or in part by the Grant (hereinafter referred to as "Inventions"). The Supervising Institution has the right to obtain letters patent or design patent in the name of the Supervising Institution or otherwise of any Inventions in the United States or in any applicable foreign countries covering such, all costs for such patenting to be paid by the Supervising Institution. The Supervising Institution agrees to grant to the Fund a paid-up, non-exclusive license to any Inventions for internal, non-commercial research purposes only.

6. To accomplish the purposes set forth above, the Principal Investigator in accordance with the Supervising Institution's policies and practices will (a) disclose promptly and report fully all Inventions to the Supervising Institution; (b) cooperate with the Supervising Institution in securing intellectual property protection for such Inventions; (c) deliver to the Supervising Institution copies of all relevant notes, drawings, blueprints and papers upon request and give other reasonable assistance in the preparation or defense of patents or patent applications for such Inventions; and (d) sign all papers as appropriate for the filing of any application for such letters patent or design patent.

7. Income received by Supervising Institution from commercially licensing any Invention shall be shared with the Fund. The Fund's share shall be determined by mutual agreement between Supervising Institution and the Fund after a license has been executed for such Invention. The Fund's share will be determined on a case-by-case basis and be proportional to the level of support provided by the Fund to the research that resulted in such Invention and will begin when Net Income on any license exceeds $250,000. Net Income is defined to be gross income less unreimbursed expenses for obtaining and maintaining patent rights and mandatory distributions under the Policy of the Supervising Institution (to include distributions to inventors).

8. If the Supervising Institution decides to abandon the commercialization or licensing activities associated with a disclosed Invention, the Fund will be notified and given the option to execute a license to Invention (under standard Supervising Institution terms), with rights to sublicense. At Fund request and expense, the Supervising Institution will continue the patent or patent application process.

9. Any activities associated with a Thrasher Research Fund Grant conducted in, or affiliated with, a country outside the United States, must be performed in accordance with U.S. export control and trade sanctions laws and regulations. The Supervising Institution agrees to take full responsibility for ensuring that any necessary U.S. Government export control or trade sanctions authorizations are obtained and maintained throughout the duration of the project. The Supervising Institution assumes responsibility for (and, to the extent allowable by law, shall indemnify Thrasher Research Fund from and against) any and all liability, loss, expense, or claims for injury or damages arising out of the Supervising Institution's performance of this Grant, but only in proportion to and to the extent such liability, loss, expense or claims for injury or damages are caused by or result from the negligent or intentional act or omissions of the Supervising Institution, its officers, employees, or agents.

10. This Grant supersedes your Grant proposal application and all other prior dealings between you and the Fund regarding your proposal.

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
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Belagavi-590 010,Karnataka

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11. In the event the Principal Investigator transfers from the within-named Supervising Institution to another institution, this Grant or the project funded thereunder may be continued with such other institution, and such other institution may become a Successor Supervising Institution, only if (a) such Successor Supervising Institution agrees to be bound by the terms and conditions of an amended Award Letter and Conditions of Grant reflecting such transfer, and (b) all of the parties hereto and the Successor Supervising Institution mutually agree upon the allocation of Grant Award funds between the respective institutions. Except as provided herein, the parties hereto may not assign, encumber or otherwise transfer this Grant, and any such attempt at assignment, encumbrance, or transfer will be void.

When both the Supervising Institution and Principal Investigator have executed this Grant, please return one fully executed copy of this Agreement to each of the parties.

We wish you success in your research.

Sincerely,

THRASHER RESEARCH FUND

By _____
R. Justin Brown, MPH
President

CHRISTIANA CARE HEALTH SERVICES, INC.

By _____

Title _____

Dated this _____ day of _____, 2012

MATTHEW K. HOFFMAN, M.D., MPH

By _____

Dated this _____ day of _____, 2012

Revised May, 2010

ATTESTED

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

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Attachment 3 Subaward Agreement	
Organization Contacts	Collaborator Contacts
Administrative Contact Name/Title: Dr. Frances Jaeger Sr. Clinical Researcher Address: CCHS Dept. of OB/GYN, Suite 1903 4755 Ogletown-Stanton Rd. Newark, DE 19718 Telephone: 302-733-3350; 708-638-7540 cell Fax: 302-733-6572 Email: Fjaeger@christianacare.org	**Administrative Contact/Research Coordinator** Name/Title: Dr. Shivaprasad Goudar Research Coordinator Address: JNMC Women's & Children's Health Research Unit Nehru Nagar, Belgaum - 590010 Karnataka, India Telephone: +91 94481 26371 Fax: +91 831 247 2891 Email: sgoudar@jnmc.edu
Principal Investigator Name/Title: Dr. Matthew K. Hoffman Address: Christiana Care Health Services Dept. of Obstetrics/Gynecology, Suite 1905 4755 Ogletown-Stanton Rd. Newark, DE 19718 Telephone: 302-733-6610 Fax: 302-733-6572 Email: MHoffman@christianacare.org	**Co-Principal Investigator** Name/Title: Dr. Mrutyunjaya B. Bellad Address: Dept. of Obstetrics/Gynecology Jawaharlal Nehru Medical College Nehru Nagar, Belgaum - 590010 Karnataka, India Telephone: +91 831 247 1525 Fax: +91 831 247 2891 Email: Mbbellad@hotmail.com
Financial Contact Name/Title: Debra Booth Grants and Contracts Manager Address: CCHS Dept. of OB/GYN, Suite1906 4755 Ogletown-Stanton Rd. Newark, DE 19718 Telephone: 302-733-1279 Fax: 302-733-6572 Email: DBooth@christianacare.org	**Financial Contact** Name/Title: Sanjay Chougule Budget Administrator Address: JNMC Women's & Children's Health Research Unit Nehru Nagar, Belgaum - 590010 Karnataka, India Telephone: +91 831 244 4195 Fax: +91 831 247 2891 Email: sanjaychgl21@gmail.com
Authorized Official Name/Title: Thomas L. Corrigan Sr. Vice President/Chief Fin. Officer Address: Christiana Care Health Services, Inc. 200 Hygeia Drive, Suite 2604 Newark, DE 19713-2049 Telephone: 302-623-7203 Fax: 302-623-7377 Email: TCorrigan@christianacare.org	**Authorized Official** Name/Title: Dr. Ashok S. Godhi Principal Address: Jawaharlal Nehru Medical College Nehru Nagar, Belgaum – 590010 Karnataka, India Telephone: +91 0831 247 1350 Fax: +91 831 247 0759 Email: drashokgodhi@jnmc.edu

ATTESTED

Dr. V.A.Kothiwale
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/PABX : 26588980, 26588707, 26589336, 26589245,
26589873, 26589414
फैक्स/FAX : 011-26588662, 011-26589791, 011-26589258

तार / GRAM : विज्ञानी / SCIENTIFIC
Web-site : www.icmr.nic.in
E-mail : icmrhqds@sansad.nic.in

भारतीय आयुर्विज्ञान अनुसंधान परिषद

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 E
Div of RCH
Email: shalinisingh.icmr@gmail.com
Ph : 9811615561, 011-26589438

No: 5/7/925/13-RCH
Dated: 18.6.2014

Sub: Indo-Foreign project entitled "Clindamucin to reduce preterm birth in a low resource setting: a randomized placebo-controlled trial"

Dear Dr Bellad,

This is to inform you that the Health Ministry's Screening Committee (HMSC) at Indian Council of Medical Research, New Delhi has approved the above mentioned proposal.

With best wishes,

Yours sincerely,

(SHALINI SINGH)
for Director General

Dr MB Bellad,
Prof, Dept of Obst & Gynae
J N 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

06

F12-00159

SUB-GRANT AGREEMENT (July 16, 2012)

Between
KLE University's JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM, INDIA
and
THE UNIVERSITY OF BRITISH COLUMBIA

I. This is a Sub-grant Agreement ("Agreement") under an Agreement (the "Prime Agreement") dated 5 November 2010 (with effect from 12 November 2010) between the Bill & Melinda Gates Foundation (the "Prime Sponsor") and the University of British Columbia, a corporation existing under the *University Act* of British Columbia with offices at 103 – 6190 Agronomy Road, Vancouver, British Columbia, V6T 1Z3, Canada, for the project PRE-EMPT (Pre-eclampsia, Eclampsia, Monitoring, Prevention & Treatment) (the "Prime Project").
The parties to this Agreement are The University of British Columbia (hereinafter referred to as "UBC") and the KLE University's Jawaharlal Nehru Medical College, Belgaum, India, (hereinafter referred to as "SUB-AWARDEE").
Further, SUB-AWARDEE will execute a separate subcontract with S Nijalingappa Medical College, Bagalkot "SNMC" for providing personnel and other resources for implementation of activities related to the research project .

UBC and SUB-AWARDEE are each referred to herein as a "Party" and jointly as "the Parties".

This Agreement sets forth the terms for a sub-grant by UBC to SUB-AWARDEE in the amount of **USD $195,230.00** in support of the research project to test new community level strategies for the monitoring, prevention, and treatment of pre-eclampsia, as more fully described in Annex 1 hereto (the "Project"). Specifically, the Agreement pertains to the CLIP Feasibility Study Project Plan.

The Sub-grant Agreement between the Parties comprises:

This Agreement;
Annex 1 – Original BMGF PRE-EMPT PROPOSOAL Research Proposal and Budget; and
Annex 2 – PROPOSAL CLIP FEASIBILITY STUDY
Annex 3 – PRIME AGREEMENT

II. The budget for the activities to be reimbursed by UBC is set out in Annex 1. Should major changes between categories of expenditure become necessary in the course of implementing the activities, SUB-AWARDEE shall proceed in accordance with the provision set forth in Article IV. 3(i) below.

III. Responsibility

1. SUB-AWARDEE Co-Principal Investigators are responsible for the proper management and conduct of the Project.

2. The UBC Principal Investigator shall be responsible for directing the Project, reviewing, evaluating and monitoring SUB-AWARDEE's technical, scientific and programmatic performance under this Agreement.

3. UBC shall be responsible for the provision of funds to SUB-AWARDEE for the Project, in accordance with the terms of this Agreement and its Annexes.

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

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IV. Financial arrangements

1. Schedule of payments

The total amount of the funds to be provided by UBC to SUB-AWARDEE (the "contribution") is **USD $195,230.00.** The amount of **$170,230.00** will be paid upon signing of this agreement, and **USD $ 25,000.00** will be paid within 30 days of receipt of the final report.

2. Payment of the contribution

Payments shall be deposited according to the above schedule of payments in the SUB-AWARDEE's bank account:

ACCOUNT DETAILS FOR USD PAYMENT

CORRESPONDENT BANK NAME AND ADDRESS:

BENEFICIARY BANK
NAME AND ADDRESS:

Syndicate Bank, JNMC Campus, Nehru Nagar, Belgaum, Karnataka – India, PIN: 590010.

BANK ROUTING NO (SORT CODE, SWIFT CODE OR IBAN): **SYNBINBB155**

DEUTSCH BANK TRUST COMPANY AMERICAS NEWYORK

ACCOUNT NAME (IN THE NAME OF THE INSTITUTE): **Principal, J. N. Medical College, Belgaum.**

ACCOUNT NUMBER: **05043030000042**

3. Utilization of funds and accounting

(i) The payment shall be used and for the purposes indicated in Annex 1 hereto and shall be administered in accordance with the terms of this Agreement and the SUB-AWARDEE Financial Regulations and Rules as contained in Annex 4. Any budget cost category change of more than 10% must be approved in writing by UBC in advance. No grant funds may be used to reimburse expenses incurred prior to the starting date of the Project.

(ii) Any interest earned on the cash balance of the contribution shall be used in accordance with SUB-AWARDEE Financial Regulations and Rules, and financial and administrative rules and practices of SUB-AWARDEE.

(iii) Any balance of the contribution that is outstanding at the time of expiration of the Project, or of termination of this Agreement, and after all properly incurred

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obligations by SUB-AWARDEE prior to expiration or termination have been fully liquidated, shall be repaid to UBC.

V. Implementation

1. Period of implementation

The starting date of the Project shall be **July 20, 2012**.
The completion date of the Project shall be **August 31, 2013**, with a Preliminary Feasibility Study report due **January 15, 2013**, an interim Feasibility Study report due by **March 31, 2013** and a final report due by **September 30, 2013**.

SUB-AWARDEE will use reasonable efforts to perform the Project substantially in accordance with the terms and conditions of this Agreement.

SUB-AWARDEE shall have no obligation to implement the Project unless all necessary and sufficient funds for the implementation have been received by SUB-AWARDEE.
A period of up to 12 months shall be allowed after completion of the Project, or of any termination of this Agreement, to liquidate all obligations for activities completed by SUB-AWARDEE prior to expiration or termination of this Agreement.

2. Completion of Deliverables

During the term of the Project and by agreement of the Party Scientific Contacts, the Parties will enter into a further agreement to conduct the CLIP RCT in India.
This commitment will be voided in case of events beyond the control of the SUB-AWARDEE. These events may include, but are not restricted to: acts of God, acts of local or provincial governments, fires, floods, epidemics, quarantine restrictions, strikes or labour unrest, freight embargoes, war or political instability and unusually severe weather.

VI. Reporting

1. Technical

SUB-AWARDEE shall transmit to UBC at quarterly intervals, a technical report on the progress in the activities financed by the contribution.

Technical Reports are due on the Target Dates outlined above, with a Preliminary Feasibility Study report due **January 15, 2013**, an interim Feasibility Study report due by **March 31, 2013** and a final report due by **September 30, 2013**.

The parties will engage in regular monthly teleconference calls during the course of the Project.

2. Financial

The income and expenditure recorded in respect of the contribution under this Agreement shall be indicated in the SUB-AWARDEE Financial Reports on an annual and biennial basis. Certified financial statements of income and expenditure shall be provided to UBC on a yearly basis. A final certified statement of income and expenditure will be provided by SUB-

ATTESTED

Dr. V.A.Kothiwale
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Belagavi-590 010,Karnataka

09

AWARDEE, after settlement of all obligations for activities started by SUB-AWARDEE prior to expiration or early termination of the Agreement.

All reports will be submitted to the UBC Principal Investigator at the address set forth in Section XXI below.

VII. Audit

It is understood that all agreements with SUB-AWARDEE are subject exclusively to its internal and external auditing procedures.

VIII. Change of SUB-AWARDEE Co-Principal Investigators

If the SUB-AWARDEE Co-Principal Investigators become unable or unwilling to continue the Project, SUB-AWARDEE will use all reasonable endeavors to find a replacement within a period not exceeding three (3) months. SUB-AWARDEE shall promptly inform UBC of any change of the SUB-AWARDEE Co-Principal Investigators.

IX. Acknowledgement

Neither party shall use the name or emblem of the other in any form of advertising or promotion without the prior written approval of the other party.

SUB-AWARDEE may not make any statement or otherwise imply to the media, the general public or any other donor or investor that SUB-AWARDEE's participation in this Project is supported by any organization other than UBC, unless SUB-AWARDEE has directly received funds from the other organization (prime sponsor). SUB-AWARDEE may state that UBC is the grantee of the Bill & Melinda Gates Foundation and that SUB-AWARDEE is a sub-grantee of UBC for the Project.

SUB-AWARDEE shall obtain advance approval from UBC for any use of the name or logo of the Prime Sponsor.

X. Termination

Either party may terminate this Agreement upon written notification to the other. Such termination shall enter into effect three months after notice has been received subject to the settlement of any outstanding obligations.

XI. Global Access

SUB-AWARDEE's activities pursuant to this Agreement must be consistent with and in furtherance of Global Access and the scientific and charitable objectives of the Prime Project, as more fully described in the Prime Agreement.

XII. Publications

SUB-AWARDEE has the right to publish and otherwise publicly disclose information it has

ATTESTED

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Belagavi-590 010,Karnataka

gained in the course of the conduct of the Project in accordance with the terms of this Agreement. The Parties agree with, and will give effect to, the publication provisions contained in the Prime Agreement.

XIII. Intellectual Property Rights

All rights in the work emanating from the Project under this Subgrant Agreement, including ownership of the SUB-AWARDEE background intellectual property and copyright thereof, shall be vested in SUB-AWARDEE. SUB-AWARDEE hereby grants UBC a royalty-free, non-exclusive license to use and reproduce the work for UBC's educational, scientific or research purposes, including the right of publication thereof, subject to an appropriate acknowledgement of SUB-AWARDEE's copyright (unless SUB-AWARDEE indicates that it does not wish to be associated with any such publication). UBC shall provide SUB-AWARDEE with an advance copy of any material intended to be published in sufficient time to allow SUB-AWARDEE to review such material, and UBC shall consider seriously and in good faith any comments offered by SUB-AWARDEE as long as they are received in sufficient time so as not to delay publication.

XIV. Data Sharing

SUB-AWARDEE grants to UBC the right to use data and other information created in the performance of this Agreement and the right to authorize others to use such data or information for non-commercial purposes in order to enable (i) the knowledge gained during the Project to be promptly and broadly disseminated, and (ii) the intended product(s) to be made available and accessible at reasonable cost to people most in need within developing countries. The foregoing is subject to any requirement for confidentiality.

XV. Human Subjects

It is understood that no clinical research involving the use of human subjects will be conducted under this Agreement.

XVI. Terrorism

The paragraph entitled "Anti-Terrorism" in the Prime Agreement shall not apply to SUB-AWARDEE. Nevertheless, SUB-AWARDEE confirms that it is the SUB-AWARDEE's policy not to engage in, support or promote terrorism, either directly or indirectly through another organization or individual.

XVII. Liability

Each Party shall be solely responsible for the manner in which it carries out its part of the collaborative activities under this Agreement. Thus, a Party shall not be responsible for any loss, accident, damage or injury suffered or caused by another Party, or that other Party's staff or sub-contractors, in connection with, or as a result of, the collaboration under this Agreement.

XVIII. Independent Contractor

For the purposes of this Agreement and all work to be performed hereunder, each Party shall be,

ATTESTED

Dr. V.A.Kothiwale
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 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, nor 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.

XIX. Assignment

This Agreement shall not be assignable by either Party without the prior written consent of the other Party. Any and all assignments not made in accordance with this Section shall be void.

XX. Settlement of disputes

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.

XXI. Contact Information

Administrative Contacts

SUB-AWARDEE

Dr Shivaprasad S Goudar,
Professor of Physiology,
JN Medical College

sgoudar@jnmc.edu; +91 94481 26371

UBC

Mario Kasapi, Associate Director
University-Industry Liaison Office
#103 – 6190 Agronomy Road
Vancouver, British Columbia
Canada V6T 1Z3
Telephone: (604) 822-8580
Email: Mario.kasapi@uilo.ubc.ca

Scientific Contacts

SUB-AWARDEE

Dr Shivaprasad S Goudar,
Professor of Physiology,
JN Medical College

sgoudar@jnmc.edu; +91 94481 26371

UBC

Dr Peter Von Dadelszen
Maternal Fetal Medicine
The University of British Columbia
Room 426B, 4500 Oak Street,
Vancouver, British Columbia V6H 3N1
Telephone: +1 875-3054
Email: pvd@cw.bc.ca

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

XXII. Entire Agreement

This Agreement constitutes the entire agreement between UBC and SUB-AWARDEE. Any changes or modifications shall be made by amendment to this Agreement in writing executed by the duly authorized representatives of the Parties.

Accepted on behalf of the
The University of British Columbia:

.....
Dr. Mario Kasapi,
University-Industry Liaison Office

Date: July 31/12

By:
Name:
Title:

Date: Aug 2/12

LEGAL APPROVED

Accepted on behalf of the
KLE University and JN Medical College:

.....
Dr Shivaprasad S Goudar,
Professor and Head, Department of Physiology,
KLE University's J N Medical College,
Belgaum 590010 Karnataka India

Date: July 20, 2012

.....
Dr V D Patil,
Principal,
J N Medical College,
Belgaum 590010 Karnataka India

Date: 20/7/2012

ATTESTED

Dr. V.A.Kothiwale
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/22/SSG/2015-16
Ministry of Science & Technology
Department of Biotechnology
Government of India

Block 2, 8th Floor
CGO Complex, Lodhi Road
New Delhi 110 003
Dated: 02nd March, 2016

ORDER

Sanction of the President is hereby accorded under Rule 18 of the Delegation of Financial Power Rules, 1978 for the implementation of the Joint Research Project titled **"Evaluation of the introduction of a novel device in the management of hypertension and shock in pregnancy in low-resource settings"** under DBT-MRC-DFID, UK Call for proposals on "Global Research Programme: addressing the health needs of women and children in the most disadvantaged populations globally" with Indian investigators as detailed in **Para 2.2.** Indian components of the project is sanctioned at a total cost of **Rs. 72.58 lakhs (Rupees Seventy two lakhs and fifty eight thousand only)** for a period of 3 years on the terms and conditions as detailed here under:

2.0 The Project :

2.1 Project Title : "Evaluation of the introduction of a novel device in the management of hypertension and shock in pregnancy in low-resource settings".

2.2 Investigators :

A. Indian Investigators:

a. Dr. Shivaprasad S. Goudar, Principal Investigator, Department of Physiology, K.L.E. University's Jawaharlal Nehru Medical College, JN Medical College, Belgaum, Karnataka- **PI and coordinator**

b. Professor Mrutyunjaya Basavanneppa Bellad, JN Medical College, Belgaum Karnataka- **Co-PI**

B. UK Investigators:

a. Professor Andrew Shennan, King's College, London.

b. Dr. Lucy Chappell, Hannah L Nathan, King's College, London.

c. Dr. Adrian Brown, Public Health England, London.

2.3 Project Objectives:

i. The main objective is to reduce (all-cause) maternal mortality and major morbidity by 25% or more, by introducing the Micro life CRADLE Vital Sign Alert (VSA) device, a novel semi-automated vital-sign measuring device, alongside a simple training programme for device-users, to community and facility levels in low- and middle-income countries (LMICs).

ii. This will be achieved in a stepped-wedge randomized controlled trial at eight low-income country areas (Zimbabwe, Zambia (x2 areas), Sierra Leone, Uganda (X2 areas), Haiti, Malawi and Ethiopia), and in one Indian, over 21 months. The primary outcome will be a composite of maternal mortality and major morbidity (one of maternal death, ICU admission, eclampsia, stroke, or hysterectomy, with no double counting).

iii. A secondary objective is to qualitatively evaluate the acceptability, usability and feasibility of the CRADLE device, through one-to-one interviews and observations of healthcare providers (HCPs) using the device.

iv. A third objective will be to evaluate the economic impact of device implementation in these areas, to inform the subsequent scale-up of device implementation.

2.4 Time Schedule: The duration of the project is three years from the date of financial sanction.

2.5 Manpower: The details of the manpower sanctioned for the implementation of the project are given at Annexure I.

2.6 The expenditure for recurring is debitable to:

Demand No.88	:	Department of Biotechnology
3425	:	Other Scientific Research (Major Head)
60	:	Others (Sub Major Head)
60.200	:	Assistance to other scientific bodies
60.200.29	:	Research and Development
60.200.29.17	:	Assistance for Research and Development
60.200.29.17.31	:	Grant in aid General 2015-16 (Plan)

ATTESTED

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

Contd. 2/-

2.7 **Project Cost:** The estimated cost for the Indian component of the project for three years is as under:

Recurring:

(Rs. in lakhs)

S. No.	Head	Year I	Year II	Year III	Total
A.	**Recurring**				
1.	**Consumables/ research expenses (incl. internet connections, communication expenses, reimbursements (Data capitation) and translation of forms)**	3.0	5.0	3.0	**11.0**
2.	**Manpower**				
	Study Personnel				
	i. Project Administrator (Sr. RS)	7.20	7.20	7.20	21.60
	ii. Data Entry Operator	2.30	2.30	2.30	6.90
	iii. Field Monitoring (LHV)	1.32	1.32	1.32	3.96
	iv. Training Coordinator (Sr. SN)	2.30	2.88	--	5.18
	v. Field Assistant 1	0.96	0.96	0.96	2.88
	Pilot Study Personnel				
	vi. Research Assistant	1.12	--	--	1.12
	vii. Field Assistant 1	0.44	--	--	0.44
Total Manpower		**15.64**	**14.66**	**11.78**	**42.08**
3.	**Travel**				
	i. Domestic	1.0	1.0	1.0	3.0
	ii. International	3.0	3.0	3.0	9.0
	iii. Local hospitality for visiting scientist	1.0	1.0	1.0	3.0
Total Travel		**5.0**	**5.0**	**5.0**	**5.0**
4.	**Contingency (Incl. printing and stationery supplies and printing of DCI)**	0.50	0.50	0.50	**1.50**
5.	**Overheads**	1.0	1.0	1.0	**3.0**
Total A (1+2+3+4+5)		**25.14**	**26.16**	**21.28**	**72.58**

Total Budget of the project = Rs. 72.58 lakhs

***Travel budget would include:**

1. The international travel cost of one visit of the PI and the fellow in the project to Netherlands partner.
2. The local hospitality towards the two visits from the Netherlands side to the Indian laboratory.

****Payment of emoluments to the research personnel engaged under this project will be made in accordance with the Department of Science and Technology's O.M. No. SR/S9/Z-09/2012 dated 21.10.2014.**

3. **Other Terms and Conditions:** The other terms and conditions governing this sanction are attached at Annexure III.

3.1 A Memorandum of Agreement (MOA) will be signed between the Department of Biotechnology and the grantee institution 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 institutions and its acceptance by DBT. A format of the MOA is enclosed in Annexure-IV.

3.2 The Institute/ Agency will keep the whole of the grant in a Bank Account earning interest, and 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 Institute/ Agency and shall be adjusted towards further installment of the grant and or at the time of Final Settlement of Accounts.

4. Any transfer of material would be regulated as per the guidelines and necessary clearances from MOEF and with a Material Transfer agreement signed between the two collaborating institutes.

5. As per rule 211(1) of GFR, the accounts of all grantee Institutions shall be open to inspection by the sanctioning authority / audit.

6. **Institution shall furnish a certificate that no UC/SE is pending for the central grants. Grants are subject to release on furnishing of the certificate.**

ATTESTED

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

Contd. 3/-

7. This issues under the powers delegated to this Department and with the concurrence of IFD vide their Dy. No. 102/IFD/SAN/ 4353 /2015-2016 dated 02.03.2016.

8. This sanction order has been noted at Serial No. 166 in the Register of Grants.

(Dr. Sanjay Kalia)
Scientist 'D'

To

The Pay & Accounts Officer
Department of Biotechnology
C.G.O. Complex, Lodhi Road
New Delhi-110 003

Copy to:

1. The Principal Director of Audit (Scientific Departments), IP Estate, AGCR Building, New Delhi-2.
2. Cash Section, DBT (2 copies)
3. IFD, DBT.
4. Dr. Shivaprasad S. Goudar, Principal Investigator, Department of Physiology, K.L.E. University's Jawaharlal Nehru Medical College, JN Medical College, Belgaum, Karnataka.
5. The Principal, Jawaharlal Nehru Medical College, Nehru Nagar, Belgaum-590 010, Karnataka.
6. Sanction folder.
7. File.

(Dr. Sanjay Kalia)
Scientist 'D'

ATTESTED

Dr. V.A.Kothiwale
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 – I

Details of the Manpower sanctioned for the implementation of the project titled "**Evaluation of the introduction of a novel device in the management of hypertension and shock in pregnancy in low-resource settings**".

Manpower-

S. No.	Positions	No.	Emoluments for three years (Rs. in lakhs)
1.	**Manpower**		
	Study Personnel		
	i. Project Administrator (Sr. RS)	2	21.60
	ii. Data Entry Operator	2	6.90
	iii. Field Monitoring (LHV)	1	3.96
	iv. Training Coordinator (Sr. SN)	1	5.18
	v. Field Assistant	1	2.88
	Pilot Study Personnel		
	vi. Research Assistant	1	1.12
	vii. Field Assistant	1	0.44
TOTAL			**42.08**

ATTESTED

Dr. V.A.Kothiwale
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/22/SSG/2015-16
Ministry of Science & Technology
Department of Biotechnology
Government of India

Block 2, 8th Floor
CGO Complex, Lodhi Road
New Delhi 110 003
Dated: 31st May, 2016

ORDER

In continuation of this Department's sanction order of even number dated **02nd March, 2016.** Sanction of the President is hereby accorded, under Rule 18 of the Delegation of Financial Power Rules, 1978 for the release of **Rs. 25.14 lakhs (Rupees Twenty five lakhs and fourteen thousand only)** being the **1st year release towards the Recurring head** for the Indian component of the joint project titled "**Evaluation of the introduction of a novel device in the management of hypertension and shock in pregnancy in low-resource settings**" executed by Dr. Shivaprasad S. Goudar, Principal Investigator, Department of Physiology, K.L.E. University's Jawaharlal Nehru Medical College, JN Medical College, Belgaum, Karnataka as per the break up given below:

Recurring Head

(Rs. in lakhs)

S. No.	Head	Year I
1.	**Consumables/ research expenses (incl. internet connections, communication expenses, reimbursements (Data capitation) and translation of forms)**	3.0
2.	**Manpower**	
	Study Personnel	
	i. Project Administrator (Sr. RS)	7.20
	ii. Data Entry Operator	2.30
	iii. Field Monitoring (LHV)	1.32
	iv. Training Coordinator (Sr. SN)	2.30
	v. Field Assistant 1	0.96
	Pilot Study Personnel	
	vi. Research Assistant	1.12
	vii. Field Assistant 1	0.44
Total Manpower		**15.64**
3.	**Travel**	
	i. Domestic	1.0
	ii. International	3.0
	iii. Local hospitality for visiting scientist	1.0
Total Travel		**5.0**
4.	**Contingency (Incl. printing and stationery supplies and printing of DCI)**	0.50
5.	**Overheads**	1.0
Total A (1+2+3+4+5)		**25.14**

Total amount to be released under recurring head = Rs. 25.14 lakhs

2. The other terms and conditions governing the financial sanction will remain unaltered.

3. The amount of **Rs. 25.14 lakhs (Rupees Twenty five lakhs and fourteen thousand only)** will be drawn by the DDO, DBT from PAO, DBT and will be disbursed to the Registrar K.L.E. University, Belgaum, Karnataka as per details given below:

Name of the Bank	:	Syndicate Bank, K.L.E. University, Jawaharlal Nehru Medical College Campus, Belgaum, Karnataka
Bank A/c No.	:	050421700000039
IFSC Code	:	SYNB0000504
MICR Code	:	590025005

4. As per rule 211(1) of GFR, the accounts of all grantee Institutions shall be open to inspection by the sanctioning authority / audit.

Contd. 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

5. The expenditure involved is debitable to:

Demand No.79	:	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 2016-17 (Plan)

6. **This is first release of the project so no UC/SE is pending with the project.**

7. 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.

8. This issues under the powers delegated to this Department with the concurrence of IFD, DBT vide their Dy. No. 102/IFD/SAN/ 199 /2016-2017 dated 26.04.2016.

9. This sanction order has been entered at Serial No. 145 in the register of grants.

(Dr. Sanjay Kalia)
Scientist 'D'

To

The Pay & Accounts Officer
Department of Biotechnology
C.G.O. Complex, Lodhi Road
New Delhi-110 003

Copy to:

1. The Principal Director of Audit (Scientific Departments), IP Estate, AGCR Building, New Delhi-2.
2. Cash Section, DBT (2 copies)
3. IFD, DBT.
4. Dr. Shivaprasad S. Goudar, Principal Investigator, Department of Physiology, K.L.E. University's Jawaharlal Nehru Medical College, JN Medical College, Belgaum, Karnataka.
5. The Registrar K.L.E. University, Belgaum, Karnataka.
6. Sanction folder.
7. File.

(Dr. Sanjay Kalia)
Scientist 'D'

ATTESTED

Dr. V.A.Kothiwale
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/22/SSG/2015-16
Ministry of Science & Technology
Department of Biotechnology
Government of India

Block 2, 8th Floor
CGO Complex, Lodhi Road
New Delhi 110 003
Dated: 31st May, 2016

ORDER

In continuation of this Department's sanction order of even number dated **02nd March, 2016**, Sanction of the President is hereby accorded, under Rule 18 of the Delegation of Financial Power Rules, 1978 for the release of **Rs. 25.14 lakhs (Rupees Twenty five lakhs and fourteen thousand only)** being the **1st year release towards the Recurring head** for the Indian component of the joint project titled "**Evaluation of the introduction of a novel device in the management of hypertension and shock in pregnancy in low-resource settings**" executed by Dr. Shivaprasad S. Goudar, Principal Investigator, Department of Physiology, K.L.E. University's Jawaharlal Nehru Medical College, JN Medical College, Belgaum, Karnataka as per the break up given below:

Recurring Head

(Rs. in lakhs)

S. No.	Head	Year I
1.	**Consumables/ research expenses (incl. internet connections, communication expenses, reimbursements (Data capitation) and translation of forms)**	3.0
2.	**Manpower**	
	Study Personnel	
	i. Project Administrator (Sr. RS)	7.20
	ii. Data Entry Operator	2.30
	iii. Field Monitoring (LHV)	1.32
	iv. Training Coordinator (Sr. SN)	2.30
	v. Field Assistant I	0.96
	Pilot Study Personnel	
	vi. Research Assistant	1.12
	vii. Field Assistant I	0.44
Total Manpower		**15.64**
3.	**Travel**	
	i. Domestic	1.0
	ii. International	3.0
	iii. Local hospitality for visiting scientist	1.0
Total Travel		**5.0**
4.	**Contingency (Incl. printing and stationery supplies and printing of DCI)**	0.50
5.	**Overheads**	1.0
Total A (1+2+3+4+5)		**25.14**

Total amount to be released under recurring head = Rs. 25.14 lakhs

2. The other terms and conditions governing the financial sanction will remain unaltered.

3. The amount of **Rs. 25.14 lakhs (Rupees Twenty five lakhs and fourteen thousand only)** will be drawn by the DDO, DBT from PAO, DBT and will be disbursed to the Registrar K.L.E. University, Belgaum, Karnataka as per details given below:

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Bank A/c No.	:	05042170000039
IFSC Code	:	SYNB0000504
MICR Code	:	590025005

4. As per rule 211(1) of GFR, the accounts of all grantee Institutions shall be open to inspection by the sanctioning authority / audit.

Contd. 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

5. The expenditure involved is debitable to:

Demand No.79	:	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 2016-17 (Plan)

6. **This is first release of the project so no UC/SE is pending with the project.**

7. 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.

8. This issues under the powers delegated to this Department with the concurrence of IFD, DBT vide their Dy. No. 102/IFD/SAN/ 199 /2016-2017 dated 26.04.2016.

9. This sanction order has been entered at Serial No. 415 in the register of grants.

(Dr. Sanjay Kalia)
Scientist 'D'

To

The Pay & Accounts Officer
Department of Biotechnology
C.G.O. Complex, Lodhi Road
New Delhi-110 003

Copy to:

1. The Principal Director of Audit (Scientific Departments), IP Estate, AGCR Building, New Delhi-2.
2. Cash Section, DBT (2 copies)
3. IFD, DBT.
4. Dr. Shivaprasad S. Goudar, Principal Investigator, Department of Physiology, K.L.E. University's Jawaharlal Nehru Medical College, JN Medical College, Belgaum, Karnataka.
5. The Registrar K.L.E. University, Belgaum, Karnataka.
6. Sanction folder.
7. File.

(Dr. Sanjay Kalia)
Scientist 'D'

ATTESTED

Dr. V.A.Kothiwale
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
Indian Council of Medical Research
Department of Health Research
Ministry of Health & Family Welfare
V. Ramalingaswami Bhawan, Ansari Nagar
New Delhi-110 029, 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

Tele.: (O) 26589258 PABX 26589334, 26589335, 26589336 Extn. 286
(R) 25082707 Fax: 26589498 E-mail: kalkatla_s_@yahoo.com, kanikaram@icmr.org.in

ATTESTED

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

दू.भा.वा.विनि./PABX : 26588980, 26588707, 26589338, 26589745,
26589833, 26589414
फैक्स/FAX 011-26588662, 011-26589791, 011-26589258

तार / GRAM : विज्ञानी / SCIENTIFIC
Web-site : www.icmr.nic.in
E-mail : icmrdg@sansad.nic.in

भारतीय आयुर्विज्ञान अनुसंधान परिषद

INDIAN COUNCIL OF MEDICAL RESEARCH

वी.रामलिंगस्वामी भवन, अन्सारी नगर, पोस्ट बाक्स 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. 5/7/624/11-RHN
Dated: Oct 7th, 2011

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

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

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

बो.रा.सा.सं./PABX : 26588980, 26589707, 26589336, 26589745,
26589873, 26589414
फैक्स/FAX : 011-26588662, 011-26589791, 011-26589358

तार / GRAM : चिकित्सी / SCIENTIFIC
Web-site : www.icmr.nic.in
E-mail : icmrhqd@hotmail.nic.in

भारतीय आयुर्विज्ञान अनुसंधान परिषद
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. Vasantha Thavaraj
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 Minuets are attached. Kindly acknowledge the receipt of this letter.

With kind regards,

Yours sincerely,

(Vasantha Thavaraj)

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 precarciniogenic lesions in individuals occupationally exposed to polycyclic aromatic hydrocarbons (PAHs) and through tobacco use under Dr. Devendra Parmar, 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 Ballabhgarh, 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 Krishnan, 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

SUBCONTRACT
AMENDMENT NUMBER FOUR (4)

Prime Recipient	Subcontractor
Institution/Organization ("Prime Recipient") Name: Regents of the University of Colorado, a body corporate, for and on behalf of the **University of Colorado Denver** Address: University of Colorado Denver, Office of Grants and Contracts, Anschutz Medical Campus Bldg. 500, W1126, 13001 E 17th Place, Mail Stop F428, Aurora, Colorado 80045	Institution/Organization ("Subcontractor") Name: **Jawaharlal Nehru Medical College** Address: Nehru Nagar, Belgaum Karnataka, India, PIN 590010

Prime Award No.	Subcontract No.	Amount Funded This Action:
OPP1055867_YR4	FY13.040.002	US$442,578
Prime Recipient's Principal Investigator	**Amendment No.**	**Project No.**
Nancy Krebs, MD (PI Change)	FY16.115.004 AMD4	2-5-81932

This Amendment modifies the following to the Original Terms and Conditions

1. PERIOD

The Current Period of Performance applicable to the Subcontract is extended to cover the Budget Period November 1, 2014 to October 31, 2016.

2. COMPENSATION

The budget available for the Budget Period is revised as follows:

Personnel	US$249,394
Consultant Costs	US$28.560
Supplies	US$62.200
Travel	US$44.696
Total Direct Costs	**US$384,850**
F&A Costs @ 15%	US$57,728
Total Costs	**US$442,578**
Cumulative Costs (Amount Funded to Subcontractor through the end of the Budget Period)	**US$1,462,955**

ATTESTED

Dr. V.A.Kothiwale
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. PAYMENT

Subcontractor may submit invoices to Prime Recipient, for costs incurred. Said invoices should include:

(a) Subcontract Amendment number: FY16.115.004 AMD4 (JNMC)
(b) Prime Award number: OPP1055867_YR4 (PI CHANGE)
(c) Project number: 2-5-81932
(d) The period for which reimbursement is being requested.
(e) An itemization of current and cumulative costs in accordance with the categories in the budget.
(f) Telephone number for Subcontractor's certifying officer.
(g) All invoices should be signed by Subcontractor's authorized official and include the following statement: *"I certify that all expenditures reported (or payments requested) are for appropriate purposes and in accordance with the provisions of the application and award document."* Promptly after approval of each invoice, Prime Recipient shall make payment thereof.

A final invoice for the Budget Period must be submitted within sixty (60) calendar days after termination or expiration of this Subcontract or the Budget Period, whichever is first, and must be marked "Final Invoice".

Invoices should be mailed to the attention of: Jamie Westcott; University of Colorado Denver; 12700 E, 19th Ave., Campus Box C225; Aurora, Colorado 80045. Jamie Westcott may be reached by telephone at (303) 724-3265.

All other terms and conditions of the Subcontract remain in full force and effect.

By an Authorized Official (UCD OGC) of Prime Recipient:	By an Authorized Official of Subcontractor: (JNMC)
Thomas Keith — 2/17/16	MH — 08/01/2016
Name — Date	Name Dr. N.S Mahantshetti — Date
Title	Title PRINCIPAL, JNMC
Acknowledged by Principal Investigator (UCD PI) of Prime Recipient	
Nancy Kent — 1-11-16	
Name — Date	
Title Professor	

July 2008 FDP

ATTESTED

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

SUBCONTRACT
AMENDMENT NUMBER FIVE (5)

Prime Recipient	Subcontractor	
Institution/Organization ("Prime Recipient") Name: Regents of the University of Colorado, a body corporate, for and on behalf of the **University of Colorado Denver** Address: University of Colorado Denver, Office of Grants and Contracts, Anschutz Medical Campus Bldg. 500, W1126, 13001 E 17th Place, Mail Stop F428, Aurora, Colorado 80045	Institution/Organization ("Subcontractor or Subrecipient") Name: Jawaharlal Nehru Medical College Address: Nehru Nagar, Belgaum Karnataka, India, PIN 590010 DUNS: 650251213	
Prime Award No.: OPP1055867_AMD03	Subcontract No.: FY13.040.002	Amount Funded This Action: USD$160,736
Prime Recipient's Principal Investigator: Nancy Krebs, MD	Amendment No.: FY17.115.007_AMD5	Project No.: 2-5-81932
Project Title: Implementing Integrated Maternal Nutrition Interventions		

1. **PERIOD**

The Current Period of Performance applicable to the Subcontract is extended to cover the Budget Period November 1, 2014 to October 31, 2017.

2. **COMPENSATION**

The budget available for the Budget Period is revised as follows:

Personnel	USD$15,050.93
Consultation Costs	USD$38,102
Supplies	USD$79,169.91
Travel	USD$7447.07
Total Direct Costs	**USD$139,770**
F&A Costs @ 15%	USD$20,966
Total Costs	**USD$160,736**
Total Cumulative Costs (Total amount funded through the budget period)	**USD$1,623,691**

3. **PAYMENT**

Subcontractor may submit invoices to Prime Recipient, for costs incurred. Said invoices should include:

(a) Subcontract Amendment number: FY17.115.007_AMD5 JNMC
(b) Prime Award number: OPP1055867_AMD03
(c) Project number: 2-5-81932
(d) The period for which reimbursement is being requested.
(e) An itemization of current and cumulative costs in accordance with the categories in the budget.
(f) Telephone number for Subcontractor's certifying officer.
(g) All invoices should be signed by Subcontractor's authorized official and include the following statement: *"I certify that all expenditures reported for payments requested) are for appropriate purposes and in accordance with the provisions of the application and award document."* Promptly after approval of each invoice, Prime Recipient shall make payment thereof.

ATTESTED

Dr. V.A.Kothiwale
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 final invoice for the Budget Period must be submitted within sixty (60) calendar days after termination or expiration of this Subcontract or the Budget Period, whichever is first, and must be marked "Final Invoice".

Invoices should be mailed to the attention of: Jamie Westcott; University of Colorado Denver; 12700 E. 19th Ave., Campus Box C225; Aurora, Colorado 80045. Jamie Westcott may be reached by telephone at (303) 724-3265.

4. REVISED TERM

Paragraph 3 of the Subcontract terms and conditions is deleted in its entirety and is replaced with the following:

A final statement of cumulative costs incurred, including cost sharing, marked "FINAL" must be submitted to UCD's Financial Contact, as shown in Attachments 3A, before the earlier of sixty (60) days after Subaward end date or fifteen (15) days prior to the date UCD's final invoice is required by the Sponsor in the Prime Award. The final statement of costs shall constitute Subcontractor's final financial report.

UNIFORM GUIDANCE/FULL FORCE AND EFFECT

The Subcontract is hereby revised to include any and all applicable changes required by the implementation of 2 C.F.R § 200 UNIFORM ADMINISTRATIVE REQUIREMENTS, COST PRINCIPLES, AND AUDIT REQUIREMENTS FOR FEDERAL AWARDS.

All other terms and conditions of the Subcontract remain in full force and effect.

By an **Authorized Official** of Prime Recipient: **(UCD OGC)** Thomas Keith 1/31/17 Name Date	By an Authorized Official of **Subcontractor: (JNMC)** 21/01/17 Name Dr. N. S. Mahantshetti Date
Acknowledged by **Principal Investigator** of Prime Recipient **(UCD PI):** 1/23/17 Name 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

29

Non-Federal Research Subcontract Amendment

Contractor	Subcontractor
Institution/Organization ("Contractor") **Name:** Regents of the University of Colorado, a body corporate, for and on behalf of the **University of Colorado Denver** **Address:** University of Colorado Denver, Office of Grants and Contracts, Anschutz Medical Campus Bldg. 500, W1126, 13001 E 17th Place, Mail Stop F428, Aurora, Colorado 80045-2571	**Institution/Organization** ("Subcontractor") **Name:** Jawaharlal Nehru Medical College **Address:** Nehru Nagar, Belgaum Karnataka, India, PIN 590010 Award: OPP1055867
Contractor Principal Investigator: Nancy Krebs, MD	**Subcontractor Principal Investigator:** Dr. Shivaprasad S. Goudar
Amendment No.: FY18.115.011_AMD6	**Subcontract No.:** FY13.040.002 / **Contractor Project No.:** 2-5-81932
Project Title: Implementing Integrated Maternal Nutrition Interventions	
Subcontract Period of Performance: **Budget Period:** Start: 11/1/2017 End: 10/31/2018 **Total Anticipated Project Period:** Start: 12/1/2012 End: 10/31/2018	**Contract Value:** Funding This Action: $ 144,176 (USD) Total Funding to Date: $ 1,767,867 (USD)

Amendment(s) to Original Terms and Conditions

1. PERIOD
The Subcontract Period of Performance is revised to cover November 1, 2017 to October 31, 2018.
2. BUDGET
The cumulative budget available for the Subcontract Period of Performance is attached.
3. INVOICING
Subcontractor's invoicing requirements are revised to include the following information as it appears in this Amendment: Subcontract Amendment Number; Contractor Project Number; Subcontract Period of Performance; and Contractor Purchase Order Number (if provided by Contractor).

All other terms and conditions of the Subcontract remain in full force and effect.

By an **Authorized Official** of Contractor: Ryan Holland Digitally signed by Ryan Holland DN: cn=Ryan Holland, o=University of Colorado Denver, ou=Office of Grants and Contracts, email=ryan.holland@ucdenver.edu, c=US Date: 2018.01.04 12:14:03 -07'00' 01/04/18 Date	By an Authorized Official of **Subcontractor**: (Dr N S Mahantshetti) 12/12/17 Date
Acknowledged by Contractor **Principal Investigator:** 12/14/17 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

Budget Period:	11/1/2017 to 10/31/2018
Personnel	$53,704.00
Salary	$53,704.00
Benefits	$0.00
Equipment	
Supplies	$70,412.00
Travel	-$420.00
Other Expenses	$1,675.00
Consulting	
Total Direct Costs	**$125,371.00**
Total BASE for F&A	**$125,371.00**
F&A Costs	$18,805.00
15.00%	
*Exclusions	
TOTAL COSTS	**$144,176.00**
TOTAL CUMULATIVE	**$1,767,867.00**

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 Research Subcontract Amendment

Contractor	Subcontractor
Institution/Organization ("Contractor") **Name:** Regents of the University of Colorado, a body corporate, for and on behalf of the **University of Colorado Denver** **Address:** University of Colorado Denver, Office of Grants and Contracts, Anschutz Medical Campus Bldg. 500, W1126, 13001 E 17th Place, Mail Stop F428, Aurora, Colorado 80045-2571	**Institution/Organization** ("Subcontractor") **Name:** Jawaharlal Nehru Medical College **Address:** Nehru Nagar, Belgaum Karnataka, India, PIN 590010 Award: OPP1055867
Contractor Principal Investigator: Nancy Krebs, MD	**Subcontractor Principal Investigator:** Dr. Shivaprasad S. Goudar
Amendment No.: FY19.115.007_AMD7	**Subcontract No.:** FY13.040.002 **Contractor Project No.:** 2-5-81932
Project Title: Implementing Integrated Maternal Nutrition Interventions	
Subcontract Period of Performance: **Budget Period:** Start: 11/1/2018 End: 1/31/2019 **Total Anticipated Project Period:** Start: 12/1/2012 End: 1/31/2019	**Contract Value:** Funding This Action: $ 29,302 (USD) Total Funding to Date: $ 1,797,169 (USD)

Amendment(s) to Original Terms and Conditions

1. PERIOD
The Subcontract Period of Performance is revised to cover November 1, 2018 to January 31, 2019.
2. BUDGET
The cumulative budget available for the Subcontract Period of Performance is attached.
3. INVOICING
Subcontractor's invoicing requirements are revised to include the following information as it appears in this Amendment: Subcontract Amendment Number; Contractor Project Number; Subcontract Period of Performance; and Contractor Purchase Order Number (if provided by Contractor).

All other terms and conditions of the Subcontract remain in full force and effect.

By an **Authorized Official** of Contractor: Ryan Holland Digitally signed by Ryan Holland DN: cn=Ryan Holland, o=University of Colorado Denver, ou=Office of Grants and Contracts, email=ryan.holland@ucdenver.edu, c=US Date: 2018.10.26 15:58:45 -06'00' 10/26/18 Date	By an Authorized Official of **Subcontractor:** (Dr N.S. Mahantshetti) Date 5/10/18
Acknowledged by Contractor **Principal Investigator:** 10-22-18 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

Budget Period:	11/1/2018 to 1/31/2019
Personnel	$7,520.00
Salary	$7,520.00
Supplies	$13,520.00
Travel	$4,440.00
Total Direct Costs	**$25,480.00**
Total BASE for F&A	**$25,480.00**
F&A Costs	$3,822.00
15.00%	
*Exclusions	
TOTAL COSTS	**$29,302.00**
TOTAL CUMULATIVE	**$1,797,169.00**

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 Research Subcontract Amendment

Contractor	Subcontractor
Institution/Organization ("Contractor") **Name:** Regents of the University of Colorado, a body corporate, for and on behalf of the **University of Colorado Denver** **Address:** University of Colorado Denver, Office of Grants and Contracts, Anschutz Medical Campus Bldg. 500, W1126, 13001 E 17th Place, Mail Stop F428, Aurora, Colorado 80045-2571	**Institution/Organization** ("Subcontractor") **Name:** Jawaharlal Nehru Medical College **Address:** Nehru Nagar, Belgaum Karnataka, India, PIN 590010 Award: OPP1055867
Contractor Principal Investigator: Nancy Krebs, MD	**Subcontractor Principal Investigator:** Dr. Shivaprasad S. Goudar
Amendment No.: FY19.115.011_AMD8	**Subcontract No.:** FY13.040.002 / **Contractor Project No.:** 2-5-81932
Project Title: Implementing Integrated Maternal Nutrition Interventions	
Subcontract Period of Performance: **Budget Period:** Start: 11/1/2018 End: 10/31/2019 **Total Anticipated Project Period:** Start: 12/1/2012 End: 10/31/2019	**Contract Value:** Funding This Action: $ 16,100 (USD) Total Funding to Date: $ 1,813,269 (USD)

Amendment(s) to Original Terms and Conditions

1. PERIOD
The Subcontract Period of Performance is revised to cover November 1, 2018 to October 31, 2019.
2. BUDGET
The cumulative budget available for the Subcontract Period of Performance is attached.
3. INVOICING
Subcontractor's invoicing requirements are revised to include the following information as it appears in this Amendment: Subcontract Amendment Number; Contractor Project Number; Subcontract Period of Performance; and Contractor Purchase Order Number (if provided by Contractor).

All other terms and conditions of the Subcontract remain in full force and effect.

By an **Authorized Official** of Contractor: Eric Maize 4/3/2019 Date	By an Authorized Official of **Subcontractor**: (DR NS MAHANTSHETTI) 28/03/2019 Date
Acknowledged by Contractor **Principal Investigator:** 3/29/19 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

Budget Period:	11/1/2018 to 10/31/2019
Travel	$4,000.00
Other Expenses (List below)	$10,000.00
Consulting	
Total Direct Costs	**$14,000.00**
Total BASE for F&A	**$14,000.00**
F&A Costs	$2,100.00
15.00%	
*Exclusions	
TOTAL COSTS	**$16,100.00**
TOTAL CUMULATIVE	**$1,813,269.00**

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 Research Subcontract Amendment

Contractor	Subcontractor
Institution/Organization ("Contractor") **Name:** Regents of the University of Colorado, a body corporate, for and on behalf of the **University of Colorado Denver** **Address:** University of Colorado Denver, Office of Grants and Contracts, Anschutz Medical Campus Bldg. 500, W1126, 13001 E 17th Place, Mail Stop F428, Aurora, Colorado 80045-2571	**Institution/Organization** ("Subcontractor") **Name:** Jawaharlal Nehru Medical College **Address:** Nehru Nagar, Belgaum Karnataka, India, PIN 590010 Award: OPP1055867
Contractor Principal Investigator: Nancy Krebs, MD	**Subcontractor Principal Investigator:** Dr. Shivaprasad S. Goudar
Amendment No.: FY20.115.006_AMD9	**Subcontract No.:** FY13.040.002 / **Contractor Project No.:** 2-5-81932
Project Title: Implementing Integrated Maternal Nutrition Interventions	
Subcontract Period of Performance: **Budget Period:** Start: 11/01/2019 End: 10/31/2020 **Total Anticipated Project Period:** Start: 12/1/2012 End: 10/31/2020	**Contract Value:** Funding This Action: $ 0 (NCE) Total Funding to Date: $ $1,813,269

Amendment(s) to Original Terms and Conditions

1. PERIOD
The Subcontract Period of Performance is extended to cover November 1st, 2019 to October 31st, 2020.
2. BUDGET
This is a no cost extension. No additional monies will be provided. For the services provided hereunder during the Budget Period, Contractor will reimburse Subcontractor for all reasonable, allocable, and allowable costs incurred up to, but not to exceed One Million, Eight Hundred and Thirteen Thousand, Two Hundred and Sixty-Nine ($1,813,269.00). Under no circumstances shall Contractor be responsible for paying Subcontractor in excess of $1,813,269.00 for the Budget Period, November 1st, 2019 to October 31st, 2020.
3. INVOICING
Subcontractor's invoicing requirements are revised to include the following information as it appears in this Amendment: Subcontract Amendment Number; Contractor Project Number; Subcontract Period of Performance; and Contractor Purchase Order Number (if provided by Contractor).

All other terms and conditions of the Subcontract remain in full force and effect.

By an **Authorized Official** of Contractor:	By an Authorized Official of **Subcontractor**:
Ryan Holland Digitally signed by Ryan Holland DN: cn=Ryan Holland, o=University of Colorado Denver, ou=Office of Grants and Contracts, email=ryan.holland@ucdenver.edu, c=US Date: 2019.11.12 08:27:23 -07'00' Date	21/10/2019 Date
Acknowledged by Contractor **Principal Investigator:** 10/23/19 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

World Health Organization

COVERING LETTER
LETTRE D'ACCOMPAGNEMENT

WHO/GSC/GPL
BLOCK 3510
JALAN TEKNOKRAT 6
CYBERJAYA 63000
Malaysia

WHO Reference/ *Référence OMS*	
WHO Reference	2014/432421-0
Purchase Order	201019382
Reg. File	R15-TSA-006
Unit Reference	A65780/India

Dr Shivaprasad Goudar
PRINCIPAL, J.N. MEDICAL COLLEGE,
BELGAUM (JAWAHARLAL NEHRU MEDICAL
COLLEGE, BELGAUM)
KARNATAKA
Nehru Nagar
Belgaum
Karnataka
India

Téléphone Central/Exchange: +60 3 8871 7111
Email / Courriel: GSCprocurement@who.int

Re: As part of multi-country study (India) Project A65780 - Carbetocin RTS for preventing postpartum haemorrhage: a randomized non-inferiority controlled 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 12,348,393.12 (Twelve Million Three Hundred Forty-Eight Thousand Three Hundred Ninety-Three), for conducting the above-mentioned work. We also enclose three attachment(s) referenced in the Agreement.

We kindly request that you return, duly signed, a copy of the Agreement, keeping one copy for your files.

For any technical or scientific questions, please contact Mariana WIDMER, widmerm@who.int .

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

WHO Global Service Centre

Cc: WHO Representative, India

Concerne: As part of multi-country study (India) Project A65780 - Carbetocin RTS for preventing postpartum haemorrhage: a randomized non-inferiority controlled trial.

Veuillez 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 12,348,393.12 (Twelve Million Three Hundred Forty-Eight Thousand Three Hundred Ninety-Three), vous permettant de mener à bien le travail susmentionné. Veuillez également trouver three pièces jointes mentionnées dans l'Accord.

Veuillez nous retourner, dûment signée, une copie de l'Accord et en garder une pour vos dossiers.

Pour toutes questions à caractère scientifique ou technique, veuillez contacter Mariana WIDMER, widmerm@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

World Health Organization

WHO/GSC/GPL
BLOCK 3510
JALAN TEKNOKRAT 6
CYBERJAYA 63000
Malaysia

WHO Reference/ *Référence OMS*	
WHO Reference	2014/432421-0
Purchase Order	201019382
Reg. File	R15-TSA-006
Unit Reference	A65780/India

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
Karnataka
India

Principal Investigator: Dr Shivaprasad Goudar
Telephone: +918312444194
Fax:
Email/Courriel: gshivaprasad@hotmail.com

The Amount of/*Un Montant de*: INR 12,348,393.00 (Twelve Million Three Hundred Forty-Eight Thousand Three Hundred Ninety-Three)
in respect of/*en vue de:* As part of multi-country study (India) Project A65780 - Carbetocin RTS for preventing postpartum haemorrhage: a randomized non-inferiority controlled trial.

For the period financed by this Agreement — From/*De* : 15-JUN-2014
***Période du projet** financée par le présent accord* — To/*A* : 30-NOV-2015

Summary of work/ *Description sommaire des travaux:*

1. Description of work under this Agreement/ *Description des travaux faisant l'objet du présent accord:*

The objectives are:
i) To evaluate non-inferiority of carbetocin RTS 100 ?g IM versus oxytocin 10 IU IM in the prevention of the composite outcome blood loss ?500 mL or the use of additional uterotonic drugs following vaginal delivery of the baby;
(ii) To evaluate non-inferiority of carbetocin RTS 100 ?g IM versus oxytocin 10 IU IM in the prevention of blood loss ?1000 mL.

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.

The Institute will provide all other facilities not provided for under this Agreement.

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 receipt of countersigned contract	15-JUN-2014	100.00	12,348,393.12
2	Upon receipt financial report	30-NOV-2015	0.00	0.00
3	Upon receipt of technical report	30-NOV-2015	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	Cover letter for TSA issued for clinical trial from Legal Office
2	Main protocol
3	Project budget

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.*

WHO Financial References/ *Références financières de l'OMS*

ATTESTED

Dr. V.A. Kothiwale
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

WHO/GSC/GPL
BLOCK 3510
JALAN TEKNOKRAT 6
CYBERJAYA 63000
Malaysia

WHO Reference/ *Référence OMS*

WHO Reference	2014/432421-0
Purchase Order	201019382
Reg. File	R15-TSA-006
Unit Reference	A65780/India

TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

	Project	Task	Award	Expenditure Type	Expenditure Organization	%	USD
1	HQRHR1409029	4.2	61980	512-Consulting, Research Serv.	HQ	100	209,153.00

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:

Mariana Widmer
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
13-JUN-2014

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. A. S. Godi
Division : .....
Date : 13/06/2014

PRINCIPAL
JNMC, BELGAUM

* 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

COVERING LETTER
LETTRE D'ACCOMPAGNEMENT

WHO/GSC/GPL
BLOCK 3510
JALAN TEKNOKRAT 6
CYBERJAYA 63000
Malaysia

WHO Reference/ *Référence OMS*	
WHO Reference	2016/647688-0
Purchase Order	201544467
Reg. File	n/a
Unit Reference	A65870

DR.Shivaprasad Goudar
PRINCIPAL, J.N. MEDICAL COLLEGE,
BELGAUM (JAWAHARLAL NEHRU MEDICAL
COLLEGE, BELGAUM)
KARNATAKA
Nehru Nagar
Belgaum
Karnataka
India

Téléphone Central/Exchange: +60 3 8871 7111
Email / Courriel: GSCprocurement@who.int

Re: CHAMPION 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 USD 302,410.00 (Three Hundred Two Thousand Four Hundred Ten), for conducting the above-mentioned work. We also enclose two attachment(s) referenced in the Agreement.

We kindly request that you return, duly signed, a copy of the Agreement, keeping one copy for your files.

For any technical or scientific questions, please contact Mariana WIDMER, widmerm@who.int .

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

WHO Global Service Centre

Cc: WHO Representative, India

Concerne: CHAMPION TRIAL

Veuillez 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 USD 302,410.00 (Three Hundred Two Thousand Four Hundred Ten), vous permettant de mener à bien le travail susmentionné. Veuillez également trouver two pièces jointes mentionnées dans l'Accord.

Veuillez nous retourner, dûment signée, une copie de l'Accord et en garder une pour vos dossiers.

Pour toutes questions à caractère scientifique ou technique, veuillez contacter Mariana WIDMER, widmerm@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

World Health Organization

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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: sgoudar@jnmc.edu

The Amount of/*Un Montant de*: USD 302,410.00 (Three Hundred Two Thousand Four Hundred Ten)
In respect of/*en vue de:* CHAMPION TRIAL

For the period financed by this Agreement — From/*De* : 25-JUL-2016
***Période du projet** financée par le présent accord* — To/*A* : 24-JUL-2017

Summary of work/ *Description sommaire des travaux:*

1. Description of work under this Agreement/ *Description des travaux faisant l'objet du présent accord:*

A phase III, randomized, double-blind, active, controlled, multinational, multicentre, non-inferiority trial using carbetocin room temperature stable (RTS) for the prevention of postpartum haemorrhage during the third stage of labour in women delivering vaginally.

Objective: To implement trial A65870 according to GCP guidelines.

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.

The Institute will provide all other facilities not provided for under this Agreement.

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	Countersigned contract	25-JUL-2016	100.00	302,410.00
2	Receipt of final financial report	24-JUL-2017	0.00	0.00
3	Receipt of final technical report	24-JUL-2017	0.00	0.00

2. USD 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.

USD 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	2016/647688 | Contractual - Budget Breakdown |
2	2016/647688 | 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.*

WHO Financial References/ *Références financières de l'OMS*

	Project	Task	Award	Expenditure Type	Expenditure Organization	%	USD
1	HQRHR1612205	10.1	61980	512-Consulting,	HQ	100	302,410.00

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

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World Health Organization

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WHO Reference/ *Référence OMS*

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TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

				Research Serv.			

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:

Mariana Widmer
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
21-JUL-2016

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. S. MAHANTSHETTI
Division : PRINCIPAL
Date : 22 July 2016

* 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
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TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

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.

ATTESTED

Dr. V.A.Kothiwale
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

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WHO Reference/ *Référence OMS*

WHO Reference	2016/647688-0
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TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

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 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 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 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. PRIVILÈGES ET IMMUNITÉS

Aucun des termes du présent Accord ne sera considéré comme constituant une

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

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World Health Organization

WHO/GSC/GPL
BLOCK 3510
JALAN TEKNOKRAT 6
CYBERJAYA 63000
Malaysia

WHO Reference/ *Référence OMS*	
WHO Reference	2016/647688-0
Purchase Order	201544467
Reg. File	n/a
Unit Reference	A65870

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

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.

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पी.ए.बी.एक्स./PABX : 26588980, 26588707, 26588330, 26589745,
26589873, 26589414
फैक्स/FAX : 011-26588662, 011-26589791, 011-26589258

तार / GRAM : चिकित्सी / SCIENTIFIC
Web-site : www.icmr.nic.in
E-mail : icmrhqdiv@sansad.nic.in

भारतीय आयुर्विज्ञान अनुसंधान परिषद

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

No. 5/7/1255/2015-RCH **Dated : 01.04.2016**

Dr. B.S Kodkany,
Principal Investigator,
KLE Universittiy's, J.N Medical College,
Women's and Children's Health Research Unit,
Belagaum - 590010

Dear Dr. Kodkany,

With reference to your proposal entitled "Aspirin Supplementation for Pregnancy Indicated Risk Reduction In Nulliparous (ASPIRIN) submitted to the Council for HMSC clearance, we wish to inform you that the project has been approved by the HMSC in a meeting held on 14th March 2016.

Placed below are the minutes :

II.1 Proposal for assistance / collaboration from National Institute of Health, USA.

5. Aspirin Supplementation for Pregnancy Indicated Risk Reduction In Nulliparous (ASPIRIN) under Dr. B.S Kodkany, KLE University's, J.N Medical College, Belgaum.

Approved .

Thanking you,

Yours sincerely,

(Dr. Anju Sinha)
Scientist 'E'
For Director General

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सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

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Certificate No.	:	IN-KA97144430181613N
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Description	:	AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	DR SMITHA K S
Second Party	:	LOTUS LABS PVT LTD
Stamp Duty Paid By	:	LOTUS LABS PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

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CLINICAL TRIAL AGREEMENT

THIS AGREEMENT FOR "CLINICAL TRIAL" ("**Agreement**") is made and entered into this 24th day of July by and among Dr. Smitha KS, "KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehrunagar, Belgaum-590010. Karanataka, India" (hereinafter referred to as the "**Principal Investigator**" or "**PI**")

AND

KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehrunagar, Belgaum-590010. Karanataka, India herein after called the "**Institution**" (which expression shall wherever the context so admits include its successors and assignees) of the second part

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AND

CMS clinical research Pvt. Ltd, # 51, 3rd Floor, Paigah Colony, S P Road, Secunderabad—500003, Telangana, INDIA (SMO) (herein after called as "Site Management Organisation" which expression shall wherever the context so admits include its successor and assignees) of the Third Part

AND

Lotus Labs Pvt. Ltd, a company incorporated under the Companies Act, 1956 of India having its registered Office at No. 7, Jasma Bhavan Road, Millers Tank Bed Area, Opp. Gurunanak Bhavan, Vasanthnagar, Bangalore – 560 052, India and include its successors and assignees (hereinafter referred to as "**Lotus**") representing the interests of Sponsor **Watson Pharma Pvt. Ltd.**, (hereinafter referred to as "**Sponsor**") in connection with conduct of clinical trial "An Open Label, Randomized, Multicentric, Two Treatment, Single Dose, Parallel Group Two Stage Adaptive Design Bioequivalence Study Of Loteprednol Etabonate Ophthalmic Suspension, 0.5 % In Aqueous Humor Of Patients Undergoing Indicated Cataract surgery." ("**Study**") bearing the protocol/study number: WAT/LTPNL/2015 ("**Protocol**") attached hereto as Exhibit A.

PI, Institution and Lotus hereinafter are individually referred to as "**the Party**" and are jointly referred to as "**the Parties**".

WHEREAS:

1. Sponsor is a pharmaceutical company and had engaged the services of Lotus for execution of a clinical trial in **India.**
2. Lotus is in the business of providing contract research services and has necessary infrastructure and facilities to provide such services for the clinical trial and in turn desires to engage the services of the Institution to conduct/assist in such a trial;
3. Institution represents that it has qualified personnel and adequate facilities and equipment to competently conduct the Study and is desirous of rendering such services upon such terms and conditions as envisaged below.
4. Institution and PI desires to engage SMO to provide qualified manpower services as required for conducting the clinical study under this agreement and rendering such services upon such terms and condition set forth herein.
5. SMO is a site management organization has qualified and trained personnel to competently conduct the Study and is desirous of rendering such services upon such terms and conditions as envisaged below.
6. SMO hereby agrees to provide its services in connection with the clinical trial and as per the approved study protocol and the terms and conditions set forth therein.

1. **Provision of Services**

1.1 **Scope of Work.**

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The Study to be performed under this Agreement shall be performed in accordance with the terms of the final Protocol, including as it may be amended in accordance with the terms of this Agreement, for the Study. Institution and Principal Investigator agree that all aspects of the Study will be conducted in conformity with all applicable laws and regulations, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Good Clinical Practice: Consolidated Guideline ("ICH Guideline,) and applicable requirements of the United States Food and Drug Administration ("FDA"). Institution and Principal Investigator further agree not to conduct any research activities with the Study Drug (as such term is defined below), which are contrary to the provisions of the Protocol or outside the scope of the Protocol.

Institution shall use best efforts to enrol up to 30 study participants capable of being evaluated and having analyzable data in the treatment portion of the Study, within 06 months of receipt of investigational supplies. The enrolment period may be extended or shortened at the sole discretion of Sponsor at any time.

1.2 **Principal Investigator.**

Institution shall appoint [Dr. Smitha KS] as Principal Investigator having the requisite education, experience and expertise to competently perform the Study according to the terms and conditions as hereafter set forth, and that said Principal Investigator shall act as representative of the Institution for medical and scientific matters arising under this Agreement. Principal Investigator will be responsible for the direction and supervision of all Study efforts in accordance with applicable Institution policies, the Protocol and this Agreement. Principal Investigator and Institution will ensure that any sub-investigators and any other staff comply with the terms of this Agreement and the Protocol. In the event that Principal Investigator leaves or is removed from the Institution, then Institution shall, within ten (10) days of such departure by Principal Investigator, provide written notice of such event to Lotus and Sponsor. Any successor to Principal Investigator must be approved, in writing, by Lotus and Sponsor and such successor shall be required to agree to all the terms and conditions of the Protocol and this Agreement and to sign each such document as evidence of such agreement (although failure to so sign will not relieve such successor from abiding with the terms and conditions of the Protocol and this Agreement).

Institution and Principal Investigator represent and warrant that they will not use in any capacity, in connection with any services to be performed under this Agreement, any individual who has been debarred pursuant to any applicable laws or regulations, including debarments under the United States Federal Food, Drug and Cosmetic Act, or exclusion from a United States federal healthcare program.

Institution and Principal Investigator agree to immediately inform Lotus and Sponsor in writing if any person who is performing services hereunder is debarred or if any action, suit, claim, investigation or legal or administrative proceeding is pending, or, to the best of their knowledge, is threatened, relating to the debarment of Institution or any person performing services hereunder. Principal Investigator represents and

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warrants that no action, suit, claim investigation or legal or administrative proceeding is pending or threatened relating to Principal Investigator's debarment and Principal Investigator agrees to immediately inform Lotus and Sponsor in writing if any such action, suit, claim, investigation or legal or administrative proceeding is threatened or commenced for Principal Investigator's debarment.

Details of Principal Investigator's responsibilities are set forth in the Protocol and on Exhibit A attached hereto.

1.3 **SMO (Site Management Organisation)**

SMO will provide the manpower services like clinical research co-ordinator(s) (hereinafter "co-ordinators") for clinical study. Such number of co-ordinators will be appointed by the institution and PI as and when required for the clinical study. All such co-ordinators will perform their services under the direction and supervision of the Institution and PI. The consultant will provide the number and details of the co-ordinators appointed for clinical study to the sponsor/Lotus.

1.4 Lotus will provide the PI with all the information, documents, and materials which, in Lotus' reasonable opinion, are required in order to carry out activities in a clinical trial.

Lotus transfers the obligations, explicitly detailed in **Exhibit A** to this Agreement, for this clinical study to the PI and the PI accepts the same and shall diligently carry them out along with other obligations under this Agreement. The PI will take all reasonable steps to ensure that personnel used to perform his/her obligations under this Agreement are appropriately trained and qualified.

1.5 Records and Reports.

Principal Investigator and Institution shall have the following record keeping and reporting obligations:

(i) preparation and maintenance of complete, accurately written records, accounts, notes, reports and data relating to the Study under this Agreement; and

(ii) preparation and submission to Lotus and Sponsor (in a periodic and timely manner during the term of this Agreement) of all raw data and other material called for in the Protocol in the form of properly completed patient case report forms ("Case Report Forms") or into an electronic database (i.e., remote data entry) supplied by Sponsor for each patient as provided in the Protocol. Case Report Forms and the electronic database shall be the exclusive property of Sponsor.

Principal Investigator and Institution agree to notify Sponsor and Lotus within one day after learning of any serious and/or unexpected adverse drug reaction affecting any patient in the Study. Principal Investigator and Institution further agree to follow up such notification of adverse drug reaction with appropriate reports in compliance with the Protocol and all applicable legal and regulatory requirements. In the event Principal Investigator and Institution become aware of any quality complaints

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associated with the Study Drug provided under this Agreement, they agree to notify Sponsor in compliance with the Protocol.

Principal Investigator and Institution further agree to conduct the Study and maintain records and data during and after the term or early termination of this Agreement in compliance with all applicable legal and regulatory requirements, including without limitation, any applicable requirements of the FDA that are provided to Principal Investigator, local regulations, applicable GCP and per the directions of Lotus. Principal Investigator and Institution further agree to permit Sponsor or Sponsor's representatives to examine and audit all records and reports, with prior written notification from Sponsor and during normal business hours (subject to applicable patient confidentiality considerations). Principal Investigator and Institution agree to take any action necessary, as reasonably requested by Lotus and Sponsor, to properly correct or address any deficiencies noted during any audit and agree to cooperate with Lotus and Sponsor with respect to any action taken to address any such deficiencies.

Principal Investigator or Institution agree to notify Sponsor within twenty-four (24) hours in the event that the FDA or any other regulatory authority notifies the Study site of a pending inspection/audit. In addition, Principal Investigator and Institution will forward to Lotus and Sponsor any written communication received as a result of the inspection/audit within twenty-four (24) hours of receipt of such communication and agrees to allow Lotus and Sponsor to assist in responding to any citations. Such responses shall be made within two (2) weeks of issuance of any citations or within any earlier deadline set by the issuing regulatory authority. Principal Investigator and Institution shall also provide to Lotus and Sponsor copies of any documents provided to any inspector or auditor. In the event the FDA or other regulatory authority requests or requires any action to be taken to address any citations, Principal Investigator and Institution agree, after consultation with Lotus and Sponsor, to take such action as necessary to address such citations, and agree to cooperate with Lotus and Sponsor with respect to any such citation and/or action taken with respect thereto.

1.6 **Project Monitor and Inspection Rights**. It is agreed that the project monitor(s) and others designated by Lotus and/or Sponsor may, at mutually agreeable times during the Study and for a reasonable time after completion or early termination of the Study, arrange with Principal Investigator or his/her designee:

(i) to examine and inspect, at regular business hours, Institution facilities required for performance of the Study; and

(ii) subject to applicable patient confidentiality considerations, to inspect, audit, and to copy or have copied, all data and work product relating to the Study conducted under this Agreement and to inspect and make copies of all data necessary for Lotus and Sponsor to confirm that the Study is being conducted in conformance with the Protocol and in compliance with all applicable legal and regulatory

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requirements, including without limitation, any applicable FDA requirements that Lotus and/or Sponsor has provided in writing.

Institution agrees to assist Lotus and Sponsor in order to facilitate the Lotus and Sponsor representatives' examination, inspection, auditing and copying of materials relating to the Study and in order to enforce the rights granted to Sponsor as per ICH Guidelines.

1.7 **Clinical Trial Approvals.**

Institution and Principal Investigator shall be responsible for obtaining the following:

(i) approval of the Protocol, any informed consent relating to the Study and advertisement, if any, pertaining to the enrolment of subjects in the Study by the appropriate Ethics Committee ("EC") prior to beginning any Study on human subjects; and

(ii) an informed consent which complies with all applicable laws and regulations signed by or on behalf of each human subject prior to the subject's participating in the Study. Additionally, Institution and Principal Investigator shall also obtain an audio-visual recording of the informed consent process of each Study subject while maintaining principles of confidentiality.

In the event the EC requires changes in the Protocol or informed consent, Lotus and Sponsor shall be advised in advance and all modifications to the Protocol and informed consent must be approved in advance by Sponsor. Institution and Principal Investigator shall not modify the Study described in the Protocol once finalized and after approval by the EC without the prior written approval of Sponsor.

2. Payment

2.1 The total fees and expenses payable by Lotus to the Institution/ SMO for the services set forth herein shall not exceed the Budget as per **Exhibit B**. However the payment to the SMO will be adjusted against the payment to the institution/site on a pro rata basis. The payments set forth in the budget are acknowledged by the Parties hereto to be adequate consideration for the work taken hereunder.

2.2 Lotus shall pay the Institution and SMO against the submission of the invoice in accordance with the terms set forth herein after deducting there from any tax as applicable.

2.3 Payment shall be made by account payee Cheque/ DD /NEFT only.

2.4 Institution agrees that, in the event of a dispute regarding Sponsor and Lotus' approval of documentation supporting costs incurred under this Agreement, data and information resulting from the Study cannot be withheld by Institution or Principal Investigator prior to the resolution of the dispute because such withholding of data may cause irreparable harm to Sponsor. The Institution further agrees to use reasonable efforts to resolve any dispute of this type in a timely manner.

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3. Term

This Agreement shall commence on the date of execution and shall continue until the date of payment of the last sum due hereunder or until the date when the last services required to be performed hereunder are performed, whichever date shall last occur, unless terminated earlier as provided herein.

4. **Termination and Consequences of Termination**

Termination:

4.1 Either Party may terminate this Agreement without any notice, only for subjects' safety or medical reasons.

4.2 Either Party may terminate this Agreement by written notice of sixty (60) days to the other Party without assigning any reason thereof and **with no penalty on either side**.

4.3 Either Party may terminate this Agreement for cause upon thirty (30) days prior written notice, provided the Party receiving such notice has neither remedied nor sufficiently explained the breach within the period specified in the notice. Notices shall be deemed delivered upon receipt by the recipient designated for each party. "Cause" shall be defined to include a material breach of this Agreement, a material violation of the Protocol, or a lack of enrolment of the stated study participant population, as described in Section 1.1.

4.4 Any failure by a Party to carry out all or part of its obligations under this Agreement resulting in such detriment to the other Party as to substantially deprive such other Party of what it is entitled to expect under this Agreement, shall be considered a substantial breach for the purpose of clause 4.3 above.

4.5 Upon receipt of a written termination notice, both the parties will work diligently, in good faith and in cooperation with each other, to conduct the orderly termination of the services set forth under this Agreement.

Consequences of Expiry or Termination:

4.6 Unless terminated pursuant to Section 4.3 above, upon the expiry or termination of this Agreement, Lotus shall, in accordance with the payment provisions of Clause 2, pay for all reasonable, verifiable and completed activities up to the date of actual termination. In no event will payments made by Lotus to the PI under this Agreement exceed the project costs as set forth in the Study Budget.

4.7 Upon expiry or termination of this Agreement, the Institution and PI shall, at Lotus' option, either immediately transfer to Lotus or destroy any or all Confidential Information, including any copies thereof, except for those materials or copies that are required by law or regulation or for archival purposes.

4.8 The expiry or termination of this Agreement shall not relieve any Party of its obligation to the other with respect to:

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(i) retaining in confidence all Confidential Information;
(ii) complying with record keeping and reporting obligations;
(iii) complying with any publication obligations and obtaining any written approval and consents for any publicity and promotional purposes;
(iv) complying with obligations relating to clinical supplies;
(v) indemnification and insurance obligations;
(vi) inspection rights; and
(vii) the obligation to assist in obtaining patent protection

all of which obligations are binding on the appropriate party and shall remain in full force and effect as set forth in this Agreement.

5. **Intellectual Property Ownership, Invention & Discoveries and Publication**

5.1 **Inventions and Patents**. The sole and exclusive right to any inventions, discoveries or innovations, whether patentable or not, arising from the performance of the Protocol and Study under this Agreement, and using Study funds or otherwise arising out of use, misuse or modification of the Study Drug provided under this Agreement (the "**Inventions**"), shall be the property of the Sponsor. Institution or Principal Investigator will promptly notify Sponsor in writing of any such Inventions, and at Sponsor's request and expense Institution and Principal Investigator will cause to be assigned to Sponsor all right, title and interest in and to any such Inventions and provide reasonable assistance to obtain patents, including causing the execution of any invention assignment or other documents.

5.2 **Data Ownership**. All case report forms and other data (including, without limitation, written, printed, graphic, video and audio material and information contained in any computer data base or computer readable form) generated by the Institution and the PI in the course of conducting the Study (the "**Data**") and results shall be the exclusive property of Sponsor, and Sponsor reserves the right to use the Data and results for any corporate purpose

5.3 The PI acknowledges that all the intellectual property rights in the Confidential Information of and belonging to Sponsor and/or Lotus which is disclosed to the PI is and shall always remain the sole and exclusive property of Sponsor and/or Lotus.

5.4 **Publication**.
As this is a multi-center study, publications derived from this Study must include input from one or more investigators, their colleagues, Lotus and Sponsor personnel. Such input shall be reflected in publication authorship, and agreement regarding order of authors shall be established before writing a manuscript. Unless specifically approved by Sponsor, results from a single center in a multi-center study will not be submitted for publication separately before results of the multi-center study are published, unless (1) more than eighteen (18) months have elapsed since completion of the Study, and (2) the Institution provides Sponsor with a proposed manuscript for review

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and comment prior to publication. Sponsor shall complete review within sixty (60) days of receipt of a manuscript, during which time Institution shall not permit publication or presentation. Sponsor shall notify Institution of any comments, deletions or modifications requested in the proposed manuscript to protect its proprietary rights, and Institution shall make any such changes reasonably requested by Sponsor.

In the event Sponsor, pursuant to this Section elects to file one or more patent applications relating to any invention made in the course of the Study, any publications and presentations will be delayed for an additional ninety (90) days to permit the preparation and filing of such patent applications.

Subject to the publication restrictions in this Agreement, Institution shall have the right to use the results of the Study provided by Institution under this Agreement, including, but not limited to the results of tests and any raw data and statistical data generated therefrom, for its own internal teaching and research purposes.

6. **Representations.**

6.1 The PI hereby warrants and represents that the following are true and correct on the date of entering into this Agreement:

(i) The PI is an individual and has the requisite qualification, legal power to enter into this Agreement and to perform his/her obligations hereunder. This Agreement, when duly executed, shall constitute the legal, valid and binding obligation on the PI and is enforceable against the PI in accordance with its terms;

(ii) All acts and conditions required by the laws in force at the date thereof to be done, fulfilled and performed in order (i) to enable him/her lawfully to enter into this Agreement and to exercise his/her rights and perform his/her obligations under this Agreement and (ii) to make this admissible in evidence have been done, fulfilled and performed in strict compliance with the applicable laws.

7. **Indemnification.**

7.1 Sponsor shall indemnify, defend and hold harmless Institution, its trustees, officers, agents, employees and Principal Investigator, (and any named co-investigator) from and against any demands, claims, actions, proceedings or costs of judgments ("**Claims**") which may be made or instituted against any of them by reason of personal injury (including death) to any person, or damage to property, arising out of or connected with the performance of the activities to be carried out pursuant to the Protocol.

Notwithstanding the foregoing, Sponsor shall have no indemnification obligation or liability and Institution and Principal Investigator shall indemnify, defend and hold harmless Sponsor, its parent corporation, subsidiaries, affiliates, officers, directors, agents, and employees for loss or damage resulting from:

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(i) failure of Institution or Principal Investigator to adhere to the terms and provisions of the Protocol or agreed amendments thereto or Sponsor's written recommendations and instructions relative to the administration and use of any drug substances involved in the Study, including, but not limited to, the Study Drug, any comparative drug and any placebo;

(ii) failure of Institution or Principal Investigator to comply with any applicable FDA or other governmental or state requirements, law, rules, ICH Guidelines or regulations applicable to the performance of its obligations under this Agreement;

(iii) failure of Institution or Principal Investigator to render professional service or to conduct the Study in a normal, prudent manner; or

(iv) negligent act or omission or willful misconduct by Principal Investigator, Institution, its trustees, officers, agents or employees related to the performance of services under this Agreement.

7.2 Institution agrees to indemnify and hold Sponsor and Lotus harmless from liability for any claim, demand or lawsuit arising out of (i) the willful, reckless or negligent act or failure to act of Institution (including failure to comply with the terms of the Study Protocol), or (ii) the breach of any of the Institution's or PI's covenants or representations contained in this Agreement.

7.3 Institution and/or Principal Investigator shall secure and maintain in full force and effect through the performance of the Study (and following termination or early termination of the Study to cover any claims arising from the Study) insurance coverage in amounts as required by applicable legal requirements and appropriate to the conduct of Institution's and Principal Investigator's activities and the services contemplated by the Study. Upon request of Lotus or Sponsor, copies of certificates evidencing such insurance coverage will be made available to Sponsor. Institution and/or Principal Investigator shall provide thirty (30) days' prior written notice to Lotus and Sponsor in the event of cancellation or any material change in such insurance.

7.4 These indemnification obligations of the Parties shall only apply provided that in regards to the Claim (i) the indemnified party promptly notifies the indemnifying party of such Claim; (ii) the indemnified party allows the indemnifying party and/or its insurers the right to assume direction and control of the defense (including settlement) of any such claim, demand or lawsuit (the indemnifying party shall not admit fault on any one or all of the indemnified party's behalf without the indemnified party's advance written permission); (iii) the indemnified party cooperates fully with the indemnifying party and/or its insurers in the defense of such claim, demand or lawsuit; and (iv) the indemnified party agrees not to settle or

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compromise any claim, demand or lawsuit without prior written authorization of the indemnifying party.

8. **Confidentiality**

8.1 Upon execution of this Agreement a confidential relationship shall exist between Lotus, Sponsor, Institution and Principal Investigator and SMO, whereby Institution and Principal Investigator and SMO agree to hold in confidence confidential information disclosed by Lotus and/or Sponsor, in connection with the Study. As used in this Agreement "Confidential Information" shall be understood to include information disclosed by Lotus and/or Sponsor which is not in the public domain, including but not limited to: technical, scientific, market and marketing information, know-how, data, formulae, processes, plans, assessments and methods for Study Drug and/or its uses or modes of action, as well as similar information relating to any other Sponsor compound. Confidential Information shall also include all test articles and proprietary data and/or information generated pursuant to the Study, including, but not limited to the Protocol, the investigator's brochure, interim results and any other information or material disclosed under secrecy agreements preciously entered into by the Parties. For purposes of this Agreement, Confidential Information supplied by Lotus and/or Sponsor to Institution shall be deemed to be in the public domain or in the possession of Institution only if the Confidential Information as a whole is in the public domain or in the prior possession of Institution.

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8.2 Confidential Information shall not be deemed to include information which: (i) is in or enters the public domain through no act or omission of Institution; (ii) is lawfully in Institution's or Principal Investigator's possession prior to disclosure, which possession can be documented through business records maintained in the ordinary course of Institution's business; (iii) is obtained by Institution or Principal Investigator from a third party having an apparent lawful right to provide such information and having no known obligation of confidentiality to Lotus or Sponsor; (iv) is independently developed by Institution personnel not privy to Lotus or Sponsor Confidential Information, as applicable, disclosed under this Agreement; or (v) is required by law to be disclosed.

8.3 Institution and Principal Investigator shall limit disclosure of Confidential Information received hereunder to only those of its (i) representatives, agents and officers bound by a written agreement with terms equivalent to or more stringent than this Agreement, and (ii) employees (collectively, "**Agents**") who are directly involved with the Study and only on a need to know basis. Institution and Principal Investigator shall advise its Agents upon disclosure to them of any Confidential Information of the proprietary nature thereof and the terms and conditions of this Agreement and shall use all reasonable safeguards to prevent unauthorized use or disclosure by such Agents. Institution and Principal Investigator shall be responsible for any breach of these confidentiality provisions by its Agents.

8.4 Institution and Principal Investigator acknowledge and expressly agree that any disclosure of Confidential Information in violation of this Agreement would be detrimental to Sponsor's business and cause it irreparable harm and damage. In accordance with applicable law and in addition to any other rights and remedies provided herein, Sponsor shall be entitled to seek equitable relief by way of injunction or otherwise.

8.5 The disclosure of Confidential Information to Institution and Principal Investigator shall not be construed in any way as a license or transfer of other rights.

9. Miscellaneous

9.1 Governing Law

This Agreement and the rights and obligations of the parties hereunder shall be governed by and construed in accordance with the laws of **India.**

9.2. Arbitration

Any dispute, controversy or claim arising out of or in connection with this agreement including any question regarding its existence, validity, interpretation or termination, shall be conclusively settled by referring the same to arbitration. The arbitration proceedings shall be conducted in the English language and be governed by the provisions of the Arbitration and Conciliation Act, 1996. The venue for arbitration proceedings shall be **Bangalore.**

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9.3 **Force Majeure (Act of God)**

In the event either Party is delayed or hindered in or prevented from the performance of any act required hereunder by reasons of restrictive government or judicial orders or decrees, riots, burglary, insurrection, war, acts of God, inclement weather or other similar reasons or causes beyond such Party's control, and such Party has exerted all reasonable efforts to avoid or remedy such event, then performance of such act shall be excused for the period of such delay (which is reasonable and consented by the other Party in writing). Notice of the start and stop of any such force majeure shall be provided to the other Party.

9.4 **Record Keeping**

During the term of this Agreement, PI shall maintain all materials and all other data obtained or generated by PI in the course of providing the services in a secure area reasonably protected from fire, theft and destruction.

9.5 **Headings.**

The headings used in this Agreement are for the sake of convenience and the same are not to be construed to define, limit or affect the construction of interpretation of this Agreement.

9.6 **Publicity.**

Except as required by applicable law, neither Institution nor PI shall use, or authorize others to use, the name, symbols, or marks of Sponsor in any advertising or publicity material or make any form of representation or statement in relation to the Study, which would constitute an express or implied endorsement by Sponsor of any commercial product or service without prior written approval from Sponsor.

9.7 **Independent Contractors.**

It is agreed by the parties that Institution and Principal Investigator are acting in the capacity of independent contractors hereunder and not as employees, agents or joint venturers of or with Sponsor. Neither Institution nor Principal Investigator shall have any authority to represent, bind or act on behalf of Sponsor. Institution represents that Principal Investigator is an employee of the Institution. Investigator acknowledges and agrees that Principal Investigator's sole recourse for compensation for his or her services, as well as the services of Principal Investigator's staff affiliated with the Study, shall be from Institution and not Watson.

9.8 **Assignment.**

This Agreement is, not assignable by Institution or Principal Investigator and any attempted assignment or delegation in violation hereof shall be void. Sponsor may assign this Agreement to an affiliated company without the prior consent of Institution or Principal Investigator. Notwithstanding such assignment, Sponsor shall remain liable for all of its obligations under this Agreement.

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9.9 **No Modifications.**

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Neither this Agreement nor the Protocol may be altered, amended or modified except by written document signed by the Parties.

9.10 **Severability**.

If any term or condition of this Agreement, the deletion of which would not adversely affect the receipt of any material benefit by a Party hereunder, shall be held illegal, invalid or unenforceable, the remaining terms and conditions of this Agreement shall not be affected thereby and such terms and conditions shall be valid and enforceable to the fullest extent permitted by law.

9.11 **No Waiver**.

Failure on the part of a Party to exercise or enforce any right conferred upon it hereunder shall not be deemed to be a waiver of any such right nor operate to bar the exercise or enforcement thereof at any time or times thereafter.

9.12 **Compliance with Anti-Corruption Laws**

(i) PI, Institution and SMO agrees to comply with applicable anti-corruption laws such as the U.S. Foreign Corrupt Practices Act (FCPA) and the UK Bribery Act of 2010 as well as any laws implementing the U.N. Convention Against Corruption and the OECD Anti-bribery Convention (collectively, "**Anti-Corruption Laws**"). PI, Institution and SMO undertakes that, in connection with its performance of its obligations under this Agreement, they will not and shall not directly or indirectly (a) offer, provide, authorize for or promise to another person, or (b) request, accept or agree to accept from another person any financial or other advantage or anything of value ("**Benefit**"), if such Benefit is for the purpose of influencing the receiving person improperly in his or her official capacity for the purpose of obtaining a business advantage, or where such Benefit would constitute a violation of any applicable Anti-Corruption Law.

(ii) In the event that PI, Institution and SMO is accused of or becomes subject to investigation by a governmental authority for an alleged violation of applicable Anti-Corruption Laws in connection with this Agreement, or LOTUS notifies PI and Institution that it has a reasonable basis for believing that PI, Institution and SMO has not complied with applicable Anti-Corruption Laws in connection with this Agreement (and discloses in reasonable detail the evidence underlying such belief), LOTUS shall have the right to request in writing that PI, Institution and SMO provide access to (either directly or through legal counsel or an internationally recognized independent auditor) such written records or other information reasonably required to credibly refute such alleged non-compliance.

(iii) If, in connection with this agreement, PI and Institution breaches its obligations under Sections 9.12(i) and 9.12(ii) above or admits to a violation or is determined by a governmental authority to have violated applicable Anti-Corruption Law, then LOTUS shall be entitled to immediately terminate this Agreement upon written notice to PI, Institution and SMO

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By signing this agreement "You are required to refer and adhere to our Business Partner Guide hosted on our website. URL for the same is http://www.lotuslabs.com/Uploads/Lotus_business_partner_guide.pdf. It gives our expectations with regard to your conduct as a Lotus Business Partner."

9.13. **Notices & Service of documents**

The notice and documents required to be given under this Agreement shall be deemed to be sufficiently given if hand delivered by one Party to the other or sent by Registered Mail with acknowledgement due.

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All the correspondence/ notices to be sent by the PI to Lotus shall be addressed to:

Lotus Labs Pvt. Ltd.
No. 7, Jasma Bhavan Road,
Millers Tank Bed Area,
Opp. Gurunanak Bhavan,
Vasanthnagar,
Bangalore – 560 052
Phone No. 080-22370982/22370912/13/14/15
Fax No. 080-2237091

All the correspondence/ notices to be sent by Lotus to PI shall be addressed to:

Dr. Smitha KS, "KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehrunagar, Belgaum-590010.

For LOTUS LABS PVT LTD

24/07/15	12/08/2015	07/08/15	
S. Hari Sankar Managing Director	Dr. Mallikarjun V. Jali Managing Director	Dr. Smitha K.S. Principal Investigator	A.V.A.Suresh Babu Director CMS Clinical Pvt. Ltd. (SMO)
Seal:	Seal:	Seal: Dr. Smitha K.S. Consultant in Ophthalmology KLES Dr. Prabhakar Kore Hospital & MRC, BELGAUM.	Seal:
Witness	Witness	Witness	Witness
Venkatesh Hegde Executive Legal	Prashant Bandiwadi	Dr. Vishwendra Sisodia.	K. Kiran Kandhan.

Medical Director & Chief Executive
KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, BELAGAVI

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Exhibit A

Responsibilities of PI for

"An Open Label, Randomized, Multicentric, Two Treatment, Single Dose, Parallel Group Two Stage Adaptive Design Bioequivalence Study Of Loteprednol Etabonate Ophthalmic Suspension, 0.5 % In Aqueous Humor Of Patients Undergoing Indicated Cataract surgery." bearing the protocol / study number: WAT/LTPNL/2015.

1. PI has sufficient time, adequate staff, and appropriate facilities to conduct and complete the clinical study. PI agrees to make these resources available for the duration of the study and agrees that other studies will not divert essential subjects or facilities away from this trial.

   PI assures Lotus Labs Pvt. Ltd., that no other clinical study conducted by him shall give rise to a conflict of interest or interfere with the clinical trial.

   PI will endeavor to ensure an adequate recruitment rate during the clinical investigation.

2. Lotus Labs Pvt. Ltd. will furnish PI with copies of the Investigator's Brochure, the Study Plan and Protocol and agrees:

   a. To become thoroughly familiar with the properties of the investigational product as described in the Investigator's Brochure, which provides full information concerning the pre-clinical investigations that justify clinical studies, together with informative material describing any prior investigations, side effects, and precautions to be taken into account in the course of the clinical investigation; and
   b. To become well acquainted with the Study Plan before signing it.

3. PI agrees to make the necessary arrangements, including provisions for emergency treatment, to ensure the proper conduct of the study.

4. PI understands that along with the Institution, he will have primary responsibility for the accuracy, legibility, and security of all study data, documents, and subject records both during and after the study. PI will be responsible for electronic signature of the Electronic Case Report Forms (e-CRF).

   PI agrees to abide by the following conditions governing his/her handling of the data associated with this study.

   a. PI is required to maintain adequate records regarding all investigational product received and used by him/her including batch numbers, dates, and quantities. If the study is terminated, suspended, discontinued, or completed, PI shall return to Lotus Labs Pvt. Ltd., any unused supplies other than retention samples unless other arrangements are made by Lotus Labs Pvt. Ltd.

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b. PI is required to prepare and maintain adequate and accurate patient case histories, recording all observations and other data pertinent to the clinical investigation of each subject in the clinical study.

c. PI understands to furnish records of the study to Lotus Labs Pvt. Ltd./Sponsor.

d. PI will maintain records of the disposition of the investigational product and other records for the longer of the following periods:
   I. the period defined by national or local law and rules
   II. five years after the study is terminated or completed, or
   III. Five years after the records are no longer required for purposes of supporting the relevant United States, other national, European (EU), or other international regulatory applications.
   IV. To avoid any possible errors PI will contact Lotus Labs Pvt. Ltd. prior to the destruction of records or in the event of accidental loss or destruction of any Study records.

e. PI, along with Institution, agrees to provide accurate information to the Ethics Committee upon request. PI, along with Institution, also agrees to provide accurate information to the regulatory authorities upon their request and within the scope of the agencies' authorities and ethical obligations, as set forth below:

   I. The patient's identity will not be released except under the following limited circumstances
      i. Upon the request of a scientifically trained and specifically authorized employee of national or international regulatory agencies, PI will make records related to the clinical study available for inspection and copying

   II. Where data verification procedures demand inspection of patient's personal identity or personal medical information, in which case this inspection may be performed only by a properly authorized person

   III. The patient's identity shall not be released to third parties without the patient's and/ or impartial witness prior consent. Accordingly, the study patient's and/ or impartial witness consent to the potential release of patient identity information to regulatory bodies for data verification purposes will be obtained as part of the informed consent procedure.

5. PI agrees to be responsible for submitting the Investigational Protocol for opinion or approval, to an appropriate Ethics Committee and shall transmit the results to Lotus Labs Pvt. Ltd.

   PI shall not commence the study without an approval or favorable opinion from the Ethics Committee of the Investigational Protocol, informed consent forms, subject

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recruitment procedures, and any written material to be provided to the patient's and/ or impartial witness.

PI shall provide the Institutional Ethics Committee or Institutional Review Board with all required information.

6. PI certifies that the investigational products for clinical investigation will be provided only to patient under his personal supervision or under the supervision of the Co-investigator/ Sub-investigator (if any) responsible to him.

   PI further certifies that the investigational products will not be supplied by him to any investigator, other than those listed above as Co-Investigator/ Sub-investigators, or to any clinic, medical facility, or study site for use.

7. No procedure will be performed until all personnel have been properly trained.

8. PI shall be responsible for completing and signing the FDA form 1572.

9. PI agrees to be responsible for the personal safety and well-being of the subjects. To this end, PI agrees to abide by the Declaration of Helsinki and their subsequent amendments, national policy, and the following conditions governing the ethical treatment of subjects in this clinical investigation:

   Following national policy and the Declaration of Helsinki, informed consent shall be documented by the subject or subject's legal representative with dated signature:

   a. PI ensures that patient and/ or impartial witness or their guardians receive adequate information to make informed consents. This information will be provided both in oral and in written form and shall be in a form easily understood by the patient's and/ or impartial witness. Additionally, as required by Indian law, Principal Investigator shall also obtain an audio-visual recording of the informed consent process for each Study subject. Such process shall be undertaken while maintaining principles of confidentiality.

      The informed consent information shall include the aims, expected benefits, risks and inconveniences of the clinical investigation, an explanation of any alternative methods or treatments available, and an explanation of possible consequences of any withdrawal from the clinical investigation.

   b. PI will ensure that the patient and/ or impartial witness are given the opportunity to inquire about the details of the clinical study. The information given to the subject /subject's legal representatives shall make clear to them that they remain free to refuse to participate in and free to withdraw from the clinical study at any time without any sanction. PI will make an effort to ascertain the reasons for any

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withdrawal while fully respecting the subject's and/ the subject's legal representative's rights.

c. PI will ensure that the patient and/ or impartial witness are provided adequate time to decide whether or not they wish to participate/ wish their ward to participate in this clinical investigation.

10. PI will discuss with Lotus Labs Pvt. Ltd. any question of modification of the study plan and obtain Lotus Labs Pvt. Ltd./ Sponsor written agreement and also approval from the ethics committee prior to implementation of any modification. PI will not proceed with a non-emergency deviation from the Clinical Protocol without approval from Lotus Labs Pvt. Ltd. and as needed the Ethics Committee. It is PI's responsibility to inform the Ethics Committee about any protocol amendment or any significant change in the Investigational Plan or Protocol that has been approved by Lotus Labs Pvt. Ltd., including the reason for the change, and to obtain the Ethics Committee's approval or favorable opinion regarding the change.

11. PI will report all adverse events/ serious adverse events to Lotus Labs Pvt. Ltd./ Sponsor.

a. PI will report within one day:
   - Deviations from or changes to the protocol to eliminate immediate hazards to the study patients.
   - Changes increasing the risk to patients and/or affecting significantly the conduct of the study.
   - All adverse drug reactions (ADRs) and Adverse Events (AEs) those are both serious and unexpected.
   - New information that may affect adversely the safety of the patients or the conduct of the study.

b. All staff in contact with the patient should be aware of their responsibility to note and report all adverse events reported by the patient's and/ or impartial witness

c. The Principal Investigator or designate should assess the patient at each visit for adverse event or serious adverse event that may have occurred since the previous visit.

d. All serious adverse events (SAEs) should be reported to Lotus within 24 hours.

e. The immediate reports should be followed promptly by detailed written reports including the completed Adverse Event Forms.

f. The immediate and follow-up reports should identify patients by unique code numbers assigned to the study patients rather than by the patients' names, personal identification numbers and/or addresses.

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Lilly

Eli Lilly and Company (India) Pvt. Ltd.
Plot No. 92, Sector-32, Gurgaon - 122001
Haryana

Phone : +91-124-4753000
Fax : +91-124-4753012-13-14

CIN – U24239HR1993PTC034844

Date: 11-Sep-15

7(F)

To:
Dr. Shailesh Veerbhadrappa Udapudi
K.L.E.S Dr. Prabhakar Kore Hospital &
Medical Research Centre
Nehrunagar, Belgaum – 590010
Karnataka.

Sub: Status of Clinical Trial I4V-MC-JADX, I4V-MC-JADZ & I4V-MC-JADY

Dear Dr. Udapudi,

We would like to thank you for your active participation and continued interest in Eli Lilly Clinical Studies I4V-MC-JADX, I4V-MC-JADZ & I4V-MC-JADY as Principal Investigator.

The Current Status of these studies is as follows:

1. Protocol I4V-MC-JADX: LPV Achieved, Database Lock Completed and Site Closed

2. Protocol I4V-MC-JADZ: LPV Achieved, Database Lock Completed

3. Protocol I4V-MC-JADY: This is an 48 months Extension study of Feeder studies JADX and JADZ. All subjects who completed JADX and JADZ and given consent to participate in the extension has been enrolled into JADY study. JADY Study is expected to achieve LPV in India by September 2018.
   From your site we currently have 3 Active Subjects in Trial I4V-MC-JADY.

We thank you and your entire team for the active participation and support in these studies.

Regards,

Sanjay Majumdar
Senior Manager, Clinical Research
Eli Lilly & Company (India) Pvt. Ltd
Phone: +91 9871707965
Mail: majumdar_sanjay_in@lilly.com

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తెలంగాణా TELANGANA
S.L. No 5347 Date 09/11/2015
Sold to
For Whom

T. Gayathri
02AA 487792
T. GAYATHRI
LICENCED STAMP VENDOR
Lic No 15-10-033/2012
Renl No 15-10-058/2016
Ph: 9666041145

CLINICAL STUDY AGREEMENT

This Clinical Study Agreement (the "**Agreement**") is made and entered into 18th day of December 2015 by and between:

CMS Clinical Research Pvt. Ltd, a company incorporated under the provisions of the Companies Act, 1956 and having its registered office at **#51, 3rd Floor, Paigah Colony, S P Road, Secunderabad-500003, Telangana**, India (hereinafter referred to as "**CMS**" which expression shall be deemed to mean and include its affiliates, successors and permitted assigns) of the **FIRST PART**

And

Dr. Rajesh Shankar Powar, Chief Consultant Plastic Surgeon, Department of Plastic Surgery, **KLES Dr Prabhakar Kore Hospital & Medical Research Centre, Belgaum, Karnataka, INDIA. ("Investigator") SECOND PART.**

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Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
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For The Site:

For The Site:

Site Details:

Site No.	Name of the Principal Investigator	Institution Name	Location
Study Site	Dr. Rajesh Shankar Powar	KLES Dr Prabhakar Kore Hospital & MRC.	Belgaum, Karnataka

WHEREAS CMS Clinical Research a private limited company incorporated under the company's act 1956 is conducting a clinical study (the "**Study**") of the product Silver Sulfadiazine Cream (Nanonized) 0.5% w/w (Silver Sulphadiazine (Nanonized) 0.5% and Chlorhexidine Gluconate 0.2%) hereinafter referred as Study Drug ; and Silver Cream 1% w/w (Silver Sulphadiazine (Nanonized) 1% and Chlorhexidine Gluconate 0.2%) as comparator in patients with Burn Wounds.

WHEREAS the Study shall be conducted in full compliance with the SPONSOR's protocol "**protocol number R2012003** and protocol title/name *of* **Comparative Efficacy, Safety and Tolerability of Silver Sulfadiazine Cream (Nanonized) 0.5% w/w and Silverex Cream 1% w/w in the Prophylaxis of Infection in Burn Wounds – A Double-Blind, Randomized, Pivotal Study** and any amendments there to (the "**Protocol**");

WHEREAS the Investigator agrees to act as the principal investigator for the Study at the Institution.

NOW, THEREFORE, in consideration of the terms and conditions set forth herein, the parties agree as follows:

1. **SERVICES AND OBLIGATIONS**

The Sponsor requires services relating to Site Management & Clinical Research Coordination activities generated in course of its business and wishes to outsource such services to SERVICE PROVIDER and SERVICE PROVIDER desires to be hired to perform such services regarding the Site Management & Administration (Clinical Research Coordinator) support for the *conduct of* **Comparative Efficacy, Safety and Tolerability of Silver Sulfadiazine Cream (Nanonized) 0.5% w/w and Silverex Cream 1% w/w in the Prophylaxis of Infection in Burn Wounds – A Double-Blind, Randomized, Pivotal Study** ("Services");

a) SMO (via Institution) and the Investigator hereby agree to conduct the study in accordance with this Agreement and the Protocol. SMO and the Investigator shall also follow, and shall ensure that the Study Personnel (defined below) and the SPONSOR's instructions as they relate to the Institution's and/or the Investigator's performance under this Agreement.

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b) The Study shall be conducted at **KLES Dr Prabhakar Kore Hospital & MRC**, Belgaum, Karnataka (the "**Investigative Site**"). SMO and the Investigator shall ensure that all individuals and entities that perform any portion of the study under the Investigator's supervision (the "**Study Personnel**") and conduct the study in accordance with the Protocol and the terms and conditions defined in this Agreement. Further, SMO and the Investigator shall ensure that all Study Personnel are trained in the Protocol and good clinical practices.

c) SMO (via Institution) and the Investigator shall start to conduct the study as soon as all of the following events have occurred: (i) The Protocol and Study have been approved by the responsible ethics committee(s) and the competent regulatory authority and registered under the Clinical Trial Registry-India; (ii) The site initiation visit at the Institution has been performed and (iii) Case Report Forms (as defined below) and the Study Drug have been delivered to the Institution and/or the Investigator.

1.1 Regulatory Compliance of Study

a) Each party shall perform its obligations under this agreement with due diligence and in strict compliance with: (i) All applicable laws and regulations applicable to the conduct of clinical trials, including without limitation the Drugs and Cosmetics Act 1940,the Drugs and Cosmetics, Rules 1945, the Indian Council of Medical research guidelines and the Medical Council of India Act, 1956, (ii) All generally accepted standards of good clinical practice, including without limitation the current Good Clinical Practices Guidelines of the International Conference on Harmonization and the Ethical Principles of the World Medical Association Declaration of Helsinki (iii) The applicable laws related to data protection and data privacy, including without limitation, and as applicable, the EU Data Protection Directive 95/46/EC and (iv) Any other applicable laws, rules, guidelines and regulations (collectively, as amended from time to time, the "**Applicable Regulatory Requirements**").

b) Any modifications to the Protocol, if required, must be made by the SPONSOR and in accordance with the Applicable Regulatory Requirements and approved by the SPONSOR.

1.2 Study Subjects

The estimated number of subjects to be enrolled by the Investigator need to be in compliance with study protocol and competitive. Detailed criteria of subjects to be enrolled in the study are to strictly in accordance with the Protocol. **SPONSOR** reserves the right to unilaterally reduce or increase the number of study subjects at any time and with immediate effect and/or to instruct the Investigator to discontinue recruiting study subjects. The Institution and the Investigator shall ensure that the rights and welfare of the study subjects are protected.

1.3 Study Drug and Study Supplies

a) Sponsor agrees to provide the Study Drug at no cost to the Institution or the Investigator in volumes sufficient for the conduct of the study. The SPONSOR may also, at its sole discretion, provide additional materials, supplies and equipment (the "**Study Supplies**").Immediately upon receipt of the Study Drug and/or any study supplies, the Institution and/or the Investigator shall provide The SPONSOR with a written acknowledgement. The Institution and the Investigator shall maintain inventory and control the Study Drug in accordance with: (i)Applicable Regulatory Requirements;(ii) In the manner outlined in the Protocol; and,(iii) According to any additional documents provided by the SPONSOR related to the storage (including temperature monitoring, if applicable), preparation and/or dispensing of the Study Drug.

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b) SMO (via Institution) and the Investigator shall ensure that the Study Drug and the Study Supplies are solely used for the purpose of conducting the Study in accordance with the Protocol and for no other purpose. Furthermore, SMO and the Investigator shall ensure that the Study Drug and the study supplies are not transferred to any third parties. Unless stated otherwise in writing by the SPONSOR, the Study Drug and the study supplies are and will remain the sole property of the SPONSOR (as the case may be). SMO and the Investigator shall be responsible to the SPONSOR for the Study Drug and the study supplies entrusted to them and shall notify SPONSOR immediately if any study drug or study supplies are lost, damaged or destroyed.

c) Upon completion or termination of the study or at SPONSOR's request, SMO/or the Investigator shall deliver all study supplies and/or all unused study drug to the address indicated by SPONSOR or destroy it/them, as instructed by SPONSOR and in accordance with the Applicable Regulatory Requirements. Neither SMO nor investigator shall destroy any study drug or study supplies without SPONSOR's written consent.

1.4 Informed Consent

a) The Investigator shall obtain in compliance with all applicable Regulatory requirements an informed consent properly signed by the or on behalf of each study subject prior to the subject's participation in the study.
The investigator or designated staff will obtain the subject's parent/subject's legally acceptable representative written and audio-visually recorded Informed Consent (As per latest DCGI guidelines) prior to any study-related procedures,

b) The Investigator shall use the form of the informed consent (the "**Informed Consent Form**") provided by SPONSOR and approved in compliance with all applicable regulatory requirements.

1.5 Case Report Forms and Study Data

a) SPONSOR shall supply (or if electronic, provide access to) the forms to be used and completed by the Investigator to document a study subject's participation in the study (the "**Case Report Forms**" or "**CRFs**"). The Investigator shall record all data generated as a result of conducting the Study (the "**Study Data**") in a timely, accurate and complete manner in the form described in the Protocol and shall ensure that the Case Report Forms for each study subject are duly signed and dated. To the extent the study requires completion of electronic Case Report Forms, the Institution and the Investigator shall ensure that they have implemented and maintain appropriate computer security sufficient to protect the confidentiality, integrity and availability of such Study Data in accordance with the Applicable Regulatory Requirements. The Investigator shall not grant unauthorized users access to the electronic data capture (EDC) system used in the Study, and in particular, shall not share or disclose his/her username and/or passwords only persons authorized to make entries and/or corrections on CRFs will use the system.

b) The Investigator and SMO shall take reasonable and customary precautions to prevent the loss or alteration of any Study Data and shall be liable for any loss or alteration of the same. SMO and the Investigator acknowledge and agree that the SPONSOR shall own all Study Data.

1.6 Adverse Events

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In case of any adverse event/events Investigator agrees to immediately and fully inform SPONSOR, the ethics committee(s) and competent authorities, of any significant risks,

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adverse events or unexpected results related to the study, according to the Applicable Regulatory Requirements and applicable Protocol provisions.

1.7 Financial Disclosure

The Investigator shall complete and return financial disclosure document provided, this document discloses the financial interests which the Investigator and/or his/her family members may have with the SPONSOR and/or the Study drug. The Investigator shall also ensure that all sub-investigators complete and provide SPONSOR with such financial disclosure forms. Such financial disclosure forms shall be kept updated for a period of one (1) year after Study completion.

2. STUDY GRANT AND INVESTIGATOR FEE

a) The investigator fee for the conduct of the Study is set out in the **Fee and Payment Schedule** enclosed as **Attachment 1**.

b) SMO and the Investigator acknowledge that SPONSOR may refuse to make payment in case of a Protocol violation or an incomplete CRF.

3. CONFIDENTIALITY

a) "**Confidential Information**" means all confidential or proprietary information or data, of any kind whatsoever and however memorialized, that is: (i) Disclosed by or on behalf of SPONSOR and/or the SPONSOR to the SMO, the Investigator or the Study Personnel in connection with this Agreement or (ii) Obtained, developed or generated by the Institution, the Investigator and/or the Study Personnel as a result of performing the Study under this Agreement. The Confidential Information shall include, without limitation, the Study, the Study Drug, the Protocol, the Investigator's Brochure, the Study Data, the Intellectual Property (defined below) and information regarding the SPONSOR, and their affiliates. All confidential information shall belong solely and exclusively to the SPONSOR, as the case may be.

b) Confidential Information does not include information (I) That is in the public domain at the time of its disclosure to SMO (II) Information that was evidenced by written records or other competent proof, in the SMO and/or Investigator's possession prior to its disclosure without obligations of confidentiality (excluding study data), or (III)Enters the public domain as a result of a third party's activities, through no act or omission by the Investigator, the SMO or any Study Personnel.

c) The SMO and the Investigator shall hold all confidential information in strict confidence and use all reasonable safeguards to prevent unauthorized use or disclosure. The SMO and the investigator shall use the confidential information only as required for the purpose of this Agreement. The SMO and the investigator shall limit their disclosure of the confidential information to those members of the Study personnel who need to know the confidential information for the conduct of the Study and are subject to obligations of confidentiality not less stringent than those contained in this Agreement. The SMO and the Investigator shall advise the Study Personnel of the confidential nature of the confidential information and remain liable for any breach of the confidentiality provisions herein.

d) Should the SMO or the investigator or any study personnel receive a court order or other legally binding request to disclose confidential information, the SMO or the investigator shall immediately inform SPONSOR upon the discovery of such request and before any confidential information is disclosed. The SMO and the investigator shall

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cooperate with the SPONSOR in any efforts to seek limitation or protection from the order demanding disclosure. In any case, the SMO and investigator shall disclose only the minimum amount of confidential information necessary to comply with such request only on the behest of the SPONSOR's legal counsel.

e) The obligations of confidentiality exist at all times during this agreement and shall survive the expiration or earlier termination of this agreement for a period of ten (10) years.

4. INTELLECTUAL PROPERTY

The SMO and the investigator acknowledge and agree that the SPONSOR shall have exclusive ownership rights to all Study data, improvements, developments, discoveries, inventions, work, know-how and other rights (whether or not patentable), created, developed, and/or reduced to practice as a result of or in connection with the conduct of the Study and/or the use of the Study drug or the confidential information, together with all intellectual property rights relating thereto ("**Intellectual Property**"). The SMO and the Investigator shall promptly disclose in writing to the SPONSOR all intellectual property made by the SMO, the Investigator and/or the Study personnel. All Intellectual Property and any information with respect thereto shall be confidential information subject to the obligations set forth in Article 3. At the SPONSOR's request, the SMO and the investigator shall cause all rights titles and interests in and to any such intellectual property to be assigned to the SPONSOR without additional investigator fee and provide reasonable assistance to obtain patents, including causing the execution of any invention assignment or other documents. In the event the SPONSOR is unable for any reason, after good faith and all reasonable effort, to secure the SMO's or the Investigator's signature on any document which the SMO or the Investigator is required to execute in accordance with the terms of this Article 4, the SMO and the Investigator hereby irrevocably designates and appoints the SPONSOR and its duly authorized officers and agents to act for and on their behalf to execute, verify and file any such documents with the same legal force and effect as if executed by the SMO or the Investigator. To the extent that the applicable law does not allow a the transfer of any of the intellectual property rights, the SMO and the investigator hereby grant the SPONSOR an exclusive, perpetual, irrevocable, worldwide, transferable, fully paid-up and royalty free license, with the right to sublicense to any third party, to use such intellectual property for any and all purposes.

5. PUBLICATION AND PUBLICITY

5.1 Publication

a) As this Study is part of a multicenter trial, publications derived from this Study may include input from the investigator, his/her colleagues, other investigators in this Study and the SPONSOR's personnel. Such input will be reflected in publication as an acknowledgement. Selection of authors will be at the sole discretion of the SPONSOR governed by the SPONSOR

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5.2 Publicity

The SMO and the Investigator shall not use SPONSOR's name, the names of any of their employees, symbols, or trademarks in any advertising, sales promotional material, or press release without the prior written permission of SPONSOR, as applicable.

6. INDEMNIFICATIONS, NOTIFICATION OF CLAIMS AND INSURANCE

6.1 SPONSOR's Indemnity Obligations and Disclaimer

a) SPONSOR undertakes to indemnify and hold harmless the SMO and the Investigator against any and all claims, damages, losses and costs arising out of (i) Any breach of this Agreement by SPONSOR or (ii) Any negligent or willful act or omission by SPONSOR, including by its officers, employees, contractors or other staff.

SPONSOR expressly disclaims any and all liability whatsoever in connection with the Study drug and the Protocol, except to the extent that such liability that arises from (i) Any negligent or willful act or omission of SPONSOR; or (ii) Any breach of this Agreement by SPONSOR.

6.2 The SMO's and the Investigator's Indemnity Obligations

The SMO and the Investigator undertake to indemnify and hold harmless the SPONSOR against any and all claims, damages, losses and costs (including reasonable attorneys' fees) arising out of (i) any breach of this Agreement by the SMO and/or the Investigator, or (ii) any negligence or willful act or omission of the SMO, the Investigator, study Personnel or any of their officers, employees, contractors or staff or (iii) any unauthorized warranties made by the SMO and/or the Investigator or any study personnel concerning the study Drug.

6.3 Notification of Claims

The SMO and the Investigator shall immediately serve a notice in writing to SPONSOR about any investigation, claim or legal proceedings related to the study against the SMO, the investigator, the study personnel or other staff in connection with the study. The SMO and the investigator shall fully cooperate in all reasonable aspects upon request and on behalf of SPONSOR in the investigation and/or defense of these claims or lawsuits.

6.4 Insurance

a) SPONSOR shall ensure it executes the mandatory clinical trial insurance (if any) required by the Applicable Regulatory Requirements.

b) The SMO shall subscribe to and maintain and shall ensure that the investigator subscribes to and maintains all insurance coverage, as required by law. They shall provide evidence of such insurance(s) upon request by SPONSOR.

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7. INSPECTIONS, AUDITS, MONITORING AND RECORDS

7.1 Regulatory Inspections

The SMO and the investigator shall promptly notify SPONSOR of any inspection or investigation relating to the Study by any regulatory, governmental or law agency (including without limitation the Drug Controller General of India, the Ethics Committee, the Central Drugs Standard Control Organization, the State Drug Control, the EMEA and the US FDA) of which they become aware. SPONSOR, and/or their representatives shall have the right to be present at and/or participate in any such inspection or investigation. Before SMO or Investigator submit any materials or information to an agency in connection with an inspection or investigation, SPONSOR shall have the right, to review, provide and/or comment on any such materials and/or information.

7.2 Audit and Monitoring by SPONSOR

SPONSOR and their representatives may audit, monitor and/or meet with the investigator and the study personnel at the SMO and/or at the investigative site during normal business hours and with reasonable frequency for audits and visits to monitor the progress of the study and review study records, documents, information, data, and materials (including the Study Data). The SMO and the investigator shall assist SPONSOR and their representative(s) in scheduling such visits.

a) SPONSOR and their representative(s) shall be entitled to: (i) Examine and inspect the facilities required for the performance of the study; (ii) Inspect source documents; and (iii) inspect, request correction of and copy all study Data (including, without limitation, Case Report Forms, original reports of laboratory tests and examination findings, and all other notes, charts, reports, or memoranda related to the study subjects or to the conduct of the study), which SPONSOR are authorized to access by the signed Informed Consent Form, and/or the applicable regulatory requirements. The investigator shall cooperate with SPONSOR and their representatives during audits and monitoring visits and in the resolution of any questions regarding the study Data.

7.3 Record Keeping

The SMO and the Investigator shall maintain accurate, complete and current records of all study data, including the Case Report Forms (or equivalent electronic data), relevant source documents and any other essential documents or materials as required by the protocol, the applicable regulatory requirements and SPONSOR's instructions (collectively the "**Records**"). The SMO and the Investigator shall keep all the Records in a safe and secure location for the period required by the applicable regulatory requirements, or for a period of fifteen (15) years following the completion of the study, whichever is longer. The SMO and/or the investigator may destroy the records at the end of the records keeping period on the condition that the institution and/or the investigator sends written notice to the SPONSOR at least sixty (60) days prior to the date deletion/disposal will occur, and, if requested by the SPONSOR, cooperates with the SPONSOR in extending the record keeping period or shipping the records at another facility for storage, at the SPONSOR's reasonable expense.

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9. NON-DEBARMENT

The SMO and the Investigator represent and warrant that neither they nor any of the study personnel is or ever has been debarred, disqualified, excluded or suspended to participate in clinical research by any competent authority or agency in any country (including in particular but without limitation the US FDA), and that it shall not make use of, nor involve in this study any person or organization which is or has been debarred, suspended, excluded or disqualified by any regulatory authority to participate in clinical research. In the event the SMO or the Investigator or any person or organization involved in the study is or becomes threatened with or becomes debarred, disqualified, suspended or excluded during the study, the SMO and the Investigator shall notify SPONSOR in writing about this fact within five (5) days of its discovery.

10. DATA TRANSFER

a) The Investigator and the SMO undertake to protect the personal data of the study subjects and to process them in accordance with the applicable data protection laws and regulations.

b) Both prior to and during the course of the study, the investigator and the study personnel may provide SPONSOR with personal data. Such data may include names, contact information, bank account details, work experience, qualifications, publications, resumes, educational background, performance information, facilities, staff capabilities, and other information relating to the study (the "**Personal Data**"). The investigator hereby consents to the processing (including use, disclosure or transfer) of his/her personal data as required for the following purposes (the "**Purposes**"): (i) The conduct of clinical trials, (ii) Review by governmental or regulatory agencies, SPONSOR, and their agents, and affiliates, (iii) Compliance with legal or regulatory requirements, and (iv) Storage in databases for use in selecting investigators and institutions for future clinical trials. The Investigator also agrees to a transfer of his/her Personal Data abroad, even if such personal data is transferred to countries that do not ensure an equivalent level of protection as that provided in India. The Investigator and the SMO represent that all study Personnel have given express consent to the processing of their Personal Data for the Purposes and shall notify SPONSOR immediately if such consent has been withdrawn.

11. EXPERIMENTAL NATURE OF INVESTIGATIONAL PRODUCT

THE SMO AND THE INVESTIGATOR ACKNOWLEDGE THAT THE INVESTIGATIONAL MEDICINAL PRODUCT IS EXPERIMENTAL IN NATURE, AND SPONSOR WILL NOT MAKE ANY WARRANTIES, EXPRESS OR IMPLIED, REGARDING THE INVESTIGATIONAL PRODUCT, INCLUDING WITHOUT LIMITATION THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. THE INSTITUTION AND THE INVESTIGATOR ACKNOWLEDGE THAT SPONSOR CANNOT GUARANTEE THE SAFETY, NON-TOXICITY, FITNESS OR EFFICACY OF THE INVESTIGATIONAL MEDICINAL PRODUCT. THE FOREGOING IS NOT INTENDED TO, AND DOES NOT, NEGATE SPONSOR'S LIABILITY UNDER LAW FOR PRODUCT LIABILITY CLAIMS ARISING OUT OF THE USE OR ADMINISTRATION OF THE STUDY DRUG IN ACCORDANCE WITH THE PROTOCOL AND THIS AGREEMENT.

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8. TERMINATION AND SUSPENSION

8.1 Term

The term of this agreement shall commence on the date of the last named party signature. Unless terminated earlier in accordance with this Section 8, this agreement shall remain in effect until the final study documentation required to be provided under the Protocol is received and accepted by SPONSOR, and SPONSOR has performed a closeout visit at the Institution.

8.2 Termination by the SPONSOR

SPONSOR, in consultation with the SPONSOR, may terminate this agreement with immediate effect (i) If the SMO and/or the Investigator is in breach of this agreement and fails to address such breach within fifteen (15) calendar days from the receipt of written notice, (ii)If SPONSOR in good faith believe the study Drug or continuation of the study presents an unreasonable medical risk to the study subjects or if there are efficacy or safety concerns, (iii) If the study is terminated, suspended or not initiated at the institutions for any reason or (iv) If the agreement between the Investigator, SMO and SPONSOR regarding the study is terminated for whatsoever reason. SPONSOR, may also terminate this agreement without cause upon thirty (30) calendar days' notice.

8.3 Termination by the SMO or the Investigator

Either the SMO or the investigator may terminate this agreement: (i) If SPONSOR breaches this agreement and fails to address such breach within thirty (30) calendar days from the receipt of written notice, or (ii) If, following consultation with SPONSOR, the SMO and/or the investigator in good faith believe that the continuation of the study presents an unreasonable medical risk to the study subjects.

8.4 Surviving Clauses

The termination or expiration of this agreement shall not relieve either party of its obligation to the other with respect of the following provisions: Section 1.4 b) and c) [Study Drug and Study Supply], Section 1.8 [Financial Disclosure], Section 3 [Confidentiality], Section 4 [Intellectual Property], Section 5 [Publication and Publicity], Section 6 [Indemnification, Notification of Claims and Insurance], Section 7 [Inspections, Audits, Monitoring and Record Keeping], Section 8.3 [Surviving Clauses], Section 10 [Data Transfer], Section 11 [Anti-Bribery and Anti-Corruption], Section 12 [Experimental Nature Of Investigational Product], Section 13[Miscellaneous] and Section 14 [Applicable Law and Place of Jurisdiction].

8.5 Suspension of the Study

The SPONSOR may suspend the study at any time for any reason upon written notice, such suspension shall not be deemed as a breach of this agreement by the SPONSOR. .

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12. MISCELLANEOUS

a) No amendment to this agreement (including its attachments) shall be effective unless such amendment is made in writing and signed by the parties hereto.

b) If any provision(s) of this agreement shall be declared invalid by a court of competent jurisdiction, such determination shall not affect the remaining provisions of this agreement which shall remain in full force and effect. The parties hereto shall, however, attempt to replace the provision(s) declared invalid as aforesaid with legally valid provision(s) which reflect(s) the same purpose of the invalid provision(s) to the greatest extent possible.

c) This agreement is entered into between the parties hereto on principal to principal basis. Nothing contained in this agreement shall be construed to imply a joint venture, employment, partnership, or principal agent relationship between the institution/investigator and SPONSOR; and neither party hereto by virtue of this Agreement shall have the right, power or authority to act or create any obligation, express or implied, on behalf of the other party.

d) The SMO and the investigator may not assign any of their rights or subcontract obligations hereunder without the prior written consent of SPONSOR. Even if SPONSOR authorizes delegation or subcontracting in full or in part, the Institution and the Investigator remain fully responsible and liable for the performance of all delegated duties.

13. APPLICABLE LAW AND PLACE OF JURISDICTION

a) This Agreement shall be governed by and construed in accordance with the laws of India, without regard to its conflict of law provisions.

b) Any claim or controversy arising out of or related to this Agreement or any breach hereof shall be submitted to the exclusive jurisdiction of the competent courts located at Hyderabad, Telangana notwithstanding the foregoing, either party may seek injunctive relief in a court of competent jurisdiction.

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[SIGNAGURE PAGE TO FOLLOW]

This Agreement has been executed two originals, one for each party.

SMO: CMS Clinical Research Pvt. Ltd

For CMS Clinical Research Private Limited

Name: Ms. Anshula Gautam

Title: Director

Authorised Signatory

Dated: _____

Investigator:

Name: Dr. Rajesh Shankar Powar,

Title: Investigator

Dated: _____

Dr. Rajesh S. Powar
Senior Consultant & Head
Dept. of Plastic & Reconstructive Surgery
KLES Dr. Prabhakar Kore Hospital &
MRC- Belgaum.

ATTESTED

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Attachment 1

Fee and Payment Schedule

I. Fees

The investigator fees shall be based on the number of study subjects randomized into the study in compliance with the protocol and the number of visits performed with respect to these study subjects in accordance with the following payments table:

All amounts stated in this Fee and Payment Schedule are inclusive of any value added tax.

A. Fixed Cost	Unit Cost (INR)	Amount (INR)
Ethics Committee Fee	@25,000/- per protocol	25,000/-
Study Equipments • BP Machine with calibration certificate - 1 • Height Measuring Scale with calibration certificate - 1 • Weighing Machine with calibration certificate - 1 • Clinical Thermometer with calibration certificate - 1 • Thermohygrometer without probe with calibration certificate – 1 • Video Camera* – 1 (*Video Camera to be returned to sponsor after the completion of study)	 • @ 2,260/- • @ 590/- • @ 2,333/- • @ 350/- • @ 915/- • @ 12,200/-	18,648/-
Sub Total		**43,648/-**
B. Variable Costs	**Unit Cost**	
Investigator Research Grant – for 15 completed subjects	@ Rs. 15,000/- per completed patient	2,25,000/-
Investigator Research Grant in case of drop out after visit 2 for 2 drop out patients	@ Rs. 2000/- per drop out patient	4,000/-
Study Coordinator Grant - for 15 completed subjects	@ Rs. 3,000/- per completed patient	45,000/-
Study Coordinator Grant in case of drop out after visit 2 for 2 drop out patients	@ Rs. 1000/- per drop out patient	2,000/-
Institutional Overhead Charges (for subjects completing the study) @ 20% of research grant – for 15 completed subjects	@ Rs. 3,600/- per completed subject	54,000/-
Institutional Overhead Charges (for drop out subjects) @ 20% of research grant – for 2 drop out subjects	@ Rs. 600/- per drop out subject	1200/-
Laboratory Investigation Charges – for 15 completed patients	@ Rs 5,450/- per completed patient as per Lab cost sheet signed (To be paid on actual as per the bills provided)	81,750/-
Photographic Charges- 60 photographs for 15 patients	@ 40/- per completed patient	600/-
Study subject travel allowance (60 visits for 15 subjects)	@ 100/- per completed visit	6000/-
Sub Total		**4,19,550/-**
	Total	**4,63,198/-**

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II. Invoicing and Payments

a) SPONSOR shall make the payments in Indian Rupees according to the grant/fee payment schedule on the date of invoicing. The Overall Budget will be shared equally between the CMS Clinical Research (SMO) & Investigator after deducting all the study related expenditure. CMS Clinical Research will pay to Investigator once fund released by sponsor.

b) EC fees and institute overhead charges will not be paid to CMS clinical Research Pvt. Ltd.

III. Account Details

The SMO and the Investigator herby instruct SPONSOR to pay the entire investigator fee under this Agreement to the following bank account:

Issuing Entity	Ranbaxy Laboratories Ltd.
Payee Name	CMS Clinical Research Pvt. Ltd.
Payee Address	#51, 3rd Floor, Paigah Colony, S P Road, Secunderabad-500003, Telangana,
PAN No:	AAFCC 8457 M
Method of Payment	Cheque
Bank Name	HDFC Bank

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CONFIDENTIAL

CLINICAL STUDY AGREEMENT

This clinical study agreement ("Agreement") is executed as of the 11th day of July 2016 (Effective Date) by and between:

Sun Pharma Advanced Research Company Ltd. (CIN L73100GJ2006PLC047837), a company registered under the Companies Act, 1956 having its registered office at SPARC Ltd, Akota Road, Akota, Vadodara - 390020 India and having a business address at 17/B, Mahakali Caves Road, Andheri East, Mumbai 400093, India, which expression shall, where the context so permits include his successors in office and assigns (hereinafter referred to as the "**Sponsor**").

AND

KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, a hospital having its registered office at Nehrunagar, 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. Rohan Bhise, MBBS, MD (Oncology), Principal Investigator, at KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehrunagar, Belgaum - 590010, Karnataka, India. (hereinafter referred as the "**Investigator**")

AND

Global Drug Development (GDD) Experts India Pvt. Ltd. , Ground floor, Gulmohar Apartment, Opp. Hislop College, Civil Lines, Nagpur-440001, Maharashtra, India. Head Off.: 910 Seventeenth Street, NW Suite 312, Washington D.C. 20006 (hereinafter referred as the "**Site Management Organization**")

(each a "Party" and Sponsor, Investigator and Investigator collectively, the "Parties")

WHEREAS:

A. The Institution is a health care and research 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. Sponsor is a pharmaceutical company involved, inter alia, in the research, development and manufacture of medicines for use in humans and has developed **Paclitaxel Injection Concentrate for Nano-dispersion (PICN)** which is intended to be used for treatment of **locally recurrent or metastatic breast cancer**. Sponsor represents that it has applied for the necessary permissions and licenses required under the provisions of relevant Acts and Rules which are required for use of the same on subjects/ healthy human volunteers etc.
Site Management Organization has agreed to provide a professionally trained and experienced Clinical Research Coordinator who will be responsible for delegated trial related activities and documentation from the start till close out of the trial

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at the Institute; a Project Manager to over-see & coordinate the progress & management of CRC activities and a Quality Control Associate to ensure adherence to the protocol, ICH-GCP, other applicable regulatory requirements and the relevant Standard Operating Procedures (SOPs). Hence GDD Experts will assist Investigator and institute for efficient Trial Management, Project Management and Quality Management.

C. Sponsor desires Institution to study the bioavailability and bioequivalence of PICN and Institution is willing to perform a clinical study of the Investigational Product (IP).

NOW THEREFORE in consideration of the promises and mutual covenants herein contained, Parties including Site Management Organization hereby agree as follows:

1. SCOPE

1.1 The Study is of mutual interest and benefit to Sponsor 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 CLR_16_13: A Randomized, Open Label, Two Period, Single Dose, Crossover, Bioavailability Study Of Paclitaxel Injection Concentrate For Nano-Dispersion (PICN) And Abraxane® In Subjects With Locally Recurrent Or Metastatic Breast Cancer, which has been provided prior to signing of this Agreement. In the event of any inconsistency between this Agreement and the Protocol, the terms of this Agreement shall govern. Changes in the Protocol may be made only through prior written agreement between the Sponsor and the Institution. The Study shall be conducted under the direction of Investigator in accordance with this Agreement, subject to review and prior approval by the institution's ethical committee.

2. CONDUCT OF THE CLINICAL TRIAL

2.1 The Investigator and the Institution shall conduct the Study in accordance with the Protocol. The Sponsor is responsible for obtaining and maintaining all applicable regulatory approvals for the Study in India. The Sponsor, Investigator and Institution shall perform the Clinical Study 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 Site Management Organization will be ensure to follow the Study Management Responsibilities Matrix which is a detail agreement to define the terms and condition and obligation of each Party between PI, Institute and Site Management Organization

2.3 It is explicitly agreed and acknowledged by the Parties including Site Management Organization that the Protocol for clinical trial/Study be reviewed and approved by the Ethical Committee ("EC") registered with DCGI before the commencement of the Study.

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The Investigator shall obtain and deliver a copy of such approval to the Sponsor. The approval must indicate the date of issuance and bear the name and signature of the Chairperson or Secretary of the EC. If any such committee do not exist in the Institution, then the approval granted to a protocol by the ethics committee of another institution will be applicable to use of that protocol in the Institution.

2.4 The Institution and Investigator agree that the Sponsor or its designee as clinical monitor will conduct routine monitoring visits at mutually convenient times and upon reasonable advance notice to the Investigator. The clinical monitor will have direct access to all original records and documents pertaining to the study to ensure that the study is conducted in accordance with the Protocol and applicable regulatory requirements and in terms of this Agreement. Similarly, sponsor may conduct audit at mutually convenient times and upon reasonable advance notice to the Investigator. The auditor will have direct access to all records and documents pertaining to the study.

2.5 It is explicitly agreed and acknowledged by the Parties including Site Management Organization that in case Investigator is unable to perform the study in accordance with this agreement, the Institution shall appoint another Investigator in consultation with the Sponsor. The Institution shall take written consent from the Sponsor prior to such appointment. The Sponsor retains the right to suggest Investigator(s) for appointment to conduct and perform the Study.

2.6 If any biological samples are to be tested as part of the Study, these are to be tested in accordance with the Protocol and at a central laboratory approved by Sponsor and with the Clinical Trial Subject's signed written informed consent form. If study requires local lab, the investigator would share applicable documents (viz. lab head CV, accreditation, Lab normal values). It is explicitly agreed and acknowledged by the Parties including Site Management Organization that Collection, Retention, Use and Destruction of Biological Samples by Institution or Investigator or Sponsor or either of the parties including Site Management Organization shall be in accordance with the applicable Protocol, acceptable clinical trial practices, applicable subject privacy and informed consent laws and in compliance with all applicable laws and regulations.

For the investigations required to be conducted at the local laboratory, the expenses will be reimbursed as per actuals, subject to submission of the original invoices and corresponding receipts for the same obliterating subject's identity.

3. OBLIGATIONS, REPRESENTATIONS &WARRANTIES OF THE PARTIES INCLUDING SITE MANAGEMENT ORGANIZATION

3.1 The Investigator shall be responsible for obtaining and maintaining all approvals from the appropriate EC for the conduct of the clinical Study and from time to time the Investigator shall inform Sponsor about the progress of EC submissions, and provide Sponsor and the Institution with all correspondences relating to such submissions. The institution shall ensure the proper conduct of Study.

3.2 The Investigator shall be responsible for obtaining a signed informed consent form from each Clinical Study Subject prior to the Clinical Study Subject's participation in the Clinical Study. For clarity **"Clinical Trial Subject"** means a person recruited to participate in the Clinical Trial. The investigator shall comply with the applicable regulatory requirement(s), and should adhere to GCP and to the ethical principles in

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obtaining and documenting informed consent. The Parties including Site Management Organization agree that in addition to the requirement of obtaining written informed consent, , including the procedure of providing information to the subject and his/her understanding on such consent is required to be done while adhering to the principles of confidentiality. As per applicable regulatory requirement, it is agreed and acknowledged by the Parties including Site Management Organization that in case of certain clinical trials, audio-video recording of the informed consent process to be maintained by the investigator for certain subjects. In such event, the Parties including Site Management Organization will agree the necessary terms and conditions relating to the audio-video recording and incorporate the same in the informed consent form.

3.3 In addition, prior to the beginning of the Study, the Investigator must have the EC's written approval/favourable opinion of the written informed consent form and any other written information to be provided to Clinical Trial Subject. Neither the investigator, nor the trial staff, should coerce or unduly influence a Clinical Trial subject to participate or to continue to participate in a trial.

It is agreed and acknowledged by the Investigator and the Institution that when a clinical trial (therapeutic or non-therapeutic) includes Clinical Trial Subjects who can only be enrolled in the trial with the consent of the Clinical Trial Subject's legally acceptable representative (e.g., minors, or subjects with severe dementia), the Clinical Trial Subject should be informed about the trial to the extent compatible with the subject's understanding and, if capable, the subject should sign and personally date the written informed consent.

3.3 The Investigator shall take reasonable efforts to recruit the agreed number of Clinical Trial Subjects on a timely basis and the Parties including Site Management Organization shall take reasonable efforts to conduct the Clinical Study in accordance with the agreed time period.

Investigator shall target to enroll (randomize) at least 6-8 subjects in the study.

3.4 The Institution and Investigator shall not permit the use of IP for any purpose (whether directly or indirectly) other than the conduct of the clinical Study and upon termination or completion of study, all used and unused IP shall, at Sponsor's instructions, either be returned to Sponsor or destroyed in accordance with the Protocol or Sponsor's written instructions.

3.5 It is explicitly agreed and acknowledged by the Parties including Site Management Organization that the Study may involve the participation of multiple sites and recruitment and in such event, when the enrolment goal for the clinical Study as a whole is reached, enrolment will be closed at all sites, including the trial Site, regardless of whether the Institution has reached its individual enrolment goal.

3.6 To the extent permitted by law, the Institution and the Investigator shall immediately inform Sponsor of:

3.6.1 Any intended or actual inspection, written inquiry or visit to the trial Site by any regulatory authority; or

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3.6.2 Any queries by State or Central Information Commission under Right to Information Act (amended up to date)

In connection with the clinical Study and forward promptly to Sponsor copies of any correspondence from any such authority.

The Institution or Investigator shall use its best efforts to obtain the approval of the regulatory authority (e.g. DCGI or state FDA personnel) to have a representative of Sponsor present during any such visit. If a representative of Sponsor is unable to be present during a visit, the Institution and the Investigator shall provide Sponsor with a prompt brief summary followed by a detailed written report following the visit.

3.7 The Institution and the Principal Investigator shall keep complete and accurate records of the conduct of the clinical Study and of all clinical Study data in accordance with generally accepted industry standards and practices and applicable Law. The Institution and the Investigator agree to retain all such records for a period of not less than fifteen (15) years from the date of completion of Study or termination of this Agreement, whichever is earlier, or any such period prescribed in the Sponsor's 'Document Retention & Destruction Policy'(the "Retention Period"). The Institution shall use reasonable efforts to give Sponsor written notice before destroying the Clinical trial documentation and clinical trial data. Any such destruction is subject to prior written consent of the Sponsor. In case, Institution and Principal Investigator do not have archival facility as per Sponsor's expectations, Institution and Principal Investigator agree to third party archival facilitated by the sponsor respecting confidentiality of subject's data.

For clinical/ therapeutic bioequivalence study, the Investigator and institution agree to retention of Investigational Product (IP) as per regulatory requirements. In case, Institution and Principal Investigator do not have archival facility for IP as per Sponsor's expectations, Institution and Principal Investigator agree to third party archival by the sponsor respecting confidentiality of subject's data.

3.8 The Investigator undertakes to document all Adverse Events (AE) on adverse event page of Case Report Form (CRF). The investigator shall report all serious adverse events (SAE) to the licensing authority (DCGI), sponsor/ CRO (if applicable) and chairperson of ethics committee within 24 hour of SAE occurrence. The investigator shall report all SAE after due analysis to the licensing authority (DCGI), chairperson of ethics committee and head of the institution where the trial has been conducted within the timelines as per the applicable regulatory requirement. Subsequent follow-up information shall be reported to all stakeholders as mentioned above. In case, Investigator fails to report any SAE within stipulated period, the investigator shall have to furnish the reason for the delay to the satisfaction of licensing authority along with the report of SAE. Sponsor's safety physician/ CRO (if applicable) shall report all SAE after due analysis to licensing authority (DCGI), chairperson of ethics committee and head of the institution where the trial has been conducted within the timelines as per the applicable regulatory requirement. Subsequent follow-up information shall be reported to all stakeholders as mentioned above. Sponsor's safety physician/ CRO (if applicable) shall report all serious adverse events to other participating Investigators within the timelines as per the applicable regulatory

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requirement. (This shall be for multi centric studies). Sponsor's safety physician/ CRO (if applicable) shall notify SAE to other regulatory authorities as applicable.

As much information as possible shall be supplied by Investigator at the time of the initial report with at least the following information using SAE Report Form.

- Name, address, and telephone number of the reporting Investigator.
- Investigational product(s).
- Protocol number.
- Subject identification number, initials, sex and date of birth.
- Description of the AE, reason considered serious, measures taken and outcome (if resolved.
- Likelihood of drug causation of the adverse event assessed by the Investigator.

A SAE is any untoward medical occurrence that, at any dose:

- results in death;
- is life-threatening;
- requires in-subject hospitalization or prolongation of existing hospitalization; [For the avoidance of doubt, A planned hospitalization for pre-existing condition, or a procedure required by the Clinical Investigation Plan, without a serious deterioration in health or if the hospitalization is clearly not associated with an AE [(e.g., social hospitalization) are not to be considered as SAEs.]
- results in persistent or significant disability/incapacity;
- is a congenital anomaly/birth defect;
- important medical event.

For the sake of clarity, the term "life-threatening" in the definition of "serious" refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event, which, hypothetically, might have caused death if it were more severe.

To the maximum extent permissible under applicable laws and DCGI regulation, the Sponsor shall pay all medical expenses pertaining to Study subject in the event of any AE or SAE. In case of trial related injury or death, the financial compensation will be paid to the subject/ nominee subject to the terms and conditions of this Agreement.

3.9 The Sponsor shall pay all medical management pertaining to Study subject in the event of any SAE, and any IP or study participation related AE, unless it has arisen due to non-adherence to the terms of the Protocol or Sponsor's written instructions on IP as agreed by Investigator EC and/or the same has resulted from the negligence or willful malfeasance or malpractices by Investigator and /or any trial staff or the Institution.

If Subject has a medical emergency, illness or injury that was caused by the research drug or study procedures, Sponsor will provide subject medical management as per the applicable regulatory requirement.

In case of Study related injury or death, to the maximum extent permissible under applicable laws and DCGI regulation, Sponsor will provide complete medical care along

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with compensation for the injury or death. In case of any SAEs (death and other than death) EC will evaluate and give its opinion regarding compensation to DCGI. Subject will get an additional compensation will be over and above any expenses incurred on subject's medical management from Sponsor if recommended by DCGI. Subject or his/her nominee(s) has the right to contact the Sponsor or his representative, for the purpose of making claim in the case of trial related injury or death.

3.10 Investigator warrants and represents that:

3.10.1 He is free to participate in the clinical trial/ Study and there are no rights, which may be exercised by, or obligations owed to any third party, which might prevent or restrict his performance of the obligations detailed in this Agreement;

3.10.2 Where the Institution is not the Investigator's principal employer, he has notified his principal employer of his proposed participation in the clinical trial/Study and, where relevant, his supervision of trial site team members. He has obtained all necessary consents from his principal employer relating to this;

3.10.3 He is not involved in any regulatory or misconduct litigation or investigation by the Drugs Controller General of India, Food and Drug Administration, the Ministry of Health, or other regulatory authorities;

3.10.4 He is qualified to provide clinical Study services based on the skills and experience and has reviewed information regarding the Sponsor's IP and the Protocol for the proposed clinical Study and wishes to conduct the trial and to supervise the team members at the trial site; and

3.10.5 During the Clinical Trial, he will not serve as an investigator or other significant participant in any clinical trial/study for another sponsor or any CRO companies if such activity might adversely affect his ability to perform his obligations under this Agreement.

3.11 Institution certifies that neither Institution nor any person (including Investigator) employed or engaged by Institution in the conduct of the Study has been debarred pursuant to applicable provisions of law (whether state or central) and that no debarred person will in the future be employed or engaged by Institution in connection with conduct of the Study. Institution further certifies that it will notify Sponsor immediately in the event of any debarment or threat of debarment of any person employed or engaged by Institution in the conduct of the Study occurring during the period of this Agreement.

3.12 Sponsor, Institution and the Investigator represent and warrant that it has the right to enter into and fully perform this Agreement and, by entering into this Agreement it is not in violation of any law, statute, agreement or any other statue.

4. FINANCIAL ARRANGEMENTS

4.1 SPARC, as Sponsor, has agreed to provide financial support for the project. The Sponsor shall pay fees for the services of the Investigator in accordance with the budget as per Exhibit-A.

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4.2 Sponsor shall make payments to Institution in accordance with the payment schedule set forth in Exhibit A and incorporated herein. Cheque (s) shall be made payable and sent to the:

Payee Name: GDD Experts India Private Limited
PAN: AADCG0363Q

4.3 The Investigator agrees to make every effort to supervise and lead the study to completion as planned and in time. Should any circumstances beyond his control delay the project or make it impossible to complete it, the Investigator shall give due notice to the Sponsor so as to minimize the overall project delay or the loss, and return funds to the sponsor on pro rata basis as per Exhibit A. The Investigator and Institution should facilitate return of unused IP to sponsor or other site as per sponsor's instructions.

4.4 The Payee shall raise invoice on the Sponsor and separately specify Service Tax payable, if applicable, on the services rendered and shall also show other necessary details such as Service Tax registration no. etc. so as to enable Sponsor to claim credit for the same as per law. The Sponsor shall verify the invoice and make the payment within 30 days from the receipt of the invoice submitted by Payee. However, if, upon verification by Sponsor, the invoice is found to be incorrect or inappropriate, the same shall be returned by Sponsor to the Payee for correction and revision. No other costs, payments and expenses would be borne by Sponsor unless specifically mentioned in this agreement or mutually agreed in writing in advance. Notwithstanding the foregoing, any payment under this Agreement is subject to deduction of applicable Tax-deduction-at-source (TDS). Sponsor shall deduct the amount and pay balance amount to the Institution.

4.5 The Parties including Site Management Organization hereby agree that Site Management Organization shall be responsible for payment of fees to Institution to performance of their obligation for conducting the clinical trial under this Agreement. The Parties including Institution further agree that SPARC shall not responsible for payment of any fees or cost to Institution. SPARC shall not be liable to pay any sum to Institution even in the event including the default of Site Management Organization in making payment to Institution SPARC shall not be liable to pay to Institution under this Agreement.

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 Clinical Study, whichever is earlier.

5.2 Parties 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. Notwithstanding to the above, the Investigator may terminate the Study, if the Investigator suspects an adverse drug reaction / adverse drug event related to the Study related procedure and of serious nature to take its cognizance, after informing Institution, EC and Sponsor in writing. 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 Sponsor to Principal Investigator, Institution or any other person under this agreement.

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5.3 Sponsor may terminate this Agreement upon thirty (30) days prior written notice to the Institution and the Principal Investigator, or such shorter notice period as required by a Regulatory Authority (whether State or Central), for any reason whatsoever.

5.4 Without limiting the generality of the foregoing, Sponsor may terminate this Agreement:

5.4.1 if the Investigator is not performing the Study as required in the protocol;

5.4.2 in case of failure of the Investigator and/ or Institution to provide access by Sponsor representatives /Clinical monitor 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 Sponsor determine that business or scientific considerations require termination of this Agreement (either full or in part);

5.4.5 if Case report forms provided to Investigator by Sponsor for use in the study are not legibly and/or accurately completed and forwarded the same to Sponsor or its designated representative persistently within 1 week of each Subject's visit date; or

5.4.6 if any malpractices adopted either by Investigator or Institution or both.

5.5 Within thirty (30) days after the termination of this Agreement, the Investigator shall deliver to Sponsor completed CRF pages on RDC.

6. INDEMNIFICATION

6.1 To the maximum extent permitted by applicable laws, the Institution agrees to defend, indemnify and hold harmless the Sponsor 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 third party against an Indemnity for harm:

6.1.1 Arising out of or relating to the negligence or willful 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 Sponsor 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 The Investigator agrees to defend, indemnify and hold harmless the Sponsor and its respective directors, officers, employees and agents (the "**indemnities**")and those of its

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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 third party against an indemnity for harm:

6.2.1 arising out of or relating to the negligence or willful misconduct or malpractices of the Investigator, his study team member/employee or any person for whom the Investigator is responsible at law in performing their obligations under this Agreement;

6.2.2 arising out of or relating to the failure of the Investigator, his or her study team members or employees and any person for whom the Investigator is responsible at law to comply with the provisions of this Agreement, the Protocol, or any written instructions of Sponsor concerning the Clinical Study ;

6.2.3 arising from a violation of applicable laws and regulations related to the conduct of the Clinical Trial by the Investigator, his or her study team members/ employees or any person for whom the Investigator is responsible at law; or

6.2.4 arising out of from or by reason of any breach or non-frivolous of alleged breach of representation, warranty or covenant herein.

6.3 To the maximum extent permitted by applicable laws, SPONSOR 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 Sponsor 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 IP used during the Study in accordance with the provisions of the Protocol and this Agreement.

6.4 Each Party shall use reasonable efforts to inform the other Parties including Site Management Organization 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 Parties including Site Management Organization 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 5. The Parties including Site Management Organization further agree that they have a right to retain their own counsel to conduct a full defense of any such claim or proceeding.

6.5 The Institution, Investigator and Sponsor 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.

6.6 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(s). 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.

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7. CONFIDENTIALITY.

"Confidential Information" means all information (including, without limitation, subject identity, Study Protocol(s), Investigator Brochure, informed consent form, subject diaries, 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 Sponsor or Sponsor's Affiliates that are: (1) provided to Institution or Investigator in connection with this Agreement or a Study; (2) cumulative Study data, results, and reports from all sites conducting the Study.

7.1 Sponsor Confidential Information and all tangible expressions, in any media, of Sponsor Confidential Information are the sole property of Sponsor. Each party shall endeavor 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 and Investigator agree to treat Sponsor's Confidential Information as it would its own proprietary and confidential information. Institution and Investigator will only accept information from Sponsor which is required for conduct of the Study and which must be maintained for Institution's records.

7.2 Investigator agrees for a period of ten (10) years after the expiration or termination of the Study not to use and disclose Sponsor Confidential Information to any third party. Institution and Investigator agrees not to disclose Sponsor Confidential Information to third parties including Site Management Organization 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 Investigator shall safeguard 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 including Site Management Organization understand and agree that information communicated to EC is "Confidential and Privileged".

7.3 The Parties including Site Management Organization 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 including Site Management Organization of any privacy or security breach it has experienced that affects Clinical Trial Subject Personal Information.

8. PUBLICATION

8.1 Institution and/or Investigator shall have the right to publish his own site patients' data generated during the Study. Upon receipt of written instruction from Sponsor, Institution and/or Investigator shall have the right to publish the results of the Study subject to the terms and conditions of this Section 8. Prior to submission for Publication purpose, the Institution and/or Investigator shall provide Sponsor thirty (30) days to review a Publication. If Sponsor requests in writing, the Institution and/or the Investigator shall withhold any publication or presentation an additional sixty (60) days solely to permit Sponsor to seek patent protection and to remove any Confidential Information from all publications. For the purpose of this Section, "Publication"

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means a paper, article, manuscript, report, poster, Internet posting, presentation slides, abstract, outline, video, instructional material, presentation (in the form of a written summary), or other disclosure of Study Results, in printed, electronic, oral or other form.

8.2 Inclusion of the Institution and/or Investigator in the authorship of any multi-center publication will be based upon substantial contribution to the design, analysis, interpretation of data, drafting and/or critically revising any Publication derived from the Study. The Institution and the Investigator agree that if a Study is part of a multi-center study, any Publication by the Institution and/or Investigator of the results of the Study conducted at Institution shall not be made before the first multi-center publication. In the event there is no multi-center publication within twelve (12) months after a Study has been completed or terminated at all Study sites, and all data has been received, Institution shall have the right to publish its results from the Study, subject to the notice requirements described above.

8.3 Any publication or disclosure by the Investigator 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 including Site Management Organization that in the event of any breach of this Section, Section (7) & (8), 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.

9. INTELLECTUAL PROPERTY RIGHTS

9.1 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.

9.2 All Intellectual Property Rights owned by or licensed to the Institution or the 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 Investigator, as applicable.

9.3 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 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 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.

9.4 The Institution and the 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.

10. MISCELLANEOUS

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10 .1 All notices required to be given by one Party to the other shall be deemed to have 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.

10 .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.

10 .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 Site Management Organization including without limitation one of principal and agent, employer and employee, or partnership.

10 .4 The Institution and Investigator will be responsible for payment to its employees, study team members and/or agents of all salaries, wages, benefits, workman compensations reimbursable travel, lodging, and other expenses to which the study team members or employees or agents may be entitled to receive for performing services. Investigator 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.

10.5 This Agreement constitutes the entire Agreement between the Parties including Site Management Organization and supersedes all prior oral and written understandings between the Parties including Site Management Organization 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 including Site Management Organization.

10.6 The Parties including Site Management Organization 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.

10.7 Neither the Investigator nor the Institution may assign this Agreement without the prior written consent of Sponsor. Sponsor may assign any or all of its rights and obligations under this Agreement at any time, provided that Sponsor ensures the assignee is bound by the terms hereof.

10.8 The Investigator and the Institution shall not subcontract the whole or any part of the performance of the clinical Study without the prior written consent of Sponsor. This Agreement ensures to the benefit of and binds the Parties including Site Management Organization and their respective administrators, successors and permitted assigns, and with respect to the Investigator, heirs and executors.

10.9 This Agreement and the obligations of the Parties including Site Management Organization shall be governed by and construed in accordance with the laws of India .The Parties including Site Management Organization agree to submit to the exclusive jurisdiction of courts at Mumbai in connection with this Agreement.

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10.10 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 including Site Management Organization 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.

10.11 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.

11. INTERPRETATION

11.1 Unless the context requires otherwise:

11.1.1. references to this Agreement are to this Agreement as it is from time to time amended;

11.1.2. headings are for convenience only and shall not affect interpretation;

11.1.3. references to the singular include the plural and vice versa, and references to one gender include all genders;

11.1.4. 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;

11.1.5. 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;

11.1.6. 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;

11.1.7. references to a numbered clause are references to the clause of or to this Agreement so numbered.

11.2 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 favoring or disfavoring any party by virtue of

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Belagavi-590 010,Karnataka

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.

Signature page follows-

BY SPONSOR:

Sun Pharma Advanced Research Company Ltd.

Signature: Ajay Singh Solanki

Name: Mr. Ajay Singh Solanki

Designation: GM, Clinical Operations
(who by his signature hereto warrants his authority)

Date: 22-Aug-2016

Place: Mumbai.

BY INSTITUTION:

KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre

Signature:

Name: Dr. M. V. Jali

Designation: Medical Director

(who by his/her signature hereto warrants his/her authority)

Date:

Place:

BY INVESTIGATOR

KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre

Signature:

Name: Dr. Rohan Bhise

Designation: Principal Investigator
(who by his signature hereto warrants his authority)

Date:

Place:

BY SITE MANAGEMENT ORGANIZATION

GDD Experts India Pvt. Ltd.

Signature:

Name: Vinod Gyanchandani

Designation: Head-Clinical Operations
(who by his signature hereto warrants his authority)

Date: 21/Aug/2016

Place: Nagpur

APPROVED BY LEGAL
No.: R31:19:08:16
INITIALS

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EXHIBIT-A

Financial Grant

Protocol No.: CLR_16_13

Protocol Title: "A Randomized, Open Label, Two Period, Single Dose, Crossover, Bioavailability Study of Paclitaxel Injection Concentrate for Nano-dispersion (PICN) and Abraxane® in Subjects with Locally Recurrent or Metastatic Breast Cancer."

Investigator's Name: Dr. Rohan Bhise

Institute Name: KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre

Heads	Amount in INR with breakup		Schedule for Generating Invoice
Screen failure cost up to 5 subjects	8000/subject		Monthly
Investigator fee per completed subjects	Screening Visit	8000	Monthly
	Cycle 1 Day1	20500	
	Cycle 1 Day 8	4500	
	Cycle 1 Day 15	4500	
	Cycle 2 Day 1	20500	
	Cycle 2 Day 8	4500	
	Cycle 2 Day 15	4500	
	End of study visit	8000	
	Total	75000	
Study coordinator salary/month (From Site Initiation date till Site Close-out date)	15000		Monthly
Phlebotomist charges/ completed subject	Cycle 1	1250	Monthly
	Cycle 2	1250	
	Total	2500	
IP reconstitute or charges per reconstitute	1000		Monthly
Subject travel reimbursement/visit	1000		Monthly
Subject study participation in period 1 and period 2 *	Cycle 1	2500	Monthly
	Cycle 2	2500	
	Total	5000	
Administrative cost/ month (Internet, courier, stationary etc.) (From Site Initiation date till Site Close-out date)	2500		Monthly
Ethics committee charges	As per actual		Monthly
Hospitalization charges for cycle 1 & cycle 2	As per actual		Monthly
SAE management	As per actual		Monthly
Local lab charges	As per actual		Monthly
Institutional overheads charges	20 %		Monthly

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1) All invoices will be addressed to: Mr. Ashok Gupta, Sun Pharma Advanced Research Company Ltd., Clinical Research Dept., 17/B, Mahal Industrial Estate, Mahakali Caves Road, Andheri (E), Mumbai 400093, Maharashtra, India.

2) *As per Indian Council for Medical Research guidelines 2006 on "Ethical Guidelines for Biomedical Research on Human Participants"

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INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA26553303732998P
Certificate Issued Date	:	03-Nov-2017 12:31 PM
Account Reference	:	NONACC (FI)/ kaksfcl08/ RAJARAJESHWARI NAGAR1/ KA-BN
Unique Doc. Reference	:	SUBIN-KAKAKSFCL0803156565987465P
Purchased by	:	QUINTILES RESEARCH INDIA PVT LTD
Description of Document	:	Article 12 Bond
Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	QUINTILES RESEARCH INDIA PVT LTD
Second Party	:	KLES KARNATAKA
Stamp Duty Paid By	:	QUINTILES RESEARCH INDIA PVT LTD
Stamp Duty Amount(Rs.)	:	300 (Three Hundred only)

SHIVAJI SOUHARDA PATHINA SAHAKARI NIYAMITHA BANGALORE

Please write or type below this line

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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 NehruNagar, Belagavi - 590 010, Karnataka, India (the "**Institution**"), and

Dr. Veerappa Annasaheb Kothiwale having a place of business at KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, NehruNagar, Belagavi - 590 010, Karnataka, India (the "**Investigator**"), and

GDD Experts India Pvt. Ltd at Ground Floor, Gulmohar Apartment, Opposite Hislop College, Nagpur - 440 001, Maharashtra, India (the "Research Company"), and

Quintiles Research (India) Private Limited, having a place of business at B 101-106, Shapath IV, Opposite Karnavati Club, Sarkhej Gandhinagar Road,, Ahmedabad 380051, Gujarat, India ("**Quintiles**"),

Each a "**Party**" and together the "**Parties**".

Protocol Number:	K-877-302
Protocol Title:	PROMINENT PEMAFIBRATE TO REDUCE CARDIOVASCULAR OUTCOMES BY REDUCING TRIGLYCERIDES IN PATIENTS WITH DIABETES
Protocol Date:	16 November 2016
Sponsor:	Kowa Research Institute, Inc.
Country where Site is Conducting Study	India
Investigator:	Dr. Veerappa Annasaheb Kothiwale *"an employee of Institution"*
Key Enrollment Date:	**100 Calendar Days after Site Initiation Visit date (being the date by which Site must enroll at least one [1] subject as more specifically set out in section 1.8 "Key Enrollment Date" below)**
IRB/IEC	Ethics Committee of KLE University, Belagavi, JNMC Campus, NehruNagar, Belagavi-590 010, Karnataka, India EC chairperson name : Dr. Subarna Roy Contact No. of the EC chairperson: +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 Sponsor (defined below).

Case Report Form or **CRF**: paper or electronic document to be used by Site to record all applicable Protocol-required information to be reported to Sponsor on each Study Subject (defined below).

Study: the clinical trial that is to be conducted in accordance with this Agreement and the Protocol for purposes of gathering information about the Investigational Product 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.

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Study Staff: the individuals involved in conducting the Study under the direction of the Investigator.

Investigational Product: the investigational drug 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: an individual, institution, company or organization that takes the responsibility to initiate, manage or finance the Study, but does not actually conduct the Study.

Medical Records: the Study Subjects' primary medical records kept by the Institution on behalf of the Investigator.

Source Documents: all recorded original observations and notations of clinical activities and all reports and records necessary for the evaluation and reconstruction of the Study, regardless of form, as maintained by the Investigators, including all laboratory reports, ECG tracings, x-rays, radiologist reports, biopsy reports, ultrasound photographs, Study Subject progress notes, hospital charts, pharmacy records and any other similar reports or records of any procedure performed during the Study. Source Documents include workbooks only when information is recorded directly onto such forms. In the event that the workbook is used as a Source Document by a physician not identified as a primary or secondary investigator in the Protocol or not under the direct supervision of the Investigator, the workbook must be signed and dated by the individual making the entry.

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 data relating to Subjects that are, collected by or on behalf of the Site in connection with the Study.

Study Documentation: all (i) Source Documents, (ii) Study Data and, (iii) to the extent not included in (i) or (ii), all records, accounts, notes and reports relating to the Study, whether in written, electronic, video or other tangible form, including: Case Report Forms; data correction forms; monitoring logs; appointment schedules; case histories; informed consent forms and related documentation; records of receipt, use, processing and disposition of the Investigational Product approvals of (a) the applicable Protocol and any amendments thereto and (b) the informed consent forms by the Investigator, Site and the IRB/IEC; copies of all correspondence to or from Quintiles related to the Study; the Investigator, any other Study Staff, any IRB/IEC and any Governmental Official with respect to the Study; any other documentation required by the Protocol, this Agreement, or Applicable Law. While "Study Documentation" may include information derived from a Study Subject's Medical Record, "Study Documentation" does not include any portion of the Medical Record.

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

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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).

Dual Capacity: the capacity of holding a Government Official position and being a party to this Agreement.

RECITALS:

WHEREAS, Quintiles is providing clinical research organisation services to Sponsor under a separate contract between Quintiles and Sponsor and Quintiles' 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 Quintiles 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 ("**Applicable Law**") including in particular, but without limitation, GCPs, MCI Regulations and state and local tax and finance regulations. Site and Study Staff acknowledge that Quintiles 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 ("**ICF**") that has been reviewed by Sponsor and is approved by and 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. Prior to a Study Subject participating in the Study,Site shall obtain from such Study Subject a properly executed ICF.

1.3. Medical Records and Study Documentation

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 Documentation.

Site shall

(i) maintain and store Medical Records and Study Documentation 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, and industry standards; and

(ii) protect the Medical Records and Study Documentation from unauthorized use, access, duplication, and disclosure. If directed by Sponsor or Quintiles, Site will

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submit Study Documentation using the electronic system provided by Sponsor or Quintiles or their designated representative and in accordance with Sponsor's instructions for electronic data entry. Site shall prevent unauthorized access to the Study Documentation 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 Documentation 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 Law. . Neither Institution nor Investigator shall destroy or permit the destruction of any Medical Records or Study Documentation and Institution shall continue to store Medical Records and Study Documentation, at the Sponsor's expense, for any period that the Sponsor may request in writing after retention is no longer required by any Applicable Law.

If the Investigator leaves the Institution, then responsibility for maintaining Medical Records and Study Documentation shall be determined in accordance with Applicable Laws but Institution will not in any case be relieved of its obligations under this Agreement for maintaining the Medical Records and Study Documentation.

1.3.2. Ownership. Institution shall retain ownership of Medical Records. Subject to Applicable, Laws, Sponsor shall have the right to access, use and disclose the Medical Records during the term of this Agreement and thereafter. 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 Documentation.

1.3.3. Access, Use, Monitoring and Inspection. Upon Quintiles' or Sponsor's request, Site shall provide original or copies (as the case may be) of all Study Documentation to Quintiles and Sponsor. Site shall afford Sponsor and Quintiles and their representatives and designees reasonable access to Site's facilities and to Medical Records and Study Documentation so as to permit Sponsor and Quintiles 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 Documentation, and the right to copy Medical Records and Study Documentation.

The Site agrees to cooperate with the representatives of Quintiles 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 Quintiles of, and provide Quintiles 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 (i) cooperate with any regulatory authority regarding an audit or inspection related to such Study, including audit or inspection of Site, (ii) permit Quintiles and Sponsor to attend any such inspections or audits and permit Sponsor and Quintiles to assist Site in responding to any such inquiries, correspondence or communications, (iii) promptly provide copies of any documents, correspondence, reports and other materials to or from the regulatory authority and/or the Institution relating to the audit, inspection, or regulatory action and (iv) keep apprised of the regulatory action, audit, or inspection and the accompanying findings and response in a timely manner. The Site will make reasonable efforts to separate, and not disclose, all Confidential Information that is not required to be disclosed during such inspections.

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1.3.4. License. Sponsor hereby grants to Institution a perpetual, non-exclusive, nontransferable, paid-up license, without right to sublicense, to use Study Documentation (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 Documentation" 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 function. 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 Investigator is an employee of Institution or an affiliate of Institution, then Institution shall ensure that Investigator complies with the terms and conditions of this Agreement and shall be responsible for Investigator's performance of this Agreement and the Study.

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 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 before the Study starts.

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 before the Study starts.

Site agrees to provide prompt advance notice) to Sponsor and Quintiles 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 Quintiles.

1.5. Adverse Events

The Site shall report adverse events and serious adverse events as directed in the Protocol and by Applicable Law. The Site shall cooperate with Sponsor in its efforts to follow-up on any adverse events. The Site shall comply with the applicable IRB/IEC reporting obligations.

Sponsor will promptly report to the Site, the applicable IRB/IEC, and Quintiles, 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 IRB/IEC's 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 Law, 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 Applicable Laws and regulations governing the disposition or destruction of Investigational Product and any instructions from Quintiles that are not inconsistent with such laws and regulations.

Based on assessment of Site's facilities and needs in connection with the conduct of the Study, Sponsor may provide to Site certain electronic and other equipment as necessary (the "**Equipment**") solely for use in performance of the Study. Such Equipment may be leased by Sponsor and provided to Site through a third party ("**Lessor**") on behalf of Sponsor or provided directly by Sponsor to Site. Equipment shall be returned to Lessor or Sponsor, as applicable, at the expense of Sponsor, upon the completion or termination of the Study or upon Sponsor's request, or shall otherwise be disposed of pursuant to the written direction of Lessor or Sponsor as applicable. Site shall implement reasonable and appropriate administrative, physical and technical safeguards to protect the Equipment, shall at all times while the Equipment is in its possession maintain adequate and appropriate insurance coverage for the Equipment, and shall promptly notify Sponsor or its designee of any malfunctioning Equipment. Sponsor shall use reasonable efforts to repair or replace any malfunctioning Equipment at its own expense.

SPONSOR MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND CONCERNING THE EQUIPMENT, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR TITLE.

1.7. Enrollment of Patients

The Effective Date of this Agreement is as listed in Section 15. Consequently, the Site will not be permitted to screen patients, randomize patients, receive Investigational Product or receive any payment until the validity 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 Quintiles may terminate this Agreement in accordance with Section 15 "Term & Termination" Sponsor/Quintiles has the right to limit enrollment at any time.

1.9. Minimum Goal

Site acknowledges that Site's minimum randomized goal is 13 subjects and that Site will use best efforts to reach the goal within a reasonable time after commencement of the Study at Site. If Site fails to adhere to this principle Quintiles may reconsider Site's suitability to continue participation in the Study.

1.10 Subcontracting. No rights or obligations of Site or Investigator under this Agreement may be assigned or subcontracted to others without Quintiles' prior written consent and pursuant to a written agreement approved by Quintiles. Site and Investigator shall ensure that all third parties who provide any services on their behalf relating to the Study comply with the terms of this Agreement, and Site and Investigator remain liable for any breach by such third parties. Site and Investigator shall cause each such subcontractor or third party to secure and maintain appropriate insurance to the reasonable satisfaction of Quintiles in amounts that will be adequate to cover the activities and obligations of the subcontractor or third party related to the Study.

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1.11. Biological Samples.

Investigator shall collect, retain, analyze and/or use biological samples from subjects enrolled in the Study solely according to the Protocol and consistent with the ICF. All biological samples shall be transferred to the organization identified in the Protocol. Sponsor shall own rights and interest in biological samples collected in connection with the Study and shall have the sole right to use the samples as permitted under the ICF and Applicable Law.

2. PAYMENT

2.1 Budget.

2.1.1 In full consideration for the performance of the Study, Quintiles shall pay Payee (as defined below in Attachment A) those fees, expenses and costs, at such times and in accordance with the payment schedule set forth in Attachment A of this Agreement. No payments shall be made for the conduct of the Study that are deemed violations or breaches of or deviations (unless approved by Sponsor or Quintiles) from the Protocol, this Agreement or Applicable Law. In no event shall the fees, expenses and costs exceed the amount set forth in Attachment A without the written prior consent of Quintiles. Institution and Investigator acknowledge and confirm that if Investigator is a named payee hereunder, such payment arrangement is in accordance with the modalities laid down by the Institution for receipt of funding for the Study and is not in violation of the MCI Regulations.

2.1.2 The Parties represent that the compensation provided for the conduct of the Study represents the fair market value of the fees, expenses and costs associated with the Study and has not been determined in a manner that takes into account the volume or value of any past, present or anticipated future referrals or business.

2.1.3 To the extent permissible under Applicable Law, budget information shall remain confidential and shall be considered Confidential Information (as defined below). Site acknowledges and agrees that in order to comply with certain legal requirements, Sponsor may be required to publicly disclose payments, gifts, and other transfers of value it provides to physicians and certain hospitals, regardless of whether such payment is remitted directly to such physicians or hospitals or passes through a separate legal entity and that Quintiles or Sponsor may report to relevant regulatory agencies the total amount paid by Quintiles for purposes of conducting the Study under this Agreement, including the estimated fair market value for Equipment and supplies provided under this Agreement. Claims for services and/or products in connection with the Study that Site and/or any Investigator may submit for reimbursement to government entitlement programs or third-party payors shall at all times be in compliance with Applicable Law, including notices, issuances and national and local coverage decisions. Neither Site nor any Investigator shall, under any circumstances, submit any invoice or charges to any subject, government entitlement program, insurer or any other person for payment with respect to the Investigational Product or any other procedures or products provided at no charge by Sponsor or Quintiles.

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

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and from regulatory authorities, information relating to the regulatory status of the Investigational Product, and Study Documentation 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.

Nothing herein shall limit the right of Site to disclose Study Documentation 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 Sponsorall Confidential Information other than Study Documentation.

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-

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existing Intellectual Property of another, except as may be otherwise expressly provided in any other written agreement between them.

4.2 Inventions

Sponsor shall own all right, title and interest in and to each invention, discovery, know-how, trade-secret and other intellectual property, including improvements, whether patentable or not, that is conceived, reduced to practice or otherwise made by Institution, the Investigator or any other person (other than Sponsor) who assists in performing the Study (whether solely or jointly with others) (each, an "**Inventor**") as a result of or in connection with the Study, the performance of obligations under this Agreement, or its/their access to or knowledge or use of Confidential Information or any drug or device which is the subject of the Study, including any patent, trade secret, trademark, copyright or other proprietary right with respect thereto (collectively, the "**Invention(s)**").

4.3 Assignment of Inventions

Site shall, and shall cause each inventor to, disclose all Inventions promptly and fully to Sponsor in writing, and Site, on behallf of itself and Inventors, 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 Patent Prosecution

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.

4.5 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 Documentation, 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 sixty (60) calendar days prior to submitting any such proposed publication to a publisher or proceeding with such proposed presentation. Within thirty (30) calendar 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 Documentation) 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 Documentation) and/or to delay the proposed publication or presentation for an additional sixty (60) calendar days to enable Sponsor to seek patent protection for Inventions.

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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 Documentation, 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 Documentation 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 Documentation 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 Documentation without the prior written consent of Sponsor. This provision does not prohibit publication or presentation of Study Documentation 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 Quintiles 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 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 Study Team Member 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.

For the Investigator, this personal data may include names, contact information, work experience and professional qualifications, medical license, publications, resumes, educational background and information related to potential Dual Capacity conflict of interest, and payments made to Payee(s) under this Agreement for the following purposes:

(i) the conduct of clinical trials;
(ii) verification by governmental or regulatory agencies, the Sponsor, Quintiles, and their agents and affiliates;
(iii) compliance with legal and regulatory requirements;

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(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; and
(vi) anti-corruption compliance.

Names of members of Study Staff may be processed in Quintiles' 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 Quintiles deals with any personal data under this Agreement in the manner of a data controller, Quintiles shall be the data controller of such personal data to the extent of such dealings.

Quintiles 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. INDEMNIFICATION : STUDY SUBJECT INJURY

To the extent not expressly prohibited by state law, Institution shall indemnify and hold harmless Sponsor, its affiliates and their respective employees, officers, and directors ("**Sponsor Indemnitees**") from and against any claims, liabilities, losses, demands, causes of action, judgments, settlements and expenses (including, but not limited to, reasonable attorneys' fees and court costs) (each a "**Claim(s)**") arising out of (i) the failure of an Institutional Indemnitee to comply with Applicable Law, rule, or Good Clinical Practices or adhere to the terms of the Protocol or this Agreement, or (ii) the negligence or willful misconduct of Institution, Institution's affiliates, Investigator, GDD Experts India Pvt. Ltd., or its or their employees, agents or contractors, provided, however, that Institution shall have no such obligation with respect to Claims arising out of the negligence or willful misconduct of Sponsor or its employees, agents or contractors.

In the event a Study Subject requires medical treatment for physical injury, Sponsor shall reimburse Site for the direct, reasonable and necessary costs associated with the treatment of the physical injury sustained as a direct result of taking the Investigational Product or undergoing a procedure required by the Protocol ("**Covered Injury**"), provided that such injury does not arise out of the negligence, willful misconduct, breach of this Agreement, Applicable Law or failure to follow and comply with the Protocol by Institution, Investigator, the sub-investigator, the Study Staff, or their employees or agents. Site shall notify Sponsor in advance of treatment, whenever practicable, but in any event within twenty-four (24) hours of provision of treatment.

Site shall coordinate and manage the request from a Study Subject for treatment and reimbursement of a Covered Injury, and shall provide to Sponsor in a timely manner, such

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supporting documentation and reports as Sponsor may reasonably request. Such documentation and reports shall include, but not be limited to, the government entitlement program health insurance claim number or, if none is available, the social security number of the Study Subject and such other information relating to the treatment and insurance coverage of the Study Subject as may be reasonably requested by Sponsor and/or as Sponsor reasonably determines is required or appropriate under Applicable Law. Reimbursement by Sponsor for a Covered Injury or otherwise shall be limited to those costs not covered by such Study Subject's insurance, excluding government entitlement programs. No party shall submit any claim for reimbursement to government entitlement programs until Sponsor has satisfied its reimbursement obligations under this Agreement and Applicable Law.

This Section 7 "Study Subject Injury" shall survive termination or expiration of this Agreement.

8. QUINTILES DISCLAIMER

Quintiles 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 Quintiles.

This Section 8 "Quintiles Disclaimer" shall survive termination or expiration of this Agreement.

9. CONSEQUENTIAL DAMAGES

Neither Quintiles nor Sponsor shall be responsible to the Site for any lost profits, lost opportunities, or other consequential damages, nor shall Site be responsible to Quintiles 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 regulatory authority for debarment or any similar regulatory action in any country, and the Site shall notify Quintiles 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 Quintiles' 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 Quintiles 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.

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Quintiles 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, Quintiles, 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 Quintiles 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 Quintiles 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, directors, employees, agents, consultants, or any payee under this Agreement may make, as a Government Official or otherwise, in order to assist Sponsor or Quintiles 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 Quintiles 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, Quintiles may terminate this Agreement if Site breaches any of the representations or warranties contained in this Section

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or if Quintiles 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 GDD Experts India Pvt. Ltd and Study Staff are acting as independent contractors of Quintiles and Sponsor and shall not be considered the employees or agents of Quintiles or Sponsor.

Neither Quintiles nor Sponsor shall be responsible for any employee benefits, pensions, workers' compensation, withholding, or employment-related taxes as to the Investigator or Institution or GDD Experts India Pvt. Ltd or their staff.

It is hereby agreed and acknowledged by the Parties and Sponsor that Quintiles 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". Quintiles 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, Quintiles shall keep the original signed Agreements until receipt of such approval, and upon receipt of such approval, Quintiles 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, Quintiles 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

Quintiles may terminate this Agreement for any reason effective immediately upon written notice. The Site may terminate upon written notice if at any time in the Investigator's professional judgment, a material adverse safety concern for the Study subjects makes continued testing inadvisable. Upon notice of termination or upon notice of suspension of the Study or this Agreement, Site shall immediately cease enrollment of subjects into the Study and, at the election of Quintiles shall (a) either (i) terminate the Agreement with respect to the enrolled subjects in an orderly and prompt manner and pursuant to consultation with Quintiles and Sponsor, including any required follow-up treatment with previously enrolled subjects, or (ii) transfer the enrolled subjects to another clinical site in accordance with Quintiles' instructions. Sponsor or its designee shall have the right to assume full control of the terminated Study and Site shall turn over all Study Documentation and materials in its possession associated with the Study, as expeditiously as possible, and shall provide such other assistance as is necessary to ensure a smooth and orderly transition of the Study without any disruption of the Protocol and (b). Site shall make all reasonable efforts to minimize further costs, and Quintiles 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

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withheld until final acceptance by Sponsor of all Study or data clarifications requested 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, Quintiles 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:	Gary Gordon, M.B.A., M.D. President Kowa Research Institute, Inc. 430 Davis Drive, Suite 200 Morrisville, NC 27560 919-433-1600 phone 919-433-1620 fax
To Quintiles	Name: Quintiles Research (India) Private Limited Address: B 101-106, Shapath IV, Opposite Karnavati Club, Sarkhej Gandhinagar Road, Ahmedabad 380051, Gujarat, India Tel: +91-79-66303300
To Institution	Name: Dr. M. V. Jali Address: KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, NehruNagar, Belagavi – 590010, Karnataka, India Tel: +91-831-2473777
To Investigator	Name: Dr. Veerappa Annasaheb Kothiwale Address: KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, NehruNagar, Belagavi - 590010, Karnataka, India Tel: +91-9448119899
To Research Company	Name: Dr. Vinod Gyanchandani Address: GDD Experts India Pvt. Ltd, Ground Floor, Gulmohar Complex, 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,

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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 Quintiles and Sponsor.

Upon Sponsor's request, Quintiles may assign this Agreement to Sponsor or to a third party, and Quintiles 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. Sponsor shall have the right to assign all of its rights under this Agreement without Site's prior written consent.

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 Governing 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.

THIS SECTION IS INTENTIONALLY LEFT BLANK

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ACKNOWLEDGED AND AGREED BY QUINTILES RESEARCH (INDIA) PRIVATE LIMITED:

By: Suneela Thatte

Title: VP, Global Operations

Signature: _____

Date: 10 | NOV | 2017

ACKNOWLEDGED AND AGREED BY THE INVESTIGATOR:

Name: Dr. Veerappa Annasaheb Kothiwale

Title: Principal Investigator

Signature: _____

Date: 23 | NOV | 2017

ACKNOWLEDGED AND AGREED BY KLES DR. PRABHAKAR KORE HOSPITAL & MEDICAL RESEARCH CENTRE:

By: Dr. M. V. Jali

Title: Medical Director

Signature: _____

Date: 25 | 11 | 17

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: _____

Date: 13 | NOV | 2017

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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	GDD Experts India Pvt. Ltd, Ground Floor, Gulmohar Apartment, Opposite Hislop College, Civil Lines, Nagpur-440001, Maharashtra, India
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 Quintiles 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 Quintiles to the Payee.

The Investigator acknowledges that if the Investigator is not the Payee, Quintiles will not pay the Investigator even if the Payee fails to reimburse the Investigator.

B. PAYMENT TERM

Quintiles 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 monies that may be payable under the terms of this Agreement, will be made based upon prior 3 months' randomization 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 Quintiles 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 Quintiles and/or Sponsor, the return of all unused supplies and Investigational Product to Quintiles or its designee, and upon satisfaction of all other applicable conditions set forth in the Agreement.

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Any expense or cost incurred by Site in performing this Agreement that is not specifically designated as reimbursable by Quintiles 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 Quintiles 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 Quintiles with an invoice, to be sent to Quintiles at the address mentioned in Section K 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. OVERPAYMENT

In the event that Quintiles determines that (i) a mistaken or otherwise erroneous payment has been made or (ii) payment was made for services that were not provided (each an "**Overpayment**") Quintiles will enter a payment adjustment against future payments and Site will not receive payment until such Overpayment is earned. If, upon completion or termination of this Agreement, the payment adjustment does not cover the Overpayment, Quintiles will issue a notice letter to the Site. Upon receipt of written notice, Site shall immediately refund such remaining Overpayment to Quintiles.

E. DISCONTINUED OR EARLY TERMINATION

Reimbursement for discontinued or early termination of randomized subjects will be prorated based on the number of confirmed completed visits.

F. SCREENING FAILURE

Reimbursement of screen failure will be at the amount indicated on the pre-screening and screening visits of the attached budget, not to exceed 3 Screen Failur(s) paid per 1 subject randomized.

To be eligible for reimbursement of a screening visit, completed screening CRF pages must be submitted to Quintiles along with any additional information, which may be requested by Quintiles to appropriately document the subject screening procedures.

G. UNSCHEDULED VISITS

Payment for unscheduled visits will be reimbursed in the amount of is Nine Thousand Five Hundred Forty Five Rupees (INR 9,545) which includes overhead. To be eligible for reimbursement for unscheduled visits, completed CRF pages must be submitted to Quintiles along with any additional information which may be requested by Quintiles to appropriately document the unscheduled visit.

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H. START UP FEE

A one-time, non-refundable Study Start-Up payment of INR 80,000 will be made after site initiation and receipt by Quintiles of all original contractual and regulatory documentation and receipt of an original invoice.

I. RECORD STORAGE FEE/ARCHIVING TOTAL COST FEE

A one-time, long-term Study document storage, archiving payment of INR 133/box/month will be made to Payee following the completion of the Study at the Institution, receipt by Quintiles of all completed contractual and regulatory documentation and receipt of invoice. Trial documents will be kept in a controlled, secure facility.

J. PATIENT TRAVEL EXPENSES

Patient travel expenses will be reimbursed upon receipt of original supporting invoices up to INR 1000 per visit per patient per round trip] and are not included in the attached Budget. Invoices must contain the Patient number, amount paid, and visit number and visit date in which patient travel is being requested.

K. INVOICES

Original Invoices pertaining to this Study for the following items must be submitted to Quintiles for reimbursement at the following address:

Quintiles Research (India) Private Ltd., Bangalore
Attention: Finance PSC – Accounts Payable (Investigator Payments)
III Floor, Etamin Block,
Prestige Technology Park,
Sarjapur - Marathahalli Outer Ring Road
Bangalore – 560103, India
Phone: [Insert Phone Number]

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

L. EC/IRB/IEC FEES

EC/IRB/IEC costs incurred 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 Quintiles and Sponsor, will be reimbursed upon receipt of appropriate documentation.

M. CONDITIONAL PROCEDURES

The following conditional procedures and related costs will be reimbursed on a pass-through basis upon receipt of an invoice at the amount indicated in the below table. Subject number and visit/dates must be included on the invoice for payment to be issued.

	Procedure Amount (INR)
Blood sample collection	300
Lab handling and/or shipping of unscheduled blood samples	130
12-lead ECG: Tracing only	500
EQ-5D-5L	500

ATTESTED

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

119

Problem focused physical exam	2,298
Serious adverse events (SAE)	1000
Genetic testing consent	330
Endpoint package preparation	13,389

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 Quintiles by wire transfer.

N. BUDGET TABLE

Visit	Total Cost Per Visit including 20% Overhead (INR)
PreScreen	13,578
Screen	19,998
Visit 2	17,331
Visit 3	4,679
Visit 4	4,679
Visit 5	13,304
Visit 6	12,535
Visit 7	12,616
Visit 8	4,679
Visit 9	13,790
Visit 10	4,679
Visit 11	12,616
Visit 12	4,679
Visit 13	12,616
Visit 14	4,679
Visit 15	13,790

ATTESTED

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

120

Visit 16	4,679
Visit 17	12,616
Visit 18	4,679
Visit 19	12,616
Visit 20	4,679
Visit 21	13,790
Visit 22	4,679
Visit 23	12,616
Visit 24	4,679
Visit 25	12,616
Visit 26	4,679
Visit 27	13,790
Visit 28	4,679
Visit 29	12,616
Visit 30	4,679
Visit 31	12,616
Visit 32	4,679
Visit 33	13,790
Visit 34	4,679
CSED Visit	15,515
Post Study Safety Call	4,060
retest	8,169
Off *	11,931
Total Cost Per Patient (Rs)	3,53,676

**** Visit can occur more than once***

ATTESTED

Dr. V.A.Kothiwale
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

ATTESTED

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

122

ATTACHMENT C
EQUIPMENT (*optional*)

ATTESTED

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

123

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA78601703451461Q
Certificate Issued Date	:	05-Nov-2018 02:18 PM
Account Reference	:	NONACC (FI)/ kaksfcl08/ UTTARHALLI1/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKAKSFCL0894226271073682Q
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	:	KLES KARNATAKA
Stamp Duty Paid By	:	IQVIA RDS INDIA PRIVATE LIMITED
Stamp Duty Amount(Rs.)	:	300 (Three Hundred only)

UTTARAHALLI SOUHARDA CREDIT CO-OPERATIVE LTD

Please write or type below this line

ATTESTED

Statutory Alert:

1. The authenticity of this Stamp Certificate should be verified at "www.shcilestamp.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.

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

AMENDMENT NUMBER ONE TO CLINICAL TRIAL AGREEMENT

This Amendment to the Clinical Trial Agreement ("Amendment #1") is between **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**") and **KLES Dr. Prabhakar Kore Hospital & Medical Research Centre** having a place of business at NehruNagar, Belgavi-590 010, Karnataka, India ("**Institution**") and **Dr.Veerappa Annasaheb Kothiwale** having a place of business at KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, NehruNagar, Belgavi-590 010, Karnataka, India ("**Investigator**") and **GDD Experts India Pvt. Ltd** having a place of business at Ground floor,Gulmohar Apartment, Opposite Hislop College, Nagpur-440 001,Maharashtra,India ("**Research Company**") and is effective as of the date last signed below.

WITNESSETH:

WHEREAS, IQVIA, Institution, Investigator and Research Company are parties to an agreement entitled **PROMINENT** ***"PEMAFIBRATE TO REDUCE CARDIOVASCULAR OUTCOMES BY REDUCING TRIGLYCERIDES IN PATIENTS WITH DIABETES"*** bearing the **Protocol number K-877-302** effective as of 25 November 2017 (the "**Agreement**"), and the parties desire to amend such Agreement;

WHEREAS, IQVIA is providing clinical research organisation services to Kowa Research Institute, Inc. ("**Sponsor**") under a separate contract between IQVIA and Sponsor, and IQVIA's services include monitoring of the Study and contracting with clinical research sites;

NOW THEREFORE, in consideration of the mutual promises and covenants set forth herein, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereby agree to amend the Agreement as follows:

1. **Change in Quintiles' corporate name.** As of the Effective Date of this **Amendment #1**, following the name change described in the above recital, the parties acknowledge that:

   (a) all references to **Quintiles Research (India) Private Limited** in the Agreement shall be updated to refer to **IQVIA RDS (India) Private Limited** (formerly **Quintiles Research (India) Private Limited**) and

   (b) all references to the defined term **"Quintiles"** shall now be deemed replaced by references to **"IQVIA"**.

ATTESTED

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

125

2. **Change in the notice details.** Section K. on Invoices, as found in Attachment A, Budget and Payment Schedule portion of the Agreement is hereby amended by deleting it in its entirety and replacing it with the paragraph below:

K. INVOICES

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: Accounts Payable
Address: III Floor, Etamin Block, Prestige Technology Park,
Sarjapur - Marathahalli Outer Ring Road Bangalore – 560103,
Karnataka, India
Phone: +91 80 71317779/78

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.

1. Attachment **A BUDGET & PAYMENT SCHEDULE**, Section N. Budget Table of the Agreement shall be deleted in its entirety and replaced as follows, to reflect the Protocol Amendment Visit 4 change from a phone visit to an on-site visit with the addition of the following assessments:
    - Blood sample collection
    - Lab handling and/or shipping of specimen
    - Physician, Simple (e.g. interim visits) - Per Visit
    - Patient Reimbursement, Expenses, Patient Travel - Per Visit

N- BUDGET TABLE:

Visit	Total Cost Per Visit including 20% Overhead (INR)
PreScreen	13,578
Screen	19,998
Visit 2	17,331
Visit 3	4,679
Visit 4	8,229
Visit 5	13,304
Visit 6	12,535
Visit 7	12,616
Visit 8	4,679

ATTESTED

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

126

Visit	Total Cost Per Visit including 20% Overhead (INR)
Visit 9	13,790
Visit 10	4,679
Visit 11	12,616
Visit 12	4,679
Visit 13	12,616
Visit 14	4,679
Visit 15	13,790
Visit 16	4,679
Visit 17	12,616
Visit 18	4,679
Visit 19	12,616
Visit 20	4,679
Visit 21	13,790
Visit 22	4,679
Visit 23	12,616
Visit 24	4,679
Visit 25	12,616
Visit 26	4,679
Visit 27	13,790
Visit 28	4,679
Visit 29	12,616
Visit 30	4,679
Visit 31	12,616
Visit 32	4,679
Visit 33	13,790
Visit 34	4,679
CSED Visit	15,515
Post Study Safety Call	4,060
Retest	8,169
Off*	11,931
Total Cost Per Patient (Rs)**	357,229

* Visit can occur more than once

**The total does not include Retest & Off.

All terms and conditions of the Agreement not expressly amended by this Amendment #1 remain in full force and effect.

ATTESTED

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

127

IN WITNESS WHEREOF, this Amendment #1 has been executed by the parties hereto through their duly authorized officers on the date(s) set forth below.

ACKNOWLEDGED AND AGREED BY IQVIA RDS (INDIA) PRIVATE LIMITED

By: **Gaurav Mathur**

Title: **Director, India Regulatory Affairs**

Signature: _____

Date: 22nd NOV 2018

ACKNOWLEDGED AND AGREED BY THE INVESTIGATOR:

Name: **Dr. Veerappa Annasaheb Kothiwale**

Title: **Principal Investigator**

Signature: _____

Date: 26/11/2018

ACKNOWLEDGED AND AGREED BY KLES DR. PRABHAKAR KORE HOSPITAL & MEDICAL RESEARCH CENTRE:

By: **Dr.M.V.Jali**

Title: **Medical Director**

Signature: _____

Date: 04/12/2018

ACKNOWLEDGED AND AGREED BY GDD EXPERTS INDIA PVT. LTD:

By: **Dr. Vinod Gvanchandani**

Title: **Head-Clinical Operations**

Signature: _____

Date: 07/Dec/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

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INDIA NON JUDICIAL

Government of Karnataka

Rs. 300

e-Stamp

Certificate No.	:	IN-KA88069366324232R
Certificate Issued Date	:	04-Apr-2019 03:30 PM
Account Reference	:	NONACC (FI)/ kaksfcl08/ UTTARHALLI1/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKAKSFCL08063751602823 25R
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	:	KLES KARNATAKA
Stamp Duty Paid By	:	IQVIA RDS INDIA PRIVATE LIMITED
Stamp Duty Amount(Rs.)	:	300 (Three Hundred only)

Please write or type below this line

Statutory Alert:

1. The authenticity of this Stamp Certificate should be verified at 'www.shcilestamp.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.

ATTESTED

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

AMENDMENT NUMBER TWO
TO CLINICAL TRIAL AGREEMENT
PROTOCOL NO. K-877-302

This Amendment Number Two to Clinical Trial Agreement ("**Amendment No. 2**") is entered by and among:

Dr. Veerappa Annasaheb Kothiwale, having a place of business at KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, NehruNagar, Belagavi- 590 010, Karnataka, India ("Investigator"), and;

KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, having a place of business at NehruNagar, Belagavi- 590 010, Karnataka, India ("Institution"), and;

GDD Experts India Pvt. Ltd having a place of business at Ground Floor, Gulmohar Apartment, Opposite Hislop College, Nagpur - 440 001, Maharashtra, 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, Sarape- Marathahalli Outer Ring Road Bangalore – 560103, Karnataka, India ("**IQVIA**"), representing the interests of **Kowa Research Institute, Inc.** (the "**Sponsor**"), and; is effective as of the date last signed below ("**Effective Date**').

WITNESSETH:

WHEREAS, IQVIA, Institution, Investigator and Research Company are parties to a Clinical Trial Agreement effective as of 25 November 2017, as amended by Amendment No. 1 dated 25 March 2019 (collectively referred to as the "**Agreement**") pursuant to which Institution and Investigator agreed to conduct a clinical trial in connection with the conduct of a study (the "Study") relating to Protocol No. K-877-302, Protocol entitled "Pemafibrate to Reduce cardiovascular OutcoMes by reducing triglycerides in diabetic patiENTs (PROMINENT)" (the "**Protocol**"), and the parties desire to amend such Agreement, and;

NOW THEREFORE, in consideration of the mutual promises and covenants set forth herein, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereby agree to amend the Agreement as follows:

1. Additional Invoiceable Items. The Agreement is hereby amendment to include the following invoiceable items:

   Subject Identification Fees. Reimbursement for Subject identification in the amount of **Seven Thousand Indian Rupees (7,000.00 INR)** will be paid to the Investigator (Payee) to cover for the time and effort expended in Subject identification, data base search, laboratory result evaluation and medical chart review. Payment will be made for each screen failed patient provided approval is obtained from IQVIA India Medical Advisor prior to pre-screening the Subject and information is entered in the interactive web response system (IWRS).

   Notwithstanding the Effective Date of this Amendment No. 2, payment for this invoiceable cost will be made retroactively from 26 February 2019

2. All terms and conditions of the Agreement not expressly amended by this Amendment #2 remain in full force and effect.

ATTESTED

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

130

IN WITNESS WHEREOF, this Amendment #2 has been executed by the parties hereto through their duly authorized officers on the date(s) set forth below.

ACKNOWLEDGED AND AGREED BY IQVIA RDS (India) Private Limited
(formerly Quintiles Research (India) Private Limited)

By: Shweta Pradhan

Title: Director, Clinical Site Management

Signature: Pradhan

Date: 29/Apr/2019.

ACKNOWLEDGED AND AGREED BY KLES DR. PRABHAKAR KORE HOSPITAL & MEDICAL RESEARCH CENTRE::

By: Dr. M V Jali

Title: Medical Director

Signature:

Date: 30/Apr/2019

ACKNOWLEDGED AND AGREED BY THE INVESTIGATOR:

By: Dr. Veerappa Annasaheb Kothiwale

Title: Principal Investigator

Signature:

Date: 26/Apr/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

131

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)

By: Dr. Vinod Gyanchandani

Title: Head – Clinical Operations

Signature: _____

Date: 11/ Apr/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

132

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Certificate No.	:	IN-KA65984783473227R
Certificate Issued Date	:	05-Mar-2019 01:01 PM
Account Reference	:	NONACC (FI)/ kaksfcl08/ UTTARHALLI1/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKAKSFCL0863928414111785R
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	:	KLES KARNATAKA
Stamp Duty Paid By	:	IQVIA RDS INDIA PRIVATE LIMITED
Stamp Duty Amount(Rs.)	:	300 (Three Hundred only)

UTTARAHALLI SOUHARDA CREDIT CO-OPERATIVE LTD

IQVIA RDS INDIA PRIVATE LIMITED
IN-KA65984783473227R
RS. 300
05-MAR-2019 01:01 PM

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

AMENDMENT NUMBER ONE TO CLINICAL TRIAL AGREEMENT

This Amendment to the Clinical Trial Agreement ("Amendment #1") is between **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**") and **KLES Dr. Prabhakar Kore Hospital & Medical Research Centre** having a place of business at NehruNagar, Belgavi-590 010, Karnataka, India ("**Institution**") and **Dr.Veerappa Annasaheb Kothiwale** having a place of business at KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, NehruNagar, Belgavi-590 010, Karnataka, India ("**Investigator**") and **GDD Experts India Pvt. Ltd** having a place of business at Ground floor,Gulmohar Apartment, Opposite Hislop College, Nagpur-440 001,Maharashtra,India ("**Research Company**") and is effective as of the date last signed below.

WITNESSETH:

WHEREAS, IQVIA, Institution, Invstigator and Research Company are parties to an agreement entitled **PROMINENT *"PEMAFIBRATE TO REDUCE CARDIOVASCULAR OUTCOMES BY REDUCING TRIGLYCERIDES IN PATIENTS WITH DIABETES"*** bearing the **Protocol number K-877-302** effective as of 25 November 2017 (the "**Agreement**"), and the parties desire to amend such Agreement;

WHEREAS, IQVIA is providing clinical research organisation services to Kowa Research Institute, Inc. ("**Sponsor**") under a separate contract between IQVIA and Sponsor, and IQVIA's services include monitoring of the Study and contracting with clinical research sites;

NOW THEREFORE, in consideration of the mutual promises and covenants set forth herein, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereby agree to amend the Agreement as follows:

1. **Change in Quintiles' corporate name.** As of the Effective Date of this **Amendment** #1, following the name change described in the above recital, the parties acknowledge that:

   (a) all references to **Quintiles Research (India) Private Limited** in the Agreement shall be updated to refer to **IQVIA RDS (India) Private Limited** (formerly **Quintiles Research (India) Private Limited**) and

   (b) all references to the defined term **"Quintiles"** shall now be deemed replaced by references to **"IQVIA"**.

ATTESTED

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

134

2. **Change in the notice details.** Section K. on Invoices, as found in Attachment A, Budget and Payment Schedule portion of the Agreement is hereby amended by deleting it in its entirety and replacing it with the paragraph below:

K. INVOICES

Original Invoices pertaining to this Study for the following items must be submitted to IQVIA for reimbursement at the following address:

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(formerly Quintiles Research (India) Private Limited)
Attn: Accounts Payable
Address: III Floor, Etamin Block, Prestige Technology Park,
Sarjapur - Marathahalli Outer Ring Road Bangalore – 560103,
Karnataka, India
Phone: +91 80 71317779/78

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.

1. Attachment **A BUDGET & PAYMENT SCHEDULE**, Section N. Budget Table of the Agreement shall be deleted in its entirety and replaced as follows, to reflect the Protocol Amendment Visit 4 change from a phone visit to an on-site visit with the addition of the following assessments:
    - Blood sample collection
    - Lab handling and/or shipping of specimen
    - Physician, Simple (e.g. interim visits) - Per Visit
    - Patient Reimbursement, Expenses, Patient Travel - Per Visit

N- BUDGET TABLE:

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Screen	19,998
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Visit 3	4,679
Visit 4	8,229
Visit 5	13,304
Visit 6	12,535
Visit 7	12,616
Visit 8	4,679

ATTESTED

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

135

Visit	Total Cost Per Visit including 20% Overhead (INR)
Visit 9	13,790
Visit 10	4,679
Visit 11	12,616
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Visit 13	12,616
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Visit 15	13,790
Visit 16	4,679
Visit 17	12,616
Visit 18	4,679
Visit 19	12,616
Visit 20	4,679
Visit 21	13,790
Visit 22	4,679
Visit 23	12,616
Visit 24	4,679
Visit 25	12,616
Visit 26	4,679
Visit 27	13,790
Visit 28	4,679
Visit 29	12,616
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Post Study Safety Call	4,060
Retest	8,169
Off*	11,931
Total Cost Per Patient (Rs)**	357,229

* Visit can occur more than once

**The total does not include Retest & Off.

All terms and conditions of the Agreement not expressly amended by this Amendment #1 remain in full force and effect.

ATTESTED

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

136

IN WITNESS WHEREOF, this Amendment #1 has been executed by the parties hereto through their duly authorized officers on the date(s) set forth below.

ACKNOWLEDGED AND AGREED BY IQVIA RDS (INDIA) PRIVATE LIMITED

By: **Gaurav Mathur**

Title: **Director, India Regulatory Affairs**

Signature: _____

Date: 07th March 2019

ACKNOWLEDGED AND AGREED BY THE INVESTIGATOR:

Name: **Dr. Veerappa Annasaheb Kothiwale**

Title: **Principal Investigator**

Signature: _____

Date: 12/Mar/2019

ACKNOWLEDGED AND AGREED BY KLES DR. PRABHAKAR KORE HOSPITAL & MEDICAL RESEARCH CENTRE:

By: **Dr.M.V.Jali**

Title: **Medical Director**

Signature: _____

Date: 25/Mar/2019

ACKNOWLEDGED AND AGREED BY GDD EXPERTS INDIA PVT. LTD:

By: **Dr. Vinod Gyanchandani**

Title: **Head-Clinical Operations**

Signature: _____

Date: 08/March/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

137

CLINICAL TRIAL AGREEMENT ORDER

This Order ("**Order**"), effective as of the Effective Date (defined below), is entered into by and among Amgen Technology Pvt. Ltd., Dynasty Business Park, A Wing, Level 4, Andheri-Kurla Road, Andheri (East), Mumbai, 400059 India ("**Company**"); KLES Dr. Prabhakar Kore Hospital and Medical Research Center, Nehru Nagar, Belgaum-590010, Karnataka, India ("**Institution**"); and Dr. Rohan Bhise, KLES Dr. Prabhakar Kore Hospital & MRC, Department of Medical Oncology, Nehru Nagar, Belagavi-590010, Karnataka, India ("**Principal Investigator**"), in accordance with, and shall be governed by, the terms of that certain Clinical Trial Agreement (contract number 181106) ("**Agreement**").

1. GOVERNING TERMS AND EFFECTIVE DATE

1.1 Governing Terms. By executing this Order, the parties agree that this Order and the parties' performance hereunder shall be governed by the terms and conditions of the Agreement, which are incorporated by this reference as if fully set forth herein. The parties hereto agree that for purposes of this Order, the term "**Site**" as used herein and in the Agreement shall be defined to include each and every non-Company party identified above, and their respective representatives. Terms used but not otherwise defined herein shall have the meanings ascribed to such terms under the Agreement.

1.2 Effective Date. For purposes of this Order, "**Effective Date**" shall mean the last date on which a party executes this Order. This Order shall remain in full force and effect until the completion by the Site of the Study or earlier termination pursuant hereto.

1.3 Records. The parties agree that for this Order the provision regarding Records in the Agreement shall be amended to state: "Site shall maintain all records required under Applicable Law and the Protocol for ten (10) years following completion of a Study or longer if required by Applicable Law. Site shall take reasonable and customary precautions to prevent the loss or alteration of any such records."

1.4 Indian Law. Without limiting the generality of Site's obligations, the Site shall carry out the Study with due observance of safety of Subjects, confidentiality and protection of Subjects' rights. The Study will be conducted by the Site in accordance with the Ethical Guidelines for Biomedical research on Human Subjects issued by the Indian Council of Medical Research Guidelines, 2000, Schedule Y of the Drug and Cosmetics Act of 1945, the Central Drugs Standard Control Organization's Good Clinical Practices Guidelines in India, and all applicable Indian regulatory requirements, whichever affords the greater protection to the Subject.

2. STUDY CONDUCT

2.1 Protocol. The Protocol for the Study is Company Protocol No. 20070782 entitled "A Randomized, Double-blind, Placebo-controlled Study to Evaluate the Long-term Safety and Efficacy of Darbepoetin Alfa Administered at 500 µg Once-Every-3-Weeks in Anemic Subjects With Advanced Stage Non-small Cell Lung Cancer Receiving Multi-cycle Chemotherapy ", as may be amended.

Site Representatives and/or Principal Investigator shall attend any meetings regarding the Study as reasonably requested by Company ("**Investigator Meetings**"). Such meetings may be conducted by Company to convey or exchange information with principal investigators, sub-investigators, or other research site staff to support the effective conduct or close-out of a Study. Site and Principal Investigator each agree that no additional compensation shall be due hereunder for Site Representatives or Principal Investigators respective participation in Investigator Meetings. Company may reimburse or pay Site for reasonable pre-approved expenses incurred by Site Representatives or Principal Investigator for participating in Investigator Meetings upon receipt of documentation in form and detail sufficient for Company to recognize such expenses for Company's tax reporting purposes, provided that Site complies with Company instructions and Company's applicable standards and policies related to travel and hospitality and other policies governing interactions with healthcare professionals.

The Principal Investigator will direct and supervise 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

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2.2 Data Protection. Subject to applicable law, Company may collect and process information regarding investigators or other personnel involved in Studies. Company will notify such personnel as required by applicable law.

2.3 Use of Electronic Data Capture. Electronic Data Capture ("**EDC**") is a technique for collecting clinical trial data where study data is delivered to Company in electronic form. For this Study, EDC will be utilized to collect Study information, specifically as the electronic case report form ("**eCRF**"), from Site. Site agrees that it shall (i) enter such Study data into EDC within five (5) business days of the Subject visit, and (ii) resolve all queries issued in the EDC system within five (5) business days of the query being issued. Site acknowledges and agrees that time is of the essence with respect to such Study data entry and query resolution. Any delay by Site in complying with these timelines may, in Company's sole discretion, result in delay of payment, lock of IVRS, suspension of enrollment, quality audit or any other remedy. Principal Investigator is responsible for and warrants quality data entry. Data entry shall be conducted under the supervision of the Principal Investigator.

2.4 Supervision. The Principal Investigator shall supervise and be responsible for all activities performed by members of the Study team or other external personnel to whom the investigator delegates some of his/her responsibilities under the Protocol. The Principal Investigator shall ensure compliance with the Protocol at all times.

2.5 Informed Consent. Site agrees and warrants that it will obtain a valid informed consent form from each Subject in the Study or its legal representative in accordance with Applicable Laws and this Agreement. Site shall ensure that such consent permits Company's use of the Biological Materials and Study data for at a minimum the purposes of monitoring the accuracy and completeness of the research data, performing clinical and scientific research, and medical product development.

3. REAGENTS AND STUDY DRUG

3.1 Company shall provide or reimburse the following Study Drug(s) to Site as required by Protocol: darbepoetin alfa ("**Study Drug(s)**"). If Site is responsible for obtaining Study Drug for use in the Study, Company will reimburse Site for purchase costs of Study Drug as detailed in a proper invoice. Such purchase or reimbursement cost shall not exceed the amount set forth in Schedule A. The Site agrees and warrants that it will not seek payment or reimbursement from any Subject or third party for the cost of the Study Drug(s) or the Study Drug that is provided without charge or reimbursed by Company under this Order.

3.2 The cost of non-Company drug(s) and/or materials and/or reagents is not paid or reimbursed by a third party; however it is required by the Protocol for Subjects participating in the Study ("**Required Material(s)**"). Company will reimburse the Site for the cost of the Required Material(s) as detailed in a proper invoice. Such purchase or reimbursement costs shall not exceed the amount set forth in Schedule A. The Site agrees and warrants that it will not seek payment or reimbursement from any Subject or third party for the cost of any Required Material(s) that is provided without charge or reimbursed by Company under this Order. Site also warrants that it shall not seek or accept reimbursement from any Subject or third party payor for procedures, tests, treatments, items or services that are funded or provided by Company pursuant to the Agreement.

4. PERFORMANCE PERIOD AND ENROLLMENT OF SUBJECTS

4.1 The Study will commence upon execution of this Order, approval of the IRB/IEC, and any required approvals of applicable governmental authorities, including the Drug Controller General of India (DCGI), and will continue until completion of the Study as required by the Protocol (including any amendments thereto) unless this Order is terminated earlier pursuant to the Agreement.

5. REQUIRED EQUIPMENT

5.1 The parties acknowledge that Site will require the following equipment for the performance of the Study ("**Required Equipment**"): Laptop. Such Required Equipment will be lent by Company or its representative to Site for use in the Study.

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Registrar
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Belagavi-590 010,Karnataka

5.2 Delivery. As necessary, Company or its representative shall arrange for the delivery of the Required Equipment, which such equipment shall be delivered to the Site at the following address: KLES Dr. Prabhakar Kore Hospital and Medical Research Center, Nehru Nagar, Belgaum-590010, Karnataka, India.

5.3 Installation of Required Equipment. Company or its representative shall provide for installation of the following equipment: Laptop.

5.4 Technical Support of Required Equipment. Company or its representative shall provide for technical support and maintenance of the following equipment: Laptop.

6. COMPENSATION

6.1 Compensation and payment terms are as set forth in Schedule A, attached hereto and incorporated herein.

6.2 Unless otherwise specified in Schedule A, in consideration for performance under the terms of this Order, Company will make payment within a reasonable time after receipt of (i) a proper invoice and (ii) the Case Report Forms or any similar document detailing the procedures performed and/or visits completed as set forth in Schedule A, as monitored by Company or its representative. It is expected that the Case Report Forms will be completed between monitoring visits.

6.3 Payments from Company to Site due hereunder shall be made payable and sent to the following:

Payments payable to:	KLES Dr. Prabhakar Kore Hospital and Medical Research Center "**Payee**"

From time to time, the Site may request in writing a change in Payee information. If Company agrees to the requested change, no additional amendment of the Order will be necessary.

7. MISCELLANEOUS

7.1 Principal Investigator understands and agrees that his/her personal information including name, contact details, financial information relating to, among other matters, compensation and reimbursement payments for study conduct, and other personal data in connection with Principal Investigator's conduct of the Study will be processed both by computer and manually, by Company and its affiliates and contractual partners in order to comply with Company's and its affiliates' obligations imposed by law, guidance or regulatory authorities and for other purposes including considering from time to time potential investigators for future studies or organizing safety reporting. Principal Investigator further understands and agrees that his/her personal data may, if necessary for these purposes, be made available to regulatory authorities and ethics committees. Principal Investigator understands and agrees that the Company's use and disclosure of personal data may involve use and disclosure in countries other than that where the Principal Investigator is located. Such countries may include but not be limited to: the United States, Japan, Canada, Australia, New Zealand, Switzerland, or countries in Latin America or Asia. Principal Investigator further understands that not all countries to which personal information may be transferred offer an equivalent level of protection of privacy of personal information. Principal Investigator is entitled to request access to his/her personal data held by Company or its affiliates and to have such data corrected if necessary.

7.2 Site acknowledges and agrees that Company shall have the right to disclose publicly the terms and conditions of the Agreement and this Order, including, without limitation, Site's name, description of services, and amount of payment.

7.3 Company Inspections/Monitoring/Audit. The parties agree that for this Order the provision regarding **Company Inspections/Audit** in the Agreement shall be amended and restated as follows: "Company Inspections/Monitoring/Audit. Company and its representatives shall have the right during reasonable business hours and after reasonable advanced notice to monitor and audit the activities of Site related to a Study. At no additional cost to Company, Site shall cooperate with any monitoring and audit conducted hereunder and make available to Company or its representatives for examination and duplication all documentation, data, and information relating to any Study. Site shall permit Company and its authorized representatives to inspect (i) the facilities where a Study is or will be performed; (ii) any equipment used or involved in the conduct of a Study; (iii) any records and source documents, including but not limited to

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medical records (whether in electronic or paper format); (iv) any related authorizations or patient informed consent forms; and (v) other relevant information necessary to determine whether a Study is being conducted in conformance with this Agreement and Applicable Laws. Further, direct access to electronic medical records for the purpose of monitoring/auditing source data is preferred, where possible, and in all cases, Site will provide the same level of access to source records to the monitor/auditor as provided to inspectors."

7.4 The parties agree that for this Order the Agreement shall be amended and supplemented by the following new provision: "Anti-Corruption. Site represents, warrants and covenants, as of the Effective Date to and through the expiration or termination of each Order or this Agreement, (i) that Site, and, to the best of its knowledge, Site Representatives, shall not, directly or indirectly, offer, pay, promise to pay, or authorize such offer, promise or payment, of anything of value, to any individual or entity for the purposes of obtaining or retaining business or any improper advantage in connection with this Agreement, or that would otherwise violate any Applicable Laws, rules and regulations concerning or relating to public or commercial bribery or corruption ("Anti-Corruption Laws"); (ii) that the books, accounts, records and invoices of Site related to this Agreement or related to any work conducted for or on behalf of Company are and will be complete and accurate; and (iii) that Company may terminate this Agreement (a) if Site or Site Representatives fails to comply with the Anti-Corruption Laws or with this provision, or (b) if Company has a good faith belief that Site or Site Representatives has violated, intends to violate, or has caused a violation of the Anti-Corruption Laws. If Company requires that Site complete a compliance certification, Company may also terminate this Agreement if Site (1) fails to complete a compliance certification, (2) fails to complete it truthfully and accurately, or (3) fails to comply with the terms of that certification. For the purposes of this Section, Site Representatives shall be deemed to further include owners, directors, officers, or other third party acting for or on behalf of Site.

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Order.

AMGEN TECHNOLOGY PVT. LTD.

_____
(signature)
By: Dr. Veena Jaguste

Title: Director, Development Operations

Date: _____

KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTER

_____
(signature)
By: _____
(print or type name)
Title: _____

Date: _____

DR. ROHAN BHISE

_____
(signature)
By: _____
(print or type name)
Title: _____

Date: _____

ATTESTED

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Belagavi-590 010,Karnataka

Planned Number of Subjects	25
Planned Number of Sites	1

Description	*Frequency/Detail*	*Unit Cost*	*Total*
Patient Milestones	In accordance with Table below	11,55,900.00	2,88,97,500.00
Radiology	In accordance with Table below	4,37,520.00	1,09,38,000.00
Additional Assessments	In accordance with Table below	22,752.00	5,68,800.00
Screen Failures	In accordance with Table below	28,800.00	5,18,400.00
Re-Screens	In accordance with Table below	10,140.00	5,07,000.00
Chemotherapy Costs	In accordance with Table below	3,73,600.00	93,40,000.00
Administrative Start-Up Costs	In accordance with Table below	40,000.00	40,000.00
Miscellaneous	In accordance with Table below	1,44,000.00	1,44,000.00
Maximum Study Cost:			**5,09,53,700.00**

Patient Milestones are inclusive of Hospital overhead fees, pharmacy costs, laboratory costs.

All Costs are denoted in: Rupees

Per Patient Fee (Overhead 20%)

Visit Type	Visit Description	Cost
Screening	Screening	28,800.00
	Week 1	14,940.00
	Week 4	12,780.00
	Week 7	12,780.00
	Week 10	25,440.00
	Week 13	12,780.00
	Week 16	12,780.00
	Week 19	25,440.00
	Week 22	12,780.00
	Week 25	12,780.00
	Week 28	25,440.00
	Week 31	12,780.00
	Week 34	12,780.00
	Week 37	25,440.00
	Week 40	12,780.00
	Week 43	7,860.00
	Week 46	20,520.00
	Week 49	7,860.00
	Week 52	7,860.00
	Week 55	20,520.00
	Week 58	7,860.00
	Week 61	7,860.00
	Week 64	20,520.00
	Week 67	7,860.00
	Week 70	7,860.00
	Week 73	20,520.00
	Week 76	7,860.00
	Week 79	7,860.00
	Week 82	20,520.00
	Week 85	7,860.00
	Week 88	7,860.00
	Week 91	20,520.00
	Week 94	7,860.00
	Week 97	7,860.00

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Treatment Phase	Week 100	20,520.00
	Week 103	7,860.00
	Week 106	7,860.00
	Week 109	20,520.00
	Week 112	7,860.00
	Week 115	7,860.00
	Week 118	20,520.00
	Week 121	7,860.00
	Week 124	7,860.00
	Week 127	20,520.00
	Week 130	7,860.00
	Week 133	7,860.00
	Week 136	20,520.00
	Week 139	7,860.00
	Week 142	7,860.00
	Week 145	20,520.00
	Week 148	7,860.00
	Week 151	7,860.00
	Week 154	20,520.00
	Week 157	7,860.00
	Week 160	7,860.00
	Week 163	20,520.00
	Week 166	7,860.00
	Week 169	7,860.00
	Week 172	20,520.00
	Week 175	7,860.00
	Week 178	7,860.00
	Week 181	20,520.00
	Week 184	7,860.00
	Week 187	7,860.00
	Week 190	20,520.00
	Week 193	7,860.00
	Week 196	7,860.00
	Week 199	20,520.00
	Week 202	7,860.00
	Week 205	7,860.00
	Week 208	20,520.00
	Week 211	7,860.00
	Week 214	7,860.00
	Week 217	20,520.00
	Week 220	7,860.00
	Week 223	7,860.00
	Week 226	20,520.00
	Week 229	7,860.00
	Week 232	7,860.00
	Week 235	20,520.00
	Week 238	7,860.00
	Week 241	7,860.00
	Week 244	20,520.00
	Week 247	7,860.00
	Week 250	7,860.00
	Last Dose of IP	22,440.00
	Next Q3W visit after disease progression	20,040.00

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Long Term Follow-Up	Month 4	480.00
	Month 7	480.00
	Month 10	480.00
	Month 13	480.00
	Month 16	480.00
	Month 19	480.00
	Month 22	480.00
	Month 25	480.00
	Month 28	480.00
	Month 31	480.00
	Month 34	480.00
	Month 37	480.00
	Month 40	480.00
	Month 43	480.00
	Month 46	480.00
	Month 49	480.00
	Month 52	480.00
	Month 55	480.00
	Month 58	480.00
	Month 61	480.00
	Month 64	480.00
	Month 67	480.00
	Month 70	480.00
	Month 73	480.00
Per Subject Totals		
Per Subject Total for Completers using CT Scans		11,55,900.00
Maximum Per Subject Total		**11,55,900.00**

Radiology Costs

Radiology procedures shall be paid at the rates below, if required. Amgen shall pay for either CT or MRI Scans and Scans per Patient.

Radiology Procedures (Payable on Invoice)	Cost	Frequency		Total per Patient
CT Chest & Interpretation	5,100.00	30	per Subject	N/A
CT Abdoman & Interpretation	5,400.00	30	per Subject	N/A
MRI Chest & Interpretation	6,780.00	30	per Subject	2,03,400.00
MRI Abdoman & Interpretation	7,680.00	30	per Subject	2,30,400.00
CT Brain	3,720.00	1	per Subject	3,720.00
Total Maximum Per Patient *Total maximum for additional costs assumes PET/CT costs*				4,37,520.00

Additional Assessments

Additional Procedures (Payable on Invoice)	Cost	Frequency		Total per Patient
Whole Body Bone Scan	10,800.00	2	per Subject	21,600.00
X-Ray Bone (max)	336.00	2	per Subject	672.00
Biopsy Sample process and handling	480.00	1	per Subject	480.00
Total Maximum Per Patient				22,752.00

Screen Failures

A max of 18 Screen Fails will be paid per Site at a rate in accordance with table below.

Visit Description	Cost
Screen Failure	28,800.00
Maximum Screen Failure Costs	28,800.00

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Re-Screens

A max of 2 Re-Screens will be paid per Subject at a rate in accordance with table below.

Visit Description	Cost
Re-Screen Labs & Procedures	10,140.00
Maximum Re-Screen Costs	10,140.00

Chemotherapy Costs (Payable only against original invoice)

Description	Cost	Frequency		Total per Patient
Pemetrexed	60,000.00	6	per Subject	3,60,000.00
Cisplatin	1,700.00	8	per Subject	13,600.00
Total Maximum Per Patient				3,73,600.00

****Inj. Pemetrexate will be reimbursed beyond 6 cycles only for the cases where it is used as first line chemotherapy, which immediately rolls into maintenance treatment with no break or change to the treatment administered and where study IP is continued.***
 # Inj. cisplatin will be reimbursed to the sites for maximum of 8 cycles/patient, with a reimbursement cost of no more than Rs 1,700/- per cycle and no more than Rs. 13,600/patient overall.

Administrative Start-Up Costs

Description	Cost	Frequency		Total
IRB Initial Review Fee	40,000.00	1	Total	40,000.00
Total Maximum				40,000.00

Miscellaneous

Description	Cost	Frequency		Total
Broadband charges for eCRF data entry	1,500.00	36	per Month	72,000.00
ISD phone line rent & monthly charges	1,500.00	36	per Month	72,000.00
Total Maximum				1,44,000.00

PAYMENT DISTRIBUTION

Initial Payment	50,000.00 (Estimated advance for 1 cycle for 1 subject) *Amgen will pay Institution this initial payment upon execution of the Agreement. In order to receive further funds towards Subject related costs, the amount earned must exceed this initial payment In the event that the total amount earned for the Study is less than this initial payment, all unearned funds are fully refundable to Amgen.*
Progress Payment Frequency	Quarterly (based on calendar quarter), in accordance with Budget Worksheet attached hereto and incorporated herein by reference

The payment of the study will be made in the favor of '----------'
The EC for this study will be 'Ethics Committee of KLE University' and the payment of the EC fees will be made in the favor of 'Registrar, KLE University, Belagavi'.

Site represents and warrants that it shall not seek or accept reimbursement from any Subject or third party payors (including any "federal health care program" as defined at 42 U.S.C. section 1320a-7b(f)) for Study Drug(s), procedures, tests, treatments, drugs, reagents, materials, items or services that are funded by Company pursuant to the Agreement or provided without charge by Company for Study purposes.

In the event Site is not reimbursed for routine clinical services contemplated in the Protocol, Site may remit an invoice to Company. If Company is in agreement with the invoice, Company will reimburse Site for the invoiced amount subject to a fair market value assessment by Company.

Company shall pay for or provide those Study Drug(s), procedures, tests, treatments, drugs, reagents, materials, items, or services identified in the Protocol's Schedule of Assessments, except that the following are not paid for or provided without charge by Company:

N/A

Invoices

1) "Any additional activities/tests/procedures performed for the Study, which are not mentioned in this budget (schedule-A) may be reimbursed on confirmation of approval from the Amgen study team and receipt of an original invoice and rationale provided by the Site."
2) For all items that are payable upon invoice as indicated above, please send invoices to Company as follows:

Amgen Technology Pvt Ltd
Dynasty Business Park,
Level 4, A wing, A.K Road
Andheri (East) Mumbai 400059
Please submit invoices only for items indicated as payable upon invoice.

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

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COLGATE-PALMOLIVE (INDIA) LIMITED
Colgate Research Centre, Main Street, Hiranandani Gardens, Powai, Mumbai 400076
CST : 27920000024/C dt. 1.4.06

26th June'15

Dr. Seema Madbhavi
PG Student in Dept. of Oral Pathology and Microbiology
Vishwanath Katti Institute of Dental Sciences
Belgaum

Re: Sponsorship of Research Grant for MDS Dissertation

Dear Dr. Seema Madbhavi,

This is with regards to your request for sponsorship of Research grant for MDS Dissertation for topic **"Evaluation of basic Fibroblast Growth Factor in Oral Squamous Cell carcinoma and the adjacent Apparently normal mucosa - An Immunohistochemical study".** We are pleased to inform you that we would sponsor the captioned dissertation-cum-research study being carried out by you, the sponsorship amount being **Rs. 10,000/-** subject to following terms and conditions.

1. Colgate-Palmolive (I) Ltd being sole sponsors of this research project, no collaboration should be entered into with any other organisation for this purpose.

2. A brief report of the project should be sent to us from time to time and on completion of the same, following documents should be mailed to us on seema_amin@colpal.com

3. Grants would be given on Submission of thesis copy and article.

a) Soft Copy of the final thesis / Dissertation submitted to the University
b) 2 Page Summary of the thesis with details like:
   - Study Topic
   - Study Objective
   - Trial Conditions & Methods
   - Study Subjects
   - Methods
   - Inclusion & Exclusion Criteria
   - Result
   - Any Graphs / Images

ATTESTED
Dr. V.A.Kothiwale
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KLE Academy of Higher Education and Research,
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Belagavi-590 010,Karnataka

- Conslusions
- References

c) Letter of the Dean & HOD stating that you have completed your thesis on College Letterhead alongwith Deans & HOD's signature
d) University approved Letter of acceptance of final thesis

4. The company should be given due acknowledgement in your project report.

5. Whenever your project is published in any journal or other publication our Sponsorship of the project should be adequately acknowledged & copy of the journal/publication has to be submitted to Colgate Palmolive (I) Ltd.

6. A student also has to submit the personal details like:
Permanent Residential Address:_____
Tel no : Resi _____ , Mobile _____
E-mail id:_____

Kindly confirm acceptance of the above conditions to enable us to take necessary action in the matter.

Very truly yours,

Seema Amin

Dr Seema Amin
Academic Affairs Manager
Colgate Palmolive India Ltd
Tel- (022) 67096588

ATTESTED

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

IACR 2015
MUMBAI - INDIA

IACR 2015

(International Association of Cancer Registries)
8th to 10th October 2015 Venue: Taj Mahal Palace, Mumbai
Website: www.iacr2015.org

31st July 2015

To,
Dr. Aishwarya Rajiv
JNMC Campus, Nehru Nagar,
Belagavi, Karnataka 590010

Subject: Registration for IACR Conference 2015

Dear Dr. Aishwarya Rajiv,

Thank you very much for your interest and submitting abstract for presentation in International Association of Cancer Registries Meeting 2015 to be held at Mumbai from 8th to 10th October 2015.

As you are aware your abstract has been selected for 'Poster' presentation. I am please to inform you that Tata Memorial Centre has accepted your application for fellowship to attend the conference. The registration fee (US$ 350) is waived off, however, you have to make your own travel and hotel arrangements.

I understand that you will be coming to Mumbai to attend meeting of National Cancer Registry Programme, which is being organized just prior to IACR meeting. You may please continue to stay in the same hotel/hostel. In case you require assistance in booking your accommodation in Mumbai during your stay for IACR meeting please contact us.

Please remember to register for the conference before deadline of 30th August 2015.

Look forward to welcome you in Mumbai.

Dr. Rajesh Dikshit
Professor-Epidemiology
Centre for Cancer Epidemiology

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
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IACR 2015
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IACR 2015

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Website: www.iacr2015.org

31st July 2015

To,
Dr. Aishwarya Rajiv
JNMC Campus, Nehru Nagar,
Belagavi, Karnataka 590010

Subject: Registration for IACR Conference 2015

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As you are aware your abstract has been selected for 'Poster' presentation. I am please to inform you that Tata Memorial Centre has accepted your application for fellowship to attend the conference. The registration fee (US$ 350) is waived off, however, you have to make your own travel and hotel arrangements.

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Look forward to welcome you in Mumbai.

Dr. Rajesh Dikshit
Professor-Epidemiology
Centre for Cancer Epidemiology

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KLES
AYURVED HOSPITAL

INSTITUTIONAL ETHICS COMMITTEE
KLE University's Shri B. M. Kankanawadi Ayurved Mahavidyalaya &
KLE Ayurved Hospital, Shahapur, Belgaum

COMMUNICATION OF DECISION OF THE INSTITUTIONAL ETHICS COMMITTEE (IEC)

Protocol No: BMK/13/BSP/01

Protocol Title: "Profiling of Overweight and Obese individuals in Indian Population using biochemical and genetic parameters along with Ayurvedic diagnostic criteria"
Principal Investigators/Co-investigators: Dr.B.S.Prasad, Dr. Supriya Bhalerao, Dr. Prabhakar Ranjekar.
Name & Address of Institution: KLE University's Shri B. M. Kankanawadi Ayurved Mahavidyalaya &KLE Ayurved Hospital, Shahapur, Belgaum
☑ New Review ☐ Revised Review ☐ Expedited Review
Date of Review (DD/MM/YY): 03.05.2014 **Date of previous review, if revised application:** **Name of the Reviewers who attended the meeting:** Dr Subarna Roy, Dr.S.K.Patil, Dr. S. K. Hiremath, Dr.Sameer N Naik, Dr. Rajashree Kamat, Mr Sudheer Kulkarni, Mrs Sarita Shirodkar, Shri Neminath Kunne , Dr.Basavaraj R Tubaki
Decision of the the Ethics Committee: **Recommended** ☑ **Recommended with suggestions** ☐ **Revision** ☐ **Rejected** ☐

ATTESTED

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Suggestions/ Clarifications / Reasons/ Remarks: Following are the suggestions/clarifications of the EC-NIL
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 Subarna Roy
(Chairperson)

ATTESTED

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KLE/BMK/IMRC/150/18

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/15/BRT/01

Protocol Title: Evaluation of clinical efficacy and safety of Alert capsule in the management of Generalized Anxiety Disorder

Principal Investigators/Co-investigators: Dr. Basavaraj Tubaki

Name & Address of Institution:
KAHER's Shri B. M. Kankanawadi Ayurveda Mahavidyalaya & KLE Ayurveda Hospital, Shahapur, Belagavi

☐ New Review ☐ Revised Review ☑ Expedited Review

Date of Review (DD/MM/YY): 20.03.2018

Date of previous review, if revised application: 18.02.2016

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,

Decision of the the Ethics Committee:

Recommended	☑	**Recommended with suggestions**	☐
Revision	☐	**Rejected**	☐

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Suggestions/ Clarifications / Reasons/ Remarks:
Recommended for a period of : OneYear

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Dr. Basavaraj R Tubaki
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Dr. Supriya Bhalerao
(Chairperson)

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RESEARCH PROJECT

EFFICACY AND SAFETY OF ALERT CAPSULE IN THE MANAGEMENT OF GENERALIZED ANXIETY DISORDER- AN OPEN LABEL CLINICAL STUDY

ABSTRACT

Generalized anxiety disorder (GAD) is characterized by excessive, uncontrolled and often irrational worry, that is, apprehensive expectation about events or activities. In India, around 6-10% population is suffering from GAD. Anxiolytic drugs are extremely tempting, and prescribed to millions of individuals suffering from anxiety and stress. But some of them (like Benzodiazepines, Buspirone) are known to produce side effects like hypotension, nausea, memory loss, sexual dysfunction, headache etc. Thus, it needs to search for safe and effective solution. The present study is to be initiated for evaluating clinical efficacy and safety of Alert Capsule in the management of Generalized Anxiety Disorder (GAD). Disease specific inclusion and exclusion criteria have been selected and shall be employed for the enrolment of patients. For the assessment of efficacy appropriate subjective parameters like Generalized Anxiety Disorder 7 (GAD-7) scale, Hamilton Anxiety Rating Scale (HAM-A), Hamilton Depression Rating Scale (HAM-D), WHO Quality of life BREF, Pittsburg sleep quality index, Clinical global Impression will be used. On another hand, bio-chemical parameter like serum cortisol level will be analysed as anxiety marker other investigations like liver Function test, Renal Function test, Complete blood profile like Hb, ESR, RBC, PCV, MCV, MCH, MCHC, WBC, WBC Differential, total platelet count, MPV and blood clotting time will be evaluated. Urine & Stool routine examination will also be carried out. Total study period in a patient will be of 60 days. Treatment with test drug will be provided for 1 month and followed by 1 month period of placebo interventional observation period. Follow-up visit is to be scheduled at every 2 weeks of interval with 4 follow up. All the laboratory investigations will be carried out at base line and 30th day. However evaluation with all the clinical assessment scales will be carried out at all the visits. Appropriate statistics tools shall be applied to find out statistical significance of undergoing therapy.

Prepared by

Vasu Research Centre [VRC]

(A Division of VASU Health Care Pvt. Ltd.)

896/A, G.I.D.C., Makarpura, Vadodara- 390010

Year- 2015

INTRODUCTION:

Generalized anxiety disorder (GAD) is characterized by excessive, uncontrolled and often irrational worry, that is, apprehensive expectation about events or activities.[1] This excessive worry often interferes with daily functioning, as individuals with GAD typically anticipate disaster, and are overly concerned about everyday matters such as health issues, money, death, family problems, friendship problems, interpersonal relationship problems, or work difficulties.[2,3]

Generalized anxiety disorder affects about 3.1% American adults age 18 years and older (about 18%) in year 2010, causing them to be filled with fearfulness and uncertainty. The average age of onset is 31 years old.[4] In India, around 6-10% population is suffering from GAD.[5]

Anxiolytic drugs are extremely tempting, and prescribed to millions of individuals suffering from anxiety and stress. But some of them (like Benzodiazepines, Buspirone) are known to produce side effects like hypotension, nausea, memory loss, sexual dysfunction, headache etc.[6] Thus, it needs to search for safe and effective solution.

In Ayurveda, various medicinal plants are recommended for management of anxiety. Thinking in the same line, Vasu Healthcare has formulated polyherbal capsule known as Alert Capsule in soft gelatine form. It contains *Celastrus paniculatus* (Jyotishmati) Seed oil,[7-11] and Cow Ghee,[12,13] processed with *Acorus calamus* (Vaj) Rhizome,[14] *Convolvulus pluricaulis* (Shankhapushpi) Whole plant,[15-19] *Nardostachys jatamansi* (Jatamansi) Rhizome,[20-21] and *Eclipta alba* (Bhringraj) Whole plant.[22] Ingredients of Alert capsule are well reported in Ayurvedic texts and scientific research publications for Anti-anxiety activity. Alert capsule at therapeutic dose levels has shown good anti-fatigue activity in experimental rats.[23]

AIM & OBJECTIVE:

Primary Objective:

To assess the clinical efficacy of Alert Capsule in the management of Generalized Anxiety Disorder (GAD)

Secondary Objective:

To assess the safety of Alert Capsule

MATERIALS AND METHODS:

Study type	: Interventional, open labelled
Purpose	: Treatment
Timing	: Prospective
End point	: Efficacy and safety (Completion of treatment and follow-up period)
No. of Group	: 1 group
Subjects	: 60 patients

Selection of patients for clinical study:

For the purpose of this study, established cases of generalized anxiety disorder who are fulfilling the inclusion criteria and willing to give their consent to participate in the clinical trial, will be selected irrespective of their sex, caste, religion, habitat from OPD & IPD of respective institute.

Patient undergoing conventional treatment if matches inclusion criteria can be included after wash out period of 15 days.

Pre-treatment Observation:
All selected patients following registration will be informed regarding the objectives of clinical trial and their consent will be taken before initiating study. After preliminary registration diagnostic medical history will be taken according to Ayurveda and modern clinical methods. Detailed proforma will be prepared to assess the status of the patient.

INCLUSION CRITERIA:

(1) Patients (Male & Female) between the age group of 18 and 60 years and willing to give consent to participate in the study.
(2) Patients having Generalized Anxiety Disorder 7 (GAD-7) score ≥ 10
(3) Patients having Hamilton Anxiety Rating Score (HAM-A) ≥ 11
(4) Patients suffering from psycho- physiological insomnia especially due to anxiety.

EXCLUSION CRITERIA:

(1) Patients below 18 years and above 60 years
(2) Patients with Hamilton Depression Rating Scale score >13
(3) Patients suffering from any serious liver, kidney and cardiac diseases.
(4) Patients having history of any genetic disorders
(5) Patients on hypnotic medicine or other drugs which known to cause drowsiness.
(6) Lactating & pregnant women
(7) Patients on any Psychotropic or Nuerotrophic drugs 4 weeks prior to the study

DRUG UNDER TRIAL: ALERT CAPSULE

Composition: Each soft gelatine capsule contains

Sr. No.	Ingredients	Part Used	Quantity
1.	*Celastrus paniculatus (Jyotishmati) oil*	Seed	75 %
2.	*Cow Ghee*	---	25 %
Processed with (Sidhdha with)			
3.	*Acorus calamus (Vaj)*	Rhizome	---
4.	*Convolvulus pluricaulis* (Shankhapushpi)	Whole plant	---
5.	*Nardostachys jatamansi* (Jatamansi)	Rhizome	---
6.	*Eclipta alba* (Bhringraj)	Whole plant	---

TEST DRUG, DOSE AND DURATION:

Test Drug: Alert Capsule
Dose: 1 capsules twice a day, after meal
Vehicle: Normal drinking water
Route of administration: Oral
Duration: 1 month

DO'S & DONT'S:

All the subjects during the course of clinical trial shall be advised to take healthy diet.

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Smoking and sedentary life shall be discouraged in the patients.

DURATION OF STUDY: 60 days. 30 days of active intervention followed by 30days of follow up observation with placebo intervention.

STUDY PERIOD: 24 Months

FOLLOW UP:

Follow up study will be carried out for 1 (One) month after completion of the treatment at interval of 2 weeks. Placebo will be provided during follow-up period.

ADR (Adverse drug reaction):- Any adverse drug reaction is to be duly attended and treated.

Rescue medicine / treatment: In case of any emergency, patients will be terminated from the study and transferred for appropriate emergency treatment.

CRITERIA FOR THE ASSESSMENT:

Assessment of therapeutic efficacy & safety will be done on the basis of subjective as well as objective parameters.

Subjective parameters:

1. Generalized Anxiety Disorder 7 (GAD-7)[24]
2. Hamilton Anxiety Rating Scale (HAM-A)[25]
3. Hamilton Depression Rating Scale (HAM-D)[26,27]
4. Pittsburg Sleep Quality Index [28]
5. WHO quality of life BREF (Ref) [29, 30]
6. Clinical Global Impression Scale [31,32]

Objective parameters:

1. Serum cortisol level
2. CBC: Hb, ESR, RBC, PCV, MCV, MCH, MCHC, WBC, WBC Differential, total platelet count, MPV and blood clotting time.
3. Liver function test: SGOT & SGPT
4. Renal function test: Blood urea nitrogen, S. creatinine & Creatinine clearance rate
5. Urine examination
6. Stool examination

PRIMARY AND SECONDARY OUTCOME MEASURES

Primary: Primary outcomes will be effect of drug on subjective and objective parameters

Secondary: Assessment of drug safety and patient's compliance

STATISTICAL ANALYSIS:

The Wilcoxon signed rank method will be used to check the significance of the subjective criteria and paired "t" test will be used for objective criteria in a single group.

Values will be expressed in Mean ± SD. The obtained results will be interpreted as follow,

$P > 0.05$	: Insignificant	$P \leq 0.01$	: Highly significant
$P \leq 0.05$	: Significant	$P \leq 0.001$	: Very highly significant

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POLICY REGARDING HANDLING OF IMPERFECT DATA

1. In case of complete failure of the treatment, all data will be submitted to sponsor company. Company is to take decision on it.
2. In case of intolerance to the drug, trial will be terminated and informed to the sponsor with detail justification.
3. In case of patients lost in follow-up, try to counsel such patients who really willing to complete the treatment. Selection of the patients is the responsibility of principal investigator.
4. In case of lost data, principal investigator and his / her team will be considered responsible.
5. In case of withdrawal from therapy due to any reason, additional 10 patients will be enrolled to avoid interference in data due to dropout / withdrawal.

FINANCIAL IMPLICATION:

Clinical examinations will be carried out at Pathology and biochemistry laboratories available in hospital. Detail financial break-up will be provided by institutes.

FREQUENCY OF ASSESSMENT PARAMETERS:

Sr. No.	Investigation	B.T.	After 15 days	After 30 days	After 45 days	After 60 days	Frequency of test / patients	No. of Patient
1	Subjective parameters	Y	Y	Y	Y	Y	5	60+5
2	Serum cortisol level	Y	---	Y	---	---	2	60+5
3	CBC	Y	---	Y	---	---	2	60+5
4	Urine examination	Y	---	Y	---	---	2	60+5
5	Stool examination	Y	---	Y	---	---	2	60+5
6	Liver function test	Y	---	Y	---	---	2	60+5
7	Renal function test	Y	---	Y	---	---	2	60+5

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Flow Chart

Content	Screening (Before treatment)	Treatment		Follow-up	
		Visit 1 (After 15 days)	Visit 2 End of the study (After 30 days)	Visit 3 (At 2 weeks after completion of treatment)	Visit 4 (At 4 weeks after completion of treatment)
Informed consent	√				
Inclusion / Exclusion criteria	√				
Medical history	√				
Subjective parameters	√	√	√	√	√
Serum cortisol level	√	√	√		
Liver function test	√		√		
Renal function test	√		√		
CBC	√		√		
Urine examination	√		√		
Stool examination	√		√		
Product dispensing	√	√	√ (Placebo)	√ (Placebo)	
Adverse event		√	√		
Follow-up				√	√
Data compilation					√
Report preparation					√

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ANNEXURE – 1

Generalized Anxiety Disorder 7-item (GAD-7)

(Ref.: Spitzer RL, Kroenke K, Williams JBW, Lowe B. A brief measure for assessing generalized anxiety disorder. Arch Inern Med. 2006;166:1092-1097.)

The Generalized Anxiety Disorder 7-item (GAD-7) is the most widely used psychological instrument for measuring the severity level of disorder. Each item is rated on a 4-point scale, as mentioned below

0 = Not at all; 1 = Several days; 2= Over half days; 3 = Nearly everyday

Kindly mention appropriate score

Sr. No.	In the last 2 weeks, how often have you been bothered by the following problems?	Score		
		Before treatment	After 15 days of treatment	After 30 days of treatment
1	Feeling nervous, anxious, or on edge			
2	Not being able to stop or control worrying			
3	Worrying too much about different things			
4	Trouble relaxing			
5	Being so restless that it's hard to sit still			
6	Becoming easily annoyed or irritable			
7	Feeling afraid as if something awful might happen			
	Total Score			

Total score & interpretation:

Total score	Your GAD level
0	Nil
1-5	Mild severity
6-10	Moderate severity
11-15	Severe
16-21	Very severe

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ANNEXURE - 2

Hamilton Anxiety Rating Scale (HAM-A)

(Ref: Hamilton M. The assessment of anxiety states by rating. Br J Med Psychol 1959; 32:50–55.)

The Hamilton Anxiety Rating Scale (HAM-A) is a rating scale developed to quantify the severity of anxiety symptomatology, often used in psychotropic drug evaluation. It consists of 14 items, each defined by a series of symptoms. Each item is rated on a 5-point scale, as mentioned below

0 = Not present; 1 =Mild; 2= Moderate; 3 =Severe; 4= Very severe

Kindly mention appropriate score

Sr. No.	Condition	Before treatment	After 15 days of treatment	After 30 days of treatment
1	**Anxious mood**: Worries, anticipation of the worst, fearful anticipation, irritability			
2	**Tension:** Feelings of tension, fatigability, startle response, moved to tears easily, trembling, feelings of restlessness, inability to relax			
3	**Fears:** Of dark, of strangers, of being left alone, of animals, of traffic, of crowds			
4	**Insomnia**: Difficulty in falling asleep, broken sleep, unsatisfying sleep and fatigue on waking, dreams, nightmares, night terrors			
5	**Intellectual**: Difficulty in concentration, poor memory			
6	**Depressed mood**: Loss of interest, lack of pleasure in hobbies, depression, early waking, diurnal swing			
7	**Somatic (muscular)**: Pains and aches, twitching, stiffness, myoclonic jerks, grinding of teeth, unsteady voice, increased muscular tone			
8	**Somatic (sensory)**: Tinnitus, blurring of vision, hot and cold flushes, feelings of weakness, pricking sensation			
9	**Cardiovascular symptoms**: Tachycardia, palpitations, pain in chest, throbbing of vessels, fainting feelings, missing beat			
10	**Respiratory symptoms**: Pressure or constriction in chest, choking feelings, sighing, dyspnea			
11	**Gastrointestinal symptoms**: Difficulty in swallowing, wind abdominal pain, burning sensations, abdominal fullness, nausea, vomiting, borborygmi, looseness of bowels, loss of weight, constipation			

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12	**Genitourinary symptoms**: Frequency of micturition, urgency of micturition, amenorrhea, menorrhagia, development of frigidity, premature ejaculation, loss of libido, impotence			
13	**Autonomic symptoms**: Dry mouth, flushing, pallor, tendency to sweat, giddiness, tension headache, raising of hair			
14	**Behavior at interview**: Fidgeting, restlessness or pacing, tremor of hands, furrowed brow, strained face etc			
	TOTAL SCORE			

Total score & interpretation:

A total score range of 0–56, where

Total score	Your anxiety level
0 to 10	Nil
11 to 17	Mild severity
18 to 25	Moderate severity
26 to 30	Severe
31 & Above	Very severe

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ANNEXURE - 3

Hamilton Depression Rating Scale (HAM-D)

(Hamilton M. A Rating Scale for Depression. J Neurol Neurosurg Psychiatry 23:56-62, 1960)
(Hamilton M. Development of Rating scale for Primary Depressive illness. Br. J Soc Clin Psychol 6: 278-296, 1967)

The Hamilton Depression Rating Scale (HAM-D) is a rating scale developed to quantify the severity of Depression symptomatology, often used in psychotropic drug evaluation. It consists of 17 items, each defined by a series of symptoms. Each item is rated on a 5-point scale, as mentioned below

0 = Not present; 1 =Mild; 2= Moderate; 3 =Severe; 4= Very severe

Kindly mention appropriate score

Sr. No.	Condition	Before treatment	After 15 days of treatment	After 30 days of treatment
1	Depressed mood This item covers both the verbal and the non-verbal communication of sadness, depression, despondency, helplessness and hopelessness.			
2	Self-depreciation and guilt feelings This item covers the lowered self-esteem with guilt feelings.			
3	Suicidal impulses			
4	Initial insomnia			
5	Middle insomnia			
6	Delayed insomnia = Premature awakening			
7	**Work and interests** This item includes both work carried out and motivation. Note, however, that the assessment of tiredness and fatigue in their physical manifestations is included in item 13 (general somatic symptoms) and in item 23 (tiredness and pain)			
8	**Retardation (general)**			
9	**Agitation**			
10	**Anxiety (psychic)** This item includes tenseness, irritability, worry, insecurity, fear and apprehension approaching overpowering dread. It may often be difficult to distinguish between the patient's experience of anxiety ("psychic" or "central" anxiety phenomena) and the physiological ("peripheral") anxiety manifestations which can be observed, e.g., hand tremor and sweating. Most important is the patient's report on worry, insecurity, uncertainty, experiences of dreadfulness, i.e. the psychic ("central") anxiety.			

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Belagavi-590 010,Karnataka

11	**Anxiety (somatic)** This item includes physiological concomitants of anxiety: All feeling states should be rated under item 10 and not here.			
12	**12. Gastro-Intestinal** Symptoms may stem from the entire gastro-intestinal tract. Dry mouth, loss of appetite, and constipation are more common than abdominal cramps and pains. Must be distinguished from gastro-intestinal anxiety symptoms ("butterflies in the stomach" or loose bowel movements) and also from nihilistic ideas (no bowel movements for weeks or months; the intestines have withered away) which should be rated under 15 (Hypochondriasis).			
13	**General Somatic** Central are feelings of fatigue and exhaustion, loss of energy. But also diffuse muscular achings and pains in neck, back or limbs, e.g. muscular headache.			
14	**Sexual interests** This subject is often difficult to approach, especially with elderly patients. In males try to ask questions concerning sexual preoccupation and drive, in females responsiveness (both to engage in sexual activity and to obtain satisfaction in intercourse).			
15	Hypochondriasis Preoccupation with bodily symptoms or functions (in the absence of somatic disease)			
16	Loss of insight This item has, of course, only meaning if the observer is convinced that the patient at the interview still is in a depressive state.			
17	Weight loss Try to get objective information; if such is not available be conservative in estimation.			
	TOTAL SCORE			

ANNEXURE - 4

Pittsburg Sleep Quality Index

[Buysse DJ, Reynolds CF, Monk TH, Berman SR, DJ Kupfer (1989) The Pittsburgh Sleep Quality Index: A New Instrument for Psychiatric Practice and Research, **Psychiatry Research, 28**: 193-213].

Instructions:

The following questions relate to your usual sleep habits during the past month ONLY. Your answers
should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

1. **During the past month, when have you usually gone to bed at night?**
   USUAL BED TIME_____
2. **During the past month, how long (in minutes) has it usually taken you to fall asleep each night?**
   NUMBER OF MINUTES_____
3. **During the past month, when have you usually gotten up in the morning?**
   USUAL GETTING UP TIME_____
4. **During the past month, how many hours of *actual sleep* did you get at night? (This may be different than the number of hours you spend in bed.)**
   HOURS OF SLEEP PER NIGHT_____

For each of the remaining questions, check the one best response. Please answer ***all*** questions.

5. **During the past month, how often have you had trouble sleeping because you.....**

   (a) cannot get to sleep within 30 minutes
   Not during the Less than Once or Three or more
   past month_____ once a week_____ twice a week_____ times a week_____

   (b) Wake up in the middle of the night or early morning
   Not during the Less than Once or Three or more
   past month_____ once a week_____ twice a week_____ times a week_____

   (c) Have to get up to use the bathroom.
   Not during the Less than Once or Three or more
   past month_____ once a week_____ twice a week_____ times a week_____

   (d) Cannot breathe comfortably.
   Not during the Less than Once or Three or more
   past month_____ once a week_____ twice a week_____ times a week_____

   (e) Cough or snore loudly.
   Not during the Less than Once or Three or more
   past month_____ once a week_____ twice a week_____ times a week_____

   (f) Feel too cold.
   Not during the Less than Once or Three or more
   past month_____ once a week_____ twice a week_____ times a week_____

   (g) Feel too hot.
   Not during the Less than Once or Three or more
   Past month_____ once a week_____ twice a week_____ times a week_____

   (h) Had bad dreams.
   Not during the Less than Once or Three or more
   Past month_____ once a week_____ twice a week_____ times a week_____

   (i) Have pain.
   Not during the Less than Once or Three or more
   Past month_____ once a week_____ twice a week_____ times a week_____

   (j) Other reason(s), please describe_____
   _____

   How often during the past month have you had trouble sleeping because of this?
   Not during the Less than Once or Three or more
   Past month_____ once a week_____ twice a week_____ times a week_____

6. **During the past month, how would you rate your sleep quality overall?**

Very good _____
Fairly good _____
Fairly bad _____
Very bad _____

7. During the past month, how often have you taken medicine (Prescribed or "over the counter") to help you sleep?

Not during the Less than Once or Three or more
Past month_____ once a week_____ twice a week_____ times a week_____

8. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

Not during the Less than Once or Three or more
Past month_____ once a week_____ twice a week_____ times a week_____

9. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

No problem at all _____
Only a very slight problem _____
Somewhat of a problem _____
A very big problem _____

10. Do you have a bed partner or share a room?

No bed partner or do not share a room _____
Partner/ flatmate in other room _____
Partner in same room, but not same bed _____
Partner in same bed _____

11. If you have a bed partner or share a room, ask him/her how often in the past month you have had.....

(a) Loud snoring.
Not during the Less than Once or Three or more
Past month_____ once a week_____ twice a week_____ times a week_____

(b) Long pauses between breaths while asleep.
Not during the Less than Once or Three or more
Past month_____ once a week_____ twice a week_____ times a week_____

(c) Legs twitching or jerking while you sleep.
Not during the Less than Once or Three or more
Past month_____ once a week_____ twice a week_____ times a week_____

(d) Episodes of disorientation or confusion during sleep.
Not during the Less than Once or Three or more
Past month_____ once a week_____ twice a week_____ times a week_____

(e) **Other restlessness while you sleep: please describe**_____
_____
Not during the Less than Once or Three or more
Past month_____ once a week_____ twice a week_____ times a week_____

ANNEXURE - 5

WHO quality of life BREF

(Skevington SM, Lotfy M, O'Connell KA. The World Health Organization's WHOQOL-BREF quality of life assessment: Psychometric properties and results of the international field trial. A report from the WHOQOL group. Qual Life Res 2004;13:299–310)
(Development of the World Health Organization WHOQOLBREF quality of life assessment. The WHOQOL Group. Psychol Med 1998;28:551–558.)

The following questions ask how you feel about your quality of life, health, or other areas of your life. I will read out each question to you, along with the response options. **Please choose the answer that appears most appropriate.** If you are unsure about which response to give to a question, the first response you think of is often the best one.

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life **in the last four weeks.**

		Very Poor	Poor	Neither Poor	Good	Very Good
1.	How would you rate your quality of life?					

		Very Dissatisfied	Dissatisfied	Neither Satisfied nor Dissatisfied	Satisfied	Very Satisfied
2.	How satisfied are you with your health?					

The following questions ask about how much you have experienced certain things in the last four weeks.

		Not at all	A Little	A moderate amount	Very Much	An extreme Amount
3.	To what extent do you feel that physical pain prevents you from doing what you need to do?					
4.	How much do you need any medical treatment to function in your daily life?					
5.	How much do you enjoy life?					
6.	To what extent do you feel your life to be meaningful?					

		Not at all	A Little	A moderate amount	Very Much	Extremely
7.	How well are you able to concentrate?					

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8.	How safe do you feel in your daily life?					
9.	How healthy is your physical environment?					

The following questions ask about how completely you experience or were able to do certain things in the last four weeks.

		Not at all	A Little	Moderately	Mostly	Completely
10.	Do you have enough energy for everyday life?					
11.	Are you able to accept your bodily appearance?					
12.	Have you enough money to meet your needs?					
13.	How available to you is the information that you need in your day-to-day life?					
14.	To what extent do you have the opportunity for leisure activities?					

		Poor	Very Poor	Neither Poor nor good	Good	Very Good
15.	How well are you able to get around?					

		Very Satisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very Satisfied
16.	How satisfied are you with your sleep?					
17.	How satisfied are you with your ability to perform your daily living activities?					
18.	How satisfied are you with your capacity for work?					
19.	How satisfied are you with yourself?					
20.	How satisfied are you with your personal relationships?					
21.	How satisfied are you with your sex life?					
22.	How satisfied are you with the support you get from your friends?					

23.	How satisfied are you with the conditions of your living place?					
24.	How satisfied are you with your access to health services?					
25.	How satisfied are you with your transport?					

The following question refers to how often you have felt or experienced certain things in the last four weeks.

		Never	Seldom	Quite often	Very often	Always
26.	How often do you have negative feelings such as blue mood, despair, anxiety, depression?					

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ANNEXURE - 6

Clinical GIobal Impression Scale

(Guy W. Patient assessment in clinical trials. Prog Neuropsychopharmacol Biol Psychiatry 1982;6:601–606)

(GuyW. ECDEU Assessment Manual for Psychopharmacology– Revised (DHEW Publ. No. ADM 76-338). Rockville, MD: U.S. Department of Health, Education, and Welfare, Public Health Service, Alcohol, Drug Abuse, and Mental Health Administration, NIMH Psychopharmacology Research Branch, Division of Extramural Research Programs, 1976: 218–222.)

Severity of illness-Considering your total clinical experiences with this particular population, how mentally ill is the patient at this time?

1.Normal, not at all ill.
2.Border line mentally ill.
3.Mildly ill.
4.Moderately ill.
5.Markedly ill.
6.Severely ill.
7.Among the most extremely ill patients

Global Improvement-Rate total improvement whether or not in your judgment it is due entirely to drug treatment. Compared to his condition at admission to the project, how much has he changed?

1.Very much improved.
2.Much improved.
3.Minimally improved.
4.No Change
5.Minimally worse.
6.Much worse
7.Very much worse.

Efficacy Index- Rate this item on the basis of drug effect only. Select the terms that best describe the degrees of therapeutic effect and side effects and make a mark in the box where the two items intersect.

Therapeutic Effect	Side effects			
	None	Do not Significantly interfere with Patient's functioning	Significantly interfere with Patient's functioning	Outweigh Therapeutic effect
4.Marked-Vast improvement complete or nearly complete remission of all symptoms	4.00	2.00	1.33	1.00
3.Moderate-Decided improvement. Partial remission of symptoms	3.00	1.5	1.00	0.75
2.Minimal-Slight improvement which doesn't alter status of care of patient	2.00	1.00	0.67	0.50
1.Unchanged or Worse	1.00	0.55	0.33	0.25

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INSTITUTIONAL ETHICS COMMITTEE
KLE University's Shri B. M. Kankanawadi Ayurved Mahavidyalaya &
KLE Ayurved Hospital, Shahapur, Belgaum

COMMUNICATION OF DECISION OF THE INSTITUTIONAL ETHICS COMMITTEE (IEC)

Protocol No: BMK/15/BRT/01

Protocol Title: "EFFICACY AND SAFETY OF ALERT CAPSULE IN THE MANAGEMENT OF GENERALIZED ANXIETY DISORDER-AN OPEN LABEL CLINICAL STUDY"
Principal Investigators/Co-investigators: Dr.B.R.Tubaki, Dr Sukumar Nandigowdar
Name & Address of Institution: KLE University's Shri B. M. Kankanawadi Ayurved Mahavidyalaya &KLE Ayurved Hospital, Shahapur, Belgaum
☐ New Review ☑ Revised Review ☐ Expedited Review
Date of Review (DD/MM/YY): 18.02.2016 **Date of previous review, if revised application:** **Name of the Reviewers who attended the meeting:** Dr Supriya Bhalerao, Dr Harsha Hegde, Dr.S.K.Hiremath, Dr. P.Shinde, Dr.Sameer N Naik, Dr. Rajashree Kamat, Dr.B.S.Hebballi, Mrs Sarita Shirodkar, Mrs. Arati S. Balikai, Mr. Sudheer kulkarni
Decision of the the Ethics Committee: **Recommended** ☑ **Recommended with suggestions** ☐ **Revision** ☐ **Rejected** ☐

ATTESTED

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Registrar
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Belagavi-590 010,Karnataka

Suggestions/ Clarifications / Reasons/ Remarks: Following are the suggestions/clarifications of the EC- NIL
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

Institute's Copy

ગુજરાત GUJARAT

43AA 431601

12 JUN 2015

ખરીદનારનું નામ VASU RESEARCH CENTRE
(A Division of Vasu Healthcare Pvt. Ltd.)

સરનામું 926/A, G.I.D.C. Makarpura,
Vadodara-390010.

લેખક સહી

ધનશ્યામ હરીભાઇ પટેલ (સ્ટેમ્પ વેન્ડરનો ધંધો)
૭, રોયલ પ્લાઝા, સંપતરાવ કોલોની, જેતલપુર રોડ,
અલકાપુરી, વડોદરા-૭ લા. નં. ૫૬/૯૦ તા. ૧૮/૦૪/૯૦

MEMORANDUM OF UNDERSTANDING

This memorandum of understanding is entered into on this *18th day of month September, 2015*

BETWEEN

M/s Vasu Research Center (A Division of Vasu Healthcare Pvt. Ltd.), Vadodara, a company incorporated under the Indian Companies Act, having its registered office at 926/A, GIDC, Makarpura, Vadodara – 390 010, Gujarat, India, through its authorized signatory Shri Haribhai R. Patel, Managing Director authorized by the Board Resolution dated 02/10/2013, hereinafter referred to as the **company**, which expression shall unless repugnant to the context and meaning thereof include its heirs, successors and assignees of the one Part.

AND

KLE University'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.

ATTESTED

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

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WHERE AS the company is engaged, interalia, in research and development of various Ayurvedic drugs.
AND WHERE AS the Institute has fully established good research facilities and hospital facility for the clinical studies in the field of Ayurved and Ayurvedic Drugs.

WHERE AS *the company has developed a drug in its laboratory for the management of Stress and wants a clinical assessment for its efficacy and safety in Generalized Anxiety Disorder, to be done in the lab & 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 the *drug Alert Capsule*, developed by the company.
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 detail 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 result 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. 4, 74,210/- only (In words: Four lakhs seventy four thousand two hundred ten only), after deduction of 10% TDS it will be Rs. 4, 26,789/- only (In words: Four lakhs twenty six thousand seven hundred eighty nine).*
   Out of the above proposed fixed expenditure of Rs. 4, 26,789/-, the company has agreed to make 10% non-refundable amount (Rs. 42,679/- via cheque no. 733817 dated 11.09.2015) along with application which will be adjustable in total project cost, 50% (2, 13,395/-) of payment will be made after ethical clearance as part of project initiation, and 30% (1, 28,036/-) payment will be made once the 50% of sample size is reached. Remaining 10% (Rs. 42,679/-) of the project cost should be paid after the completion of the project.
5. That the said trial shall be completed in a period of *24 months*.
6. The Institute has agreed to provide trimonthly basis progress report of the clinical trial of the said drug.
7. The company has agreed to provide all detail of work, raw drugs, finished drugs and all other necessary co-operation in order to complete the research activities of the drugs.
8. *It has been agreed between the parties that all rights arising out of research and clinical activities of the said drug, including patent right shall vest with the company and the Institute shall never claim any right over the drugs any time in future.*
9. *important research findings arising out of the activities covered under this MOU will be published in presented at National/International journals/conferences with joint authorship of both the parties.*
10. All notices and other communication required to be served on parties under the terms of this agreement shall be considered duly served if the same have been delivered to or posted by registered mail to:

In case of Vasu Research Center:

Manager R&D,
Vasu Research Centre
(A Division of Vasu Healthcare Pvt. Ltd.)
896/A, GIDC, Makarpura, Vadodara-390010, Gujarat, India
Tel.: 91-265-2657701 2 Fax: 91-265-2647331
Web: www.[illegible].com; www.vasuhealthcare.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

भारतीय गैर न्यायिक

बीस रुपये

रू.20

Rs.20

TWENTY RUPEES

INDIA

INDIA NON JUDICIAL

ગુજરાત GUJARAT

43AA 431602

12 JUN 2015

ખાતું નં. 98539 તા. 9/6/2015 રૂ. 201-

પરીક્ષાકાર્યનું નામ VASU RESEARCH CENTRE
(A Division of Vasu Healthcare Pvt. Ltd.)

સરનામું B/29-A, G.I.D.C. Makarpura,
Vadodara-390010 [illegible]

[illegible]

ધનશ્યામ હરીભાઇ પટેલ (સ્ટેમ્પ વેન્ડરની સહી)
૭, શેલ પ્લાઝા, નંદનરાય કોમ્પ્લેક્ષ, મેતલપુર રોડ,
અલકાપુરી, વડોદરા-૭ (લા. નં. ૧૬/૦૭ તા. ૧૮/૦૪/૯૦

In case of Shri B M Kankanawadi Ayurved Mahavidyalaya:
Coordinator,
Medical Research Centre, KLE University's
Shri B M Kankanawadi Ayurved Mahavidyalaya,
Shahapur, Belagavi-590003, Karnataka, India
Fax:0831-2424157, Tel:0831-2486286
Website: www.kleayurvedmrc.edu.in
Email: mrc.klebmk@gmail.com

11. 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 use the same as per the law. Hence in order to save the proprietary information / trade secrets, both the parties has agreed as follows:

(i) All rights to the proprietary information to the developed product shall remain the sole property of the company.

ATTESTED

Dr. V.A. Kothiwale
Registrar
KLE Academy of Higher Education and Research,
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(iii) The Institute undertakes do not disclose to any third party about the present Agreement understanding.

12. None of the Parties to this MOU shall make any public disclosure 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 Governmental Reviews or approvals of the proposed business arrangement discussed in this MOU.

13. 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

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 of termination.

14. 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.

15. Time is the essence of this agreement.

16. Any dispute, difference or claim arising out of or in connection with this 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 Act, 1996, as amended (the "**Arbitration Act**"). Such arbitration shall be held at Vadodara, Gujarat. All proceedings of such arbitration shall be in the English language.

17. The courts of Vadodara shall have the sole and exclusive jurisdiction to resolve any dispute if not solved amicably between the Parties.

In witness whereof the parties hereto have signed this agreement on the day month and year mentioned hereinabove.

PARTIES

For and on behalf of
Vasu Research Center
(A Division of Vasu Healthcare Pvt. Ltd.)

Mr. Haribhai B. Patel

For and on behalf of
KLE University's Shri B M Kankanawadi Ayurved Mahavidyalaya

Dr. B. Sreepadas Prasad

WITNESSES

Mr. Vikram Trivedi

Dr. Hardik Soni

Dr. R. B. Tuloli

Dr.

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
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Belagavi-590 010,Karnataka