TJU Renewal

FIRST AMENDMENT TO THE INDIA CENTER AT JEFFERSON FOR HEALTH PROFESSIONS EDUCATION AND RESEARCH AFFILIATION AND SUPPORT AGREEMENT

This **FIRST AMENDMENT TO THE INDIA CENTER AT JEFFERSON FOR HEALTH PROFESSIONS EDUCATION AND RESEARCH AFFILIATION AND SUPPORT AGREEMENT** ("First Amendment") is entered into by and between **THOMAS JEFFERSON UNIVERSITY** ("Jefferson") and **KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH-BELGAUM** ("KLE").

WHEREAS, Jefferson and KLE entered into **THE INDIA CENTER AT JEFFERSON FOR HEALTH PROFESSIONS EDUCATION AND RESEARCH AFFILIATION AND SUPPORT AGREEMENT** ("Agreement") effective July 26, 2017; and

WHEREAS, in accordance with Agreement Paragraph 2.2, Amendment, the parties desire to modify the terms of the Agreement to renew the term of the Agreement and change the funding support.

NOW, THEREFORE, in consideration of the mutual covenants herein contained and intending to be legally bound hereby, the parties agree as follows:

1. Article 1.1 shall be revised to read as "in priority areas that may include Integrative Medicine, Public Health, Urology, Neurology, Psychiatry, Radiology, Nursing Sciences, Physical/Rehabilitative/Occupational therapy and other areas that may be identified by mutual consultation".

2. Paragraph 2.1, Term shall be revised to read as follows:

   2.1. **Term.** This Agreement shall be effective as of the Agreement Effective Date and will remain in force for a period of two (2) years until 2019. The Term shall be renewed for an additional three (3) year period beginning July 1, 2019 and ending June 30, 2022 (the "Renewal Term"). All terms of the Agreement shall apply to the Renewal Term.

3. Paragraph 3.1, Support Funding shall be revised to read as follows:

   3.1 **Support Funding.** KLE shall provide funding to Jefferson for the India Center, which funding may be used to provide general program support to accomplish the goals and purpose of the India Center for the term of the Agreement, including but not limited to, salaries and personnel costs, materials and services, telephone, and overhead. KLE shall pay Jefferson One Hundred Thousand Dollars ($100,000 US) annually during the Renewal Term.

4. Paragraph 3.2.1, shall be revised to read as "for two visitors for visits of one (1) to two (2) weeks in priority areas to include Integrative Medicine, Public Health, Urology, Neurology, Psychiatry, Radiology, Nursing Sciences, Physical/Rehabilitative/Occupational therapy and other areas that may be identified by mutual consultation".

5. The address noted in paragraph 9.8 for Jefferson's legal counsel shall be changed to: Thomas Jefferson University, Office of Legal Affairs, 834 Chestnut Street, Suite 400, Philadelphia, PA 19107, Attention: Chief Counsel.

6. This First Amendment is effective on June 1, 2019, (the "Amendment Effective Date").

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

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7. This First Amendment to the Agreement is incorporated into and made part of the Agreement and all provisions of the Agreement not expressly modified or amended hereby shall remain in full force and effect.

IN WITNESS WHEREOF, the duly authorized representatives of Jefferson and KLE have executed this First Amendment to the Agreement as of the Amendment Effective Date.

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH, BELGAUM

By: Dr. V D Patil
Its: Registrar

By: Dr. Vivek A Saoji
Its: Vice Chancellor

By: Dr. Prabhakar B. Kore
Its: Chancellor and Chairman

THOMAS JEFFERSON UNIVERSITY, PHILADELPHIA

By: Richard J Derman, MD
Its: Associate Provost, Global Affairs

By: Mark L. Tykocinski, MD
Its: Provost

By: Stephen K Klasko, MD, MBA
Its: President Chief Executive Officer

KLE Academy of Higher Education and Research Deemed-to-be University BELAGAVI

41072v4 (Execution Document)

ATTESTED
Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

MEMORANDUM OF UNDERSTANDING

KLE UNIVERSITY
EMPOWERING PROFESSIONALS

KLE University

(Formerly known as KLE Academy of Higher Education and Research),
herein represented by
Dr. Prabhakar Kore,
Chancellor, KLE University and
Dr. V.D.Patil,
Registrar, KLE University
A Deemed University u/s 3 of the UGC Act 1956
vide Government of India notification No.9-19/2000-U.3A
Belagavi-590010, Karnataka, India

AND

Thomas Jefferson University, Philadelphia, USA,

herein represented by

Dr. Stephen K.Klasko, MD, MBA
President and Chief Executive Officer,
Thomas Jefferson University and Jefferson Health

Dr. Richard J.Derman, MD, MPH
Associate Provost, Global Affairs,
Thomas Jefferson University

THOMAS JEFFERSON UNIVERSITY

Dr. Stephen K.Klasko, MD, MBA
President and Chief Executive Officer,
Thomas Jefferson University and Jefferson Health

KLE UNIVERSITY-BELAGAVI

Dr. Prabhakar B. Kore
Chancellor and Chairman

Dr. Richard J.Derman, MD, MPH
Associate Provost, Global Affairs,
Thomas Jefferson University

ATTESTED

OFFICE OF THE REGISTRAR • KLE UNIVERSITY, BELAGAVI • KLE UNIVERSITY

Dr. V.D.Patil
Registrar

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

THE INDIA CENTER AT JEFFERSON FOR HEALTH PROFESSIONS EDUCATION AND RESEARCH

AFFILIATION AND SUPPORT AGREEMENT

This Affiliation and Support Agreement ("Agreement") is entered into on _____, 2017 ("**Effective Date**") by and between **Thomas Jefferson University** ("**Jefferson**") and **KLE University-Belgaum** ("KLE") JEFFERSON and KLE are collectively referred to as the "Parties".

BACKGROUND

WHEREAS, Jefferson and KLE desire to collaborate to work toward the creation of The India Center at Jefferson (the "**India Center**") to promote collaboration in the fields of health professions education and research as more fully set forth herein; and

WHEREAS, the Parties recognize that with the establishment of the Center, meaningful exchanges of health professionals will be possible through an organized system for coordinating these visits that will be provided by the India Center.

WHEREAS, the Parties further believe that the India Center has the potential to facilitate international research between the Parties.

NOW, THEREFORE, the Parties agree as follows:

ARTICLE I: THE GOALS, PURPOSE, AND STRUCTURE OF THE INDIA CENTER

1.1 **Goals.** The goals of the India Center are to support education, research and professional collaboration of health professionals in three (3) priority areas to include Integrative Medicine, Public Health and Urology.

1.2 **Purpose.** The purpose of the India Center is to achieve the following:

- Provide support for the newest, best clinical practices at KLE in the priority areas;
- Provide for the sharing of clinical protocols to support practice change directed at improving clinical outcomes for KLE patients in the priority areas;
- Supplement the development of health professionals in each of the priority areas by facilitating the exchange of health personnel by providing educational experiences at Jefferson for KLE health professionals and identifying opportunities for similar experiences at KLE for Jefferson health professionals;
- Collect information on the exchanges to assess the satisfaction of the exchanges;
- Support academic collaborations for generating scholarly publications;
- Facilitate the development of research collaborations and the potential for conducting research as resources permit, including generating fundable research;
- Explore the development of data registries;
- Develop a platform of distance learning including online programs for health care professionals including medical students and medical residents in each of the priority areas; and
- Establish a collaborative clinical conference for India that will be held annually, alternating the site between India and Philadelphia, Pennsylvania, USA.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

1.3 **Structure.** Jefferson shall work toward establishing the India Center at Jefferson and appoint a Director of the India Center and provide personnel to staff the India Center to accomplish its purpose. Academicians from Jefferson and KLE shall be appointed to the India Center's Advisory Committee. The Advisory Committee will work to achieve the goals and purpose of the India Center. The Advisory Committee will also provide appropriate advice to the Director of the India Center to enhance satisfaction with the exchange program. The Advisory Committee will assess the progress of the India Center in meeting its goals and purposes on an annual basis.

ARTICLE II: TERM, AMENDMENT, RENEWAL AND TERMINATION

2.1 **Term.** This Agreement shall be effective as of the Effective Date and will remain in force for a period of two (2) years until 2019 (the "Expiration Date").

2.2 **Amendment.** This Agreement may be amended by written agreement signed by authorized representatives of the Parties.

2.3 **Renewal.** The Agreement shall be automatically renewed for an additional one (1) year period without change unless one party gives the other party at least three (3) months written notice prior to the Expiration Date.

2.4 **Termination.** The Agreement may be terminated with three (3) months advance notice to the other party at any time for any reason by the appropriate authority of the party, unless an earlier date is mutually agreed upon. In this case, the Parties shall talk in good faith before terminating the Agreement.

ARTICLE III: FUNDING OF THE INDIA CENTER AND VISITATION COSTS

3.1 **Support Funding.** KLE shall provide funding to Jefferson for the India Center, which funding may be used to provide general program support to accomplish the goals and purpose of the India Center for the term of the Agreement, including but not limited to, salaries and personnel costs, materials and services, telephone, and overhead. KLE shall pay Jefferson One Hundred and Fifty Thousand Dollars ($150,000 US) annually.

3.2 **Visitation Costs.**

3.2-1 No visitation fees shall be charged for annual planned visits of KLE professionals to Jefferson for two (2) visitors for visits of one (1) to two (2) weeks in duration in each of the three (3) priority areas to include Integrative Medicine, Public Health and Urology with follow up visits by Jefferson professionals to KLE. In addition, for these visitors, Jefferson shall be responsible to pay the reasonable cost of hotel accommodations for visits by KLE professionals to Jefferson and KLE shall be responsible to pay the reasonable cost of hotel accommodations for visits by Jefferson professionals to KLE.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

3.2-2 Jefferson agrees to accept additional visitors from KLE during the term of the Agreement. For such additional visitors, KLE shall pay Jefferson visitation costs as follows:

Discounted Costs for KLE based on duration of the exchange (US $)					
	1 week	2 weeks	1 month	2 months	3 months
Medical Students	600	1,200	1,800	3,600	5,400
Physicians	900	1,800	3,000	6,000	9,000
Nurses	450	900	1,500	3,000	4,500
Other health professionals	450	900	1,500	3,000	4,500

KLE agrees to pay visitation costs at the rates specified in Section 3.2-2, according to the type of Exchange Visitors sent to Jefferson and the duration of the exchange. Payment for the visitation costs of each exchange (single or group) shall be paid in full a minimum of thirty (30) days before the arrival of the visitor(s).

3.3 **Online Course and Distance Learning Costs.** When developed, KLE shall be offered a discount for online courses and distance learning to include online courses and distance learning in certain Masters' degree programs (Safety, Quality and Health Outcomes) through the Jefferson College of Population Health.

ARTICLE IV: EXCHANGE VISITORS AND PROGRAMS

4.1 **Definitions:**

4.1-1 **"Home Facility"** means the party sending staff or students to the Host Facility.

4.1-2 **"Host Facility"** means the facility accepting the staff or students from the Home Facility.

5.1-3 **"Inviting Facility"** means the facility requesting a staff or student to participate in a cultural exchange program.

4.2 **Staff Exchange Programs**

4.2-1 Reciprocal Exchange of Academic Staff/Staff Program

The Parties may select staff to participate in an exchange for the purpose of studying or lecturing in the other facility on a reciprocal basis. The visiting staff participant (each, an **"Exchange Visitor"**) shall be subject to all applicable laws of the host country, including but not limited to immigration laws, and subject to approval by the Host Facility. The Host Facility will assist the Exchange Visitor in locating living accommodations and in matters of health, language and local custom.

4.2-2 Visiting Academic Staff/Cultural Exchange Program

In addition to the reciprocal exchanges, either facility may invite members of the other facility for the purpose of participating in conferences, attending symposia, lecturing or consulting for a specified period of time, subject to the approval of the Home Facility. In such cases, the Inviting Facility makes appropriate funding arrangements with the invited faculty member. Each invited faculty member shall be considered an Exchange Visitor.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

4.3 **Student Exchange Program**

Each party may send students to the other to participate in appropriate fields of study, subject to the availability of a Host Facility supervisor and resources. In such cases, students will submit a proposal, signed by both the Home Facility and the Host Facility supervisors, outlining how the study undertaken at the Host Facility shall contribute towards the student's degree at their Home Facility. Each student shall be considered an Exchange Visitor.

4.4 **Selection of Exchange Visitor Candidates**

Each Exchange Visitor must meet applicable requirements of the Host Facility. Exchange Visitors selected for the exchange will be required to have sufficient knowledge of the language appropriate to the Host Facility to carry out their studies and research at the Host Facility. A Host Facility may not discriminate against an Exchange Visitor candidate based on the candidate's race, sex, color, religion, or age. Selection in an exchange program does not entitle the Exchange Visitor to pursue a degree at the Host Facility. The India Center will also be the agent for any exchange involving Jefferson personnel visiting India through this Agreement.

4.5 **Description of Exchange Experiences**

4.5-1 General Terms for Each Exchange Experience. Prior to the beginning of each exchange experience for Exchange Visitors, the Parties shall discuss and agree upon a curriculum for the Exchange Visitors, which shall be placed in writing. The Parties understand that each exchange experience will be dependent on the availability of funds.

4.5-2 Description of Exchange Experiences. The curriculum of exchange experiences shall be set by the India Center with the advice and consultation of KLE. While consideration will be given to the individual interests and objectives of the visitor(s) in establishing the curriculum for a specific visitor or group of visitors, the objective of the program, especially for groups of visitors, is to develop and offer a specific model program for a given type of visitor or group of visitors. Further, because the India Center must rely on the availability of Jefferson facilities including its Thomas Jefferson University Hospitals, Inc. ("Hospital") and personnel at the time of the visit to prepare and organize a specific program or educational experience, the template of a given model experience may not be able to be reproduced as presented.

4.6 **Joint Research Program**

Parties may seek opportunities to cooperate in research through the India Center. The details of specific research proposals will be determined by the mutual agreement of the Parties. The form of research cooperation may vary with the goal of each research project. Prior to the initiation of a specific research project, the parties shall discuss each project and agree that, *prior to the commencement of each research project*, a Research Program Agreement ("Program Agreement") must be entered into that shall include terms to address the policies of the Parties on intellectual property, any event of research collaboration leading to patent rights, copyrights and other intellectual property rights, the timing of the program, and details deemed relevant to the program.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Each Program Agreement entered into will form an Appendix and be attached to and incorporated into this Agreement. Research exchange will also be coordinated through the India Center contingent on fulfilling the obligations under this Agreement and the availability of funds.

4.7 **Exchange Visitor Status**

The Parties shall be responsible to notify each student Exchange Visitor that the student shall not be deemed to be a student of Jefferson or KLE. Parties agree that the exchange program for degree training should follow the educational system and regulations of the Home Facility.

4.8 **Exchange Visitor Requirements**

4.8-1 Exchange Visitor Discipline and Removal. Parties agree to terminate the participation of any Exchange Visitor assigned to Jefferson, upon request of Jefferson, if Jefferson has determined that the Exchange Visitor failed to abide by the standards, practices, rules, policies, or procedures of Jefferson or in any way threatens to impair the delivery of education to Jefferson students or clinical care to its patients. In addition, each Host Facility shall have full responsibility for conducting any Exchange Visitor disciplinary proceedings in accordance with its own rules and regulations. Notwithstanding the above, the Home Facility agrees to terminate the participation of any Exchange Visitor assigned to the Host Facility, upon request of the Host Facility, if the Host Facility has determined that the Exchange Visitor fails to abide by the practices, rules, policies, or procedures of the Host Facility or in any way threatens to impair the delivery of educational services to the Host Facility.

4.8-2 Educational Records. Jefferson shall maintain all educational records and reports relating to the participation by each student assigned to the classroom experience at Jefferson for a reasonable period. In the event of pending litigation involving such records, those records shall be maintained until a resolution of the legal action is reached. The India Center shall provide KLE with an annual report detailing the activities of the India Center.

4.8-3 Exchange Visitor Health Status/Prerequisites. Jefferson shall require KLE, as appropriate considering the training period and type of professional, to provide to Jefferson satisfactory evidence that each Exchange Visitor assigned to Jefferson has: (a) proof of an acceptable criminal background check, including without limitation, no criminal history related to health care or adult or child abuse or neglect; (b) qualifying health status to work directly with patients; (c) immunization documentation and compliance with health requirements established by Home Facility; (d) infection control and universal precautions training; (e) certification in basic cardiac life support; and (f) any other prerequisite reasonably requested by Host Facility prior to the exchange and from time to time during the exchange. The Exchange Visitor shall be responsible to provide a copy of all such prerequisites to Host Facility and to maintain a record documenting these prerequisites.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Some or all of the above requirements may be waived by Jefferson out of consideration for the nature of the exchange program and the visit.

4.8-4 Emergency Medical Treatment. If any of the Exchange Visitors participating at Jefferson covered by this Agreement should require emergency medical treatment while at Jefferson, Jefferson shall follow its procedures for handling such emergencies. Any expenses related to the emergency transport and treatment shall be the sole responsibility of the Exchange Visitor.

4.8-5 Health and Accident Insurance. Parties shall require each Exchange Visitor to maintain health and accident insurance during participation in a program at Jefferson. Jefferson shall accept the travel insurance that includes health and accident insurance provided by KLE for Exchange Visitors to satisfy this requirement as long as this insurance coverage satisfies the US Department of State's minimum requirements. Parties are aware that the US Department of State requires no less than $100,000 US for accident or illness, plus $25,000 US for repatriation of remains and a $50,000 US for medical evacuation for each Exchange Visitor.

4.8-6 Exchange Visitor Expenses. Jefferson shall not be responsible for any compensation for services or expenses including but not limited to meals, travel or other incidental expenses incurred by Exchange Visitors assigned to Jefferson. Each Exchange Visitor is responsible for travel (airfare and local transportation); accommodations and other expenses related to his/her participation in the exchange program, except for invited Exchange Visitors for whom appropriate funding arrangements have been made.

4.8-7 Housing. KLE will advise Exchange Visitors that room and board will not be provided by Jefferson. KLE will advise Exchange Visitors that they will be responsible for obtaining housing and will be required to pay all expenses associated with room and board.

4.8-8 Publications. Exchange Visitors must obtain prior written approval of KLE and Jefferson before publishing any material relating to the experience at Jefferson. Upon approval, Exchange Visitors shall be able to publish material relating to the exchange in accordance with the Home Facility's policies, provided however, that the Exchange Visitor shall give the Host Facility an advance copy of the proposed publication and allow Host Facility at least a sixty (60) day opportunity to remove any confidential information of the Host Facility prior to publication.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

4.8-9 Exchange of Academic Materials. Each party shall exchange all relevant materials, such as those relating to the library, on a regular basis. The libraries can also exchange reference materials for research purposes. The exchange of academic materials shall be consistent with applicable legal and contractual requirements including U.S. laws applicable to international studies governing universities.

4.8-10 Assigning. KLE shall assign only those Exchange Visitors who meet the requirements and prerequisites set forth in this Agreement.

4.8-11 Scheduling Exchange Visitors. Parties shall annually agree upon the number and schedule for Exchange Visitors prior to placement at Jefferson.

4.8-12 Compliance with Host Facility Policies. Each Exchange Visitor must comply with applicable policies of the Host Facility throughout his/her participation in the exchange program.

4.8-13 Visas. Each Exchange Visitor is responsible for obtaining and maintaining any visa needed for participation in the exchange program. The Host Facility will provide the Exchange Visitor with the documents necessary for obtaining a visa. Each Exchange Visitor must keep the Host Facility apprised of any changes in his/her visa status.

4.8-14 Patient Confidentiality. Home Facility shall ensure that each Exchange Visitor placed at Host Facility has been educated as to the concepts of privilege and confidentiality in a health care system. The Parties recognize that personal information of patients and protected health information as defined in HIPAA described below ("Patient Information") is confidential and the Exchange Visitors are under an obligation to maintain the confidentiality of such Patient Information in accordance with State and Federal laws of the United States of America. Notwithstanding the generality of the foregoing, the Parties specifically covenant and agree to comply, and the Home Facility covenants to cause its Exchange Visitors to comply, with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) in all respects and to amend this Agreement as may be required to be HIPAA compliant, including without limitation to: (1) refrain from using or disclosing any Patient Information for any unauthorized purpose; (2) maintain safeguards as necessary when using, disclosing or accessing Patient Information, such as not talking about patients in public areas, not removing patients official medical records from a health care facility, and not downloading Patient Information on personal electronic devices; and (3) report to the Host Facility any use or disclosure of Patient Information of which the Home Facility or exchange visitor become aware that is not authorized.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

ARTICLE V: CONFIDENTIALITY.

KLE agrees that any information and documents including, without limitation, data, educational materials, medical records, materials relating to business, protocols, guidelines, pricing, strategies, compensation levels, financial information, trade secrets, and technology (collectively, the "Confidential Information") concerning Jefferson, its patients, affiliates, employees, agents, or representatives that are submitted under this Agreement or which KLE or its Exchange Visitors become aware of during term of the Agreement are confidential and proprietary to Jefferson. KLE shall hold all Confidential Information in the strictest confidence and shall protect all Confidential Information with the same degree of care that it exercises with respect to its own proprietary information and in accordance with any and all applicable laws and regulations and Jefferson's policies and procedures. KLE shall obtain no proprietary rights (directly or indirectly) in or to any such materials. KLE shall not disclose the Confidential Information to any third party without the prior written consent of Jefferson unless required by law, in which event KLE will promptly notify Jefferson of such request. Upon the expiration or termination of this Agreement, for any reason, KLE shall promptly turn over and return to Jefferson all Confidential Information (in whatever form or media) or upon the written direction of Jefferson, destroy the Confidential Information.

ARTICLE VI: INSURANCE.

Each party shall provide and maintain Comprehensive General Liability and such insurance for itself, its agents, its employees, at levels sufficient to support the indemnification obligations assumed herein. Upon request of a party, the other party shall supply certificates of insurance evidencing such coverage.

ARTICLE VII: INDEMNIFICATION.

Each party shall indemnify, defend and hold the other party, their respective trustees, directors, officers, agents, employees, and Exchange Visitors participating in a program at Jefferson, harmless from and against any and all liabilities, suits, actions, claims, demands, damages, losses, expenses and costs of every kind and character, including defense cost and legal fees, suffered or incurred by or asserted or imposed against the party seeking indemnification and resulting from, connected with, or arising out of any negligent or wrongful act or omission of the indemnifying party or any other agent or employee of the indemnifying party occurring at any time during the term of this Agreement. This section shall survive the expiration or termination of this Agreement.

ARTICLE VIII: NAME AND LOGO.

No party shall use, or permit others to use, the other's name, trademark or logo for any purpose or in any descriptive or promotional literature or communication of any kind without the other party's prior written approval.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

ARTICLE IX: GENERAL PROVISIONS

9.1 Exclusivity. This Agreement is not intended to conflict with or affect any existing or future affiliation between the Parties and institutions not a party to this Agreement. This Agreement is not exclusive.

9.2 Applicable Law. This Agreement shall be deemed to have been made and shall be construed in accordance with the laws of the Commonwealth of Pennsylvania, United States of America, without regard to its choice of law doctrine. All disputes related to this Agreement shall be brought in federal or state courts located in Philadelphia, Pennsylvania, USA and the Parties agree to the exclusive jurisdiction of those courts and waive any rights or defenses to such exclusive jurisdiction.

9.3 Entire Agreement. This Agreement constitutes the entire agreement between the Parties with respect to the subject matter hereof and all prior discussions, agreements or understandings, whether verbal or in writing, are hereby merged into this Agreement.

9.4 Non-Discrimination. Neither party shall discriminate in the performance of this Agreement because of race, color, sex, sexual orientation, age, religion, handicap, marital status, or national origin in violation of any applicable federal, state or local law or regulation.

9.5 Assignment. No party shall assign any of its rights or obligations under this Agreement without the prior written consent of the other party. Any such assignment is expressly prohibited and shall be deemed null and void.

9.6 Severability. If any provision of this Agreement shall be declared by a court of competent jurisdiction to be invalid, or the Parties determine any provision to be in conflict with any applicable federal, state or local law or regulation, then the remaining provisions of this Agreement shall be unaffected thereby and shall remain in full force and effect.

9.7 Authority. Each party represents that it has the authority to enter into and be bound by this Agreement.

9.8 Notices. Any notice required to be provided under the terms and provisions of this Agreement shall be in writing, and shall be deemed to be delivered when deposited in the United States mail or national delivery service such as UPS or Federal Express, postage prepaid, certified mail, return-receipt requested, and addressed to the respective party at the address set forth below, or any such address as specified by written notice given to the other party in the manner described herein:

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

If to JEFFERSON: Thomas Jefferson University
1020 Walnut Street, 6th Floor
Philadelphia, PA 19107
Attn: Provost

With a Copy To: Office of University Counsel
Thomas Jefferson University
1020 Walnut Street, 6th Floor
Philadelphia, PA 19107
Attn: University Counsel

If to KLE: Office of the Registrar,
KLE University, JNMC Campus, Belagavi-590 010,
Karnataka, India

With a Copy To: Office of the Chancellor,
KLE Society, Head Office,
College Road, Belagavi-590 001,
Karnataka, India

Notwithstanding the above, any party may also provide notice by personal delivery.

9.9 Cooperation Regarding Claims. The Parties agree to fully cooperate in assisting each other and their duly authorized employees, agents, representatives and attorneys, in investigating, defending or prosecuting incidents involving potential claims or lawsuits arising out of or in connection with this Agreement. This Paragraph shall be without prejudice to the prosecution of any claims which any of the parties may have against each other and shall not require cooperation in the event of such claims.

9.10 Relationship of Parties. Nothing in this Agreement gives rise to a relationship of agency among or between the Parties.

9.11 Compliance with Laws. Each party shall comply with all relevant laws applicable in its jurisdiction, including taxation and privacy laws.

9.12 Misunderstandings. If any misunderstandings arise during the term of this Agreement, the Parties will seek to resolve the matter by discussion between them.

9.13 Reputation. Notwithstanding other clauses in this Agreement, the parties will use their best endeavors not to carry out any action that is likely to damage the reputation of any other party.

9.14 English. This Agreement has been made in English in two identical copies for signature by each of the Parties.

IN WITNESS WHEREOF, this Agreement has been executed by each party's duly authorized representatives as of the Effective Date.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA12639285524752P
Certificate Issued Date	:	04-Oct-2017 02:46 PM
Account Reference	:	NONACC (FI)/ kacrsfl08/ MANGALORE/ KA-DK
Unique Doc. Reference	:	SUBIN-KAKACRSFL0874783702008413P
Purchased by	:	YENEPOYA UNIVERSITY
Description of Document	:	Article 12 Bond
Description	:	M O U
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	YENEPOYA UNIVERSITY
Second Party	:	K L E UNIVERSITY
Stamp Duty Paid By	:	YENEPOYA UNIVERSITY
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

ATHMASHANTHI MULTIPURPOSE CO-OP. SOCIETY LTD. Authorised Signatory BRANCH HEAD O.O. OFFICE MANGALORE D.K.

Please write or type below this line

MEMORANDUM OF UNDERSTANDING

BETWEEN

DEPARTMENT OF ORTHODONTICS AND DENTOFACIAL ORTHOPAEDICS, YENEPOYA DENTAL COLLEGE, YENEPOYA UNIVERSITY AND DEPARTMENT OF ORTHODONTICS AND DENTOFACIAL ORTHOPAEDICS, KLE ACADEMY OF HIGHER EDUCATION, KLE UNIVERSITY, BELGAUM

This Memorandum of Understanding is entered into on this day of 5th October 2017 and executed between Department of Orthodontics and Dentofacial Orthopaedics,

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Yenepoya Dental College, Yenepoya University, Deralakatte, Mangaluru 575018 (hereinafter called First Party) and Department of Orthodontics and Dentofacial Orthopaedics, KLE Academy of Higher Education, KLE University, Belgaum (hereinafter called the Second Party).

The objective of this Memorandum of Understanding is mutual Cooperation between the Department of Orthodontics and Dentofacial Orthopaedics, Yenepoya Dental College, Yenepoya University and KLE Academy of Higher Education, KLE University, Belgaum.

1. To collaborate in academic activities, research and advanced clinical care.
2. Exchange of teachers and academic staff.
3. Exchange of Postgraduate students and Post Doctoral scholars with emphasis on short term stays (2 to 3 months).
4. Exchange of undergraduate students.
5. Assistance for exchange of students in applying for scholarships and internships.
6. Exchange of publications, teaching, research programs and guidelines for clinical practice.
7. Cooperation in scholarly research, exchange of research findings, and publications.
8. Mutual invitations to participate in scholarly seminars, lectures, educational program and consultations.
9. Making local hospitality arrangements for Guest faculty on short term teaching program.
10. Cooperation in education which includes the opportunity of joint excursions, consultations and guidance from the host institution.

Duration

This Memorandum of Understanding will remain in force for 3 years from the date of execution and is subject to renewal for a further period as may be decided by mutual discussion and consent.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Nomination of a representative

Both the parties to this Memorandum of Understanding shall nominate a representative for coordination and supervision of all aspects of cooperation.

Funds for the program

There will be no financial obligations for either party. Any financial or logistical assistance will be given at the discretion of the signatories.

Any changes or additions to this Memorandum of Understanding shall be made effective with mutual agreement by both the parties.

IN WITNESS WHEREOF, THE PARTIES TO THIS memorandum of understanding have set their hands on the day, month and year first above written.

On Behalf of First Party:

Signature

Registrar
Yenepoya University
Mangalore

Dr. G. Shreekumar Menon
Registrar
Yenepoya University
Mangaluru - 575 018

Seal of the University

Dean
Yenepoya Dental College

Witness: Dr. Akhter Husain

Place: Mangalore

Date: 05-10-2017

On Behalf of Second Party:

Signature

Registrar
KLE Academy of Higher Education
KLE University, Belgaum

Registrar
K.L.E. UNIVERSITY
BELAGAVI

Seal of the University

Dean
KLE Institute of Dental Sciences

Witness: Dr. Keluskar K.M.

Place:

Date: 27 NOV 2017

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

MEMORANDUM OF CO-OPERATION

BETWEEN

KLE University,
herein represented by
Dr. V.D.Patil,
Registrar, KLE University
A Deemed University u/s 3 of the UGC Act 1956
vide Government of India Notification No. 9-19/2000-U.3A
Belagavi-590010 (Belgaum), Karnataka, India

AND

Oman Medical College,
Sultanate of Oman

herein represented by
Dr. Yaseen Moosa Malallah Al Lawatia,
Vice Dean,
Oman Medical College, Bousher Campus,
Azaiba, Post Box No.620, Post Code : 130, Muscat Sultate of Oman

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

MEMORANDUM OF COOPERATION
(MOC)

Between

KLE University,
Belagavi (Belgaum), Karnataka State,
India

and

Oman Medical College,
Sultanate of Oman

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

THIS CONFIDENTIALITY AGREEMENT is entered on the ..... th day of .....2016.

BETWEEN:

Oman Medical College is a premier institution in the Sultanate of Oman imparting Doctor of medicine and Bachelor of Pharmacy program (hereinafter referred to as "**OMC**", which expression shall, unless it be repugnant to the context or meaning thereof, to be deemed to include its successors, executors, administration and assignee), being of the FIRST PART;

AND

KLE University- Department of Pharmacy Practice, College of Pharmacy, Belagavi is a University constituent unit (hereinafter referred to as **KLEU**) which expression shall, unless repugnant to the context in which it is used, includes its successor and administration) of the SECOND PART

KLEU and **OMC** individually referred to herein as a 'party' and collectively as the 'parties'.

A: Preamble:

Whereas, Oman medical College (OMC) is a premier academic institution in the Sultanate of Oman imparting doctor of medicine and bachelor of pharmacy programs since 2004 and it is in academic partnership with West Virginia University, US. Both the programs are approved by ministry of higher education and ministry of health, Oman .

Whereas, **KLEU** is a vibrant research institute engaged in the research activity in several contemporary areas of pharmaceutical sciences especially pharmaceutics, pharmacognosy, pharmaceutical chemistry, pharmaceutical biotechnology and pharmacology. It involves in R&D as well as human resource development in a wide range of topics in pharmaceutical sciences and technologies,

Whereas, it is highly desirable to develop multi-disciplinary training and research through involvement and integration of diverse but relevant disciplines through synergy and knowledge sharing, and ensure dissemination to all corners of the country;

Both parties felt that a sustained, synergetic and effective collaboration between OMC and **KLEU** will enhance the strength, and add value to, the efforts of each party;

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

The Parties therefore agree on the objective of creating an institutional framework for enriching scientific endeavors in mutually agreed fields of research and training with the following broad objectives:

B: Broad Objectives:

1. Develop synergetic collaborations in a resource-sharing and knowledge-sharing environment in various areas of science research and technology
2. Develop training programmes and share expertise in training activities through joint organization of events and exchange of faculty and students.
3. Develop collaborations in laboratories and equipments sharing as well as publications, patents (if any).

C: Mode of Operation:

Both parties will provide mutual support for effective implementation of the MOC within then institutional rules and procedures

1. This MOC shall be effective from the date it is signed by the two Parties.
2. Within the broad framework of the MOC, a **KLEU**, and OMC can develop joint research, academic and training program for students and faculty.
3. Any financial commitment for joint activities under this MOC shall be subject to the approval by the competent authority of the respective organization.
4. The activities under this MOC shall be coordinated, monitored and recorded by a Coordination Committee constituted with members nominated by both parties; each organization will appoint a coordinator who will supervise joint activities and maintain records of agreements, work plan and progress.
5. The visitors will be bound by the rules and regulations as well as code of conduct of the host institution.
6. The Internal Coordination Committee will also formulate procedure for exchange of students, faculty and other visitors, in accordance with the rules of the host participating institutions as defined in preamble.
7. The mode and quantum of resource sharing will be decided based on recommendation of the Coordination Committee on a case to case basis, **subject to approval of competent authority as required.**
8. The Coordination Committee will formulate action plans at its meetings and communicate for information and necessary approvals by the concerned authorities.

D: Obligations of the Parties

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

1. In accordance with the clause C-4 above, each party shall nominate a Coordinator and members to the Coordination Committee within 15 days of signing the MOC.
2. Each Party shall provide all necessary support at its disposal and as allowed by its institutional rules, for implementing this MOC effectively.
4. **KLEU** will train & guide students and faculties from **OMC** based on need and availability of resources as per institutional procedure.
3. The Parties shall share knowledge and facilities within the institutional rules of each Party, to:
   (a) Provide access to libraries, archives, research laboratories and other facilities.
   (b) Provide access to Clinical Training in its teaching hospital as mutually agreed.
   (d) Share knowledge/ information and publications/magazines/literature essential for the academic pursuit.
   (g) No financial commitment from either Organization shall be assumed unless a formal approval/acceptance to that effect has been accorded through signed documents by both the Organizations.

E: Duration and Termination

1. This MOC shall remain in force initially for a period of five years, however, where after, it may be **renewed automatically for an extended period unless any of the parties seeks termination in writing.**
2. This MOC may be terminated prior to the expiry of the MOC as indicated above with three months notice and with the written consent of the Heads of the two organizations.
3. After termination of **MOC,** neither of the **Parties** will be responsible for any losses, financial or otherwise, which the other **Party** may suffer. Upon termination or expiry of the **MOC, Parties** are obliged to keep the information confidential, as agreed above.

F: Data Sharing and Intellectual Property Rights

1. No rights in Industrial and/or Intellectual Property (Including without limitation, letters, patent, registered design, software copyrights, trademark and copyright) owned by the **Parties** on the date of signature of this **MOC** and independently developed on their part are hereby granted by the owning **Party** to the other **Party,** nor shall any such rights be deemed to be granted except specified by the owning **Party** in writing. Each Party will have the exclusive ownership and rights on the independently developed intellectual property after the signing of **MOC.**
2. The Intellectual Property Rights in respect of joint project will be decided on case-to-case basis. **Parties** will mutually decide on sharing of required information by way of joint publication in journals and seminars or workshops etc. All publications resulting from the collaboration between the **Parties** will be mentioned in the scientific reports of the either **Party.**

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

4. Each Party shall duly acknowledge the contribution/involvement of the other Party in a given activity in its bulletins/publications/media release/outreach and any other official communication.

5. Every member of both Parties in any activity under the aegis of this MOC shall abide by the prevailing policies of Govt. of India with respect to classified information/data. During the tenure of this MOC and for ***Five years*** thereafter, **Parties** undertake on their behalf and on behalf of their sub-contractors or employees or representatives or associates to maintain strict confidentiality and prevent disclosure thereof to any third party, all the information and data exchanged or generated during the operation of MOC.

G: GENERAL PROVISIONS

1. Neither **Party** shall assign, or in any manner, transfer its interest or any part thereof in this **MOC**, except to wholly owned subsidiaries and agreed explicitly to that effect in writing. This **MOC** shall be binding up on and inure to the benefit of the **Parties** hereto and their respective heirs, personal representatives, successors and assignees; and,

2. This **MOC** constitutes the entire understanding between the **Parties** relating to the subject matter hereof and supersedes and cancels any and all previous or collateral **MOCs**, negotiations, commitments, representations or understandings between the **Parties** with respect to this **MOC**, and the subject matter hereof. If any of the provisions of this **MOC** are determined to be invalid under applicable law, they are, to that extent, deemed omitted. The invalidity of any portion of this **MOC** shall not render any other portion invalid; and,

3. No amendments or modifications of this **MOC** shall be valid unless the same are made in writing by both the **Parties** or their authorized representatives and specifically stating the same to be an amendment of this **MOC**. The modifications/changes shall be effective from the date on which they are made or executed unless otherwise agreed to.

4. This **MOC** is not intended to constitute, create, give effect to, or otherwise recognize a joint venture, partnership, or formal business organization of any kind, and the rights and obligations of the **Parties** shall be only those expressly set forth herein. Nothing in this **MOC** shall be construed to grant either **Party** the right to make commitments of any kind for or on behalf of the other without the other's prior written consent. At all times contemplated herein, and **OMC-KLEU** shall remain independent entities, each responsible for its own employees and students . Each **Party** assumes no responsibility to the other for costs, expenses, risks, and liabilities arising from the efforts of the **Party**.

H: FORCE MAJEURE

Neither **Parties** shall be held responsible for non-fulfillment of their respective obligations under this **MOC** due to the exigency of one or more of the Force Majeure events such as, but not limited to, the acts of War, Flood, Earthquake, Strikes, Lockouts, Epidemic, Riots, Civil commotions etc. provided on the occurrence and cessation of any such event the **Party** affected thereby shall give a notice in writing to the other **Party** within 30 (Thirty) days of such occurrence or cessation. If the Force Majeure conditions continue beyond 6 (six) months, the **Parties** shall jointly decide about the future course of action.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

J: GOVERNING LAWS AND DISPUTES RESOLUTION

1. This **MOC** shall, in all respects, be governed by and construed in all respects in accordance with the laws of the Republic of India and Sultanate of Oman.
2. This **MOC** is to create a framework for enriching scientific endeavors in mutually agreed fields of research through collaboration in developing and implementing new academic and research programmes and faculty and students exchange. Hence any question, doubt or dispute arising out of the interpretation of any term or usage herein or on the implementation and functioning of the various understandings forming a part of this **MOC** shall be resolved by the Heads of the two organizations or their authorized representatives for the purpose mentioned herein by discussions and negotiations based on consensus in the spirit of developing and strengthening the mutual relationships.
3. Any unresolved dispute if any, shall be referred to Sole Arbitrator in accordance with **Arbitration and Conciliation Act, 1996** and rules framed thereof. Arbitrator shall be appointed on mutual consent of Parties. Arbitration shall be conducted at New Delhi in English language. The decision of arbitrator so reached shall be final and binding on both the parties.

K: SEAL OF THE PARTIES

In witness whereof, the **PARTIES** represented by their authorized representatives, set forth their hands on this the day, month and year first stated above, agreed and accepted this **MOC** to be signed in the presence of the following witnesses:

IN WITNESS WHEREOF, each of the parties has caused this agreement to be executed by its duly authorized officer(s) as of date first written above.

Sealed & signed for and on behalf of	Sealed & signed for and on behalf of
KLE University- **College of Pharmacy, Belagavi** **(Belgaum), Karnataka, India**	**Oman Medical College, Muscat, Oman**
Prof. Dr. V.D.Patil, **Registrar,** **KLE University,** **JNMC Campus,** **Belagavi (Belgaum),** **Karnataka, India**	**Dr. Yaseen Moosa Malallah Al Lawatia** Vice Dean, Oman Medical College, Bousher campus Azaiba, Post Box No. 620 Post Code: 130 Muscat Sultate of Oman

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

ATTESTED

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

K.L.E. Society's
SHRI KADASIDDHESHWAR ARTS COLLEGE AND
H. S. KOTAMBRI SCIENCE INSTITUTE
VIDYANAGAR, HUBBALLI-580031 (Karnatak State)
(Re-Accredited with 'A' Grade by NAAC)
Office: 0836-2372097 Website: skahsk.com E-mail:skahsk_hbl@yahoo.co.in

Date: 13-01-2017

MOU

2017-2021(five years)

DEPARTMENT OF CHEMISTRY
S.K.ARTS & H.S.K. SCIENCE INSTITUTE, HUBBALLI.
With
K.L.E. UNIVERSITY'S COLLEGE OF PHARMACY,
VIDYANAGAR, HUBBALLI.

Aims:

The aim of the **MOU** is to set up a frame work to encourage and develop collaboration between the two Institutions in the areas of mutual Interest in Organic compounds as a base of medicine.

Several analytical techniques have been developed and applied for identification & quantification of chemical present in different drug sample.

To build scientific temper amongst the student & staff about research field.

Objectives:

- To conduct Pharmaceutical techniques / programmes for mutual benefits.
- To share literature relating to pharmaceutical area like Books, Journals, Magazines and E-Journals.
- To arrange experimental demonstration of some significant drugs.
- To facilitate information about synthetic herbal drugs, Natural Dyes and Cosmetics.
- To conduct experiments like Separation of Organic mixture (Binary) and Analysis of Organic Compounds.
- Extraction of crude drugs in Indigenous weeds.
- To give idea about instrument such as Gas Chromatography, High Performance Liquid Chromatography (HPLC), Thin Layer Chromatography (TLC).
- Determination of toxic compounds in the drug by using several techniques.
- To give knowledge about chemicals in food such as i) Their preservation ii) Enhancing their appeal iii) Adding Nutritive value in them.

H.O.D
DEPARTMENT OF CHEMISTRY

PRINCIPAL
K.L.E. UNIVERSITY'S COLLEGE OF PHARMACY
HUBBALLI

Principal
S. K. Arts College & H.S.K. Sci Inst.
HUBLI.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

KLE COLLEGE OF PHARMACY
Vidyanagar, HUBBALLI-580 031, Karnataka
A constituent unit of
KLE Academy of Higher Education & Research, Belagavi
(Deemed-to-be-University)
✆ : 0836-2373174, 🖷 : 0836-2371694, 2371048, 🌐 : http://www.klescoph.org, ✉ : principal.klescoph@gmail.com
✉ : principharmhbl@kledeemeduniversity.edu.in

Ref. No. : KLECOPH/MOU/2018-19/1089 Date : 02/01/2019

MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding on 2nd day of January, 2019 between the Shri S.K. Arts & H.S.K. Science Institute, Hubballi.

And

KLE College of Pharmacy, Hubballi which is established 1985 carrying on Teaching, Training and Research, herein called Institute represented by Dr.V.G.Jamakandi, Principal on the other part.

Aims and objectives of the MoU

The aim of MoU is to conduct various cultural activities and develop collaboration between Institutions and following are specific objectives:

- To utilize auditorium for various cultural activities.
- To provide an opportunity and encourage the students to actively participate.

This MoU shall be operation for period of 05 years from the date of signing.

Signed on behalf of
Shri S.K. Arts & H.S.K.
Science Institute, Hubballi.

(Dr.L.D.Horakeri)
Principal.

Signed on behalf of
KLE College of Pharmacy, Hubballi.

(Dr.V.G.Jamakandi)
Principal.

KLE'S COLLEGE OF PHARMACY HUBBALLI 580031

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

MEMORANDUM OF UNDERSTANDING

BETWEEN

MAHATMA GANDHI AYURVED COLLEGE, HOSPITAL AND RESEARCH CENTER

DATTA MEGHE INSTITUTE OF MEDICAL SCIENCES (DU), WARDHA

AND

KLEU'S SHRI B M KANKANAWADI AYURVED MAHAVIDYALAYA,

KLE UNIVERSITY, BELAGAVI, KARNATAKA.

For

Research, Training programs, Collaborative programs on Education, Faculty & Students Exchange

ATTESTED

Memorandum of Understanding between Mahatma Gandhi Ayurved College, Hospital and Research Center, Sawangi Meghe, WardhaWardha of Datta Meghe Institute of Medical Sciences (Deemed University), Wardha and KLEU's Shri B. M. Kankanawadi Ayurved Mahavidyalaya, KLE University, Belagavi, Karnataka

This Memorandum of Understanding(MoU) (this "Understanding") is executed on 8th day of the August month of 2016 by and between the Mahatma Gandhi Ayurved College, Hospital and Research Center, Sawangi Meghe, Wardha of Datta Meghe Institute of Medical Sciences (Deemed University), established by u/s 3 of the UGC Act, 1956 having its registered offices at JNMC Campus, Sawangi, Meghe, Wardha – 442001, Maharashtra (here in after referred to as **"MGAC of DMIMS(DU)"** which expression shall, unless repugnant to the subject or context thereof, be deemed to include and mean to its nominees, successors and permitted substitutes or assigns) of the ONE PART

With

KLEU's Shri B. M. Kankanawadi Ayurved Mahavidyalaya, KLE University, Shahapur, Belagavi, Karnataka, 590003, a premier institute of University having its place of activity in Belagavi, (here after referred as **'KLEU SBMKAM'**, which expression shall, unless repugnant to the subject or thereof, be deemed to include and mean to its nominees, successors and permitted substitutes or assigns) on another PART either or both of which may be referred to as a "party" or the "Parties" respectively as the context demands.

WHERE AS

A. The **DMIMS (DU)** and **KLEU SBMKAM** desire to collaborate in the field of intra and interdisciplinary research, Ayurvedic Medical Education, Panchakarma Ergonometrics, Drug development, Faculty and student exchange program for the mutual benefit by utilizing the expertise and infrastructure existing in both institutions.

B. Based on the strengths of the MGAC of DMIMS (DU) and **KLEU SBMKAM**, the MGAC of DMIMS (DU) is desirous of collaborating with **KLEU SBMKAM**, which would provide education/ research program/ faculty, student exchange/ academic programs.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

MOU is to establish hereby a formal understanding of cooperation and friendship which is intended to have further the academic objectives of each institution and to promote better understanding between the faculty and students of MGAC of DMIMS (DU) and the faculty and students of **KLEU SBMKAM.**

Background:

Datta Meghe Institute of Medical Sciences is a Public Trust registered under Bombay Public Trust Act, 1950. It was previously known as Smt. Radhikabai Meghe Memorial Medical Trust reaccredited 'A' Grade by NAAC and placed in Category 'A' by MHRD (Gol). Mahatma Gandhi Ayurved College, Hospital and Research Center, Sawangi Meghe established in 2007 and is a constituent Institution of DMIMS (DU). It has recognized by CCIM 8 PG Departments with 38 seats and 60 UG seats intake. The New PG courses are under LOP from CCIM. The MGAC has good infrastructure for teaching and research with innovative ideology staff.

KLE University is Declared as Deemed-to-be-University u/s 3 of the UGC Act, 1956 vide Government of India Notification No.F.9.19/2000-U.3 (A), Re-accredited (2^{nd} cycle) as 'A' Grade by NAAC and placed in Category 'A' by MHRD (Gol). KLEU's Ayurveda Hospital & Medical Research Center has been accredited by NABH, the first Ayurvedic institute to get NABH accreditation in Karnataka. Shri BMK Ayurveda Mahavidyalaya is established in 1933 and is a constituent Institution of KLEU. It has been recognized by CCIM for 11 PG departments with 65 seats and 100 UG seats. It is also conducting PhD program in Ayurveda and Interdisciplinary areas of KLEU. PG certificate programs on various domains like Vajeekarana, Ksharasutra, Panchakarma, Herbal Drug Research, Ayurgenomics etc. It has good infrastructure for teaching as well has research. Its Central Research facility has been approved as DTL for ASU drugs by AYUSH, Govt. of Karnataka. DAME has been recognized by CCIm as Regional Teacher Training center.

Under this Memorandum of Understanding, the two institutions will proceed to implement the following endeavors and exchanges of materials and personnel.

ARTICLE I: OBJECTIVE

The Parties, subject to the terms of this Memorandum of Understanding and the laws, rules, regulations and national policies from time to time in force, agree to strengthen, promote and develop co-operations in the field of Indian system of medicine (Ayurveda) and Inter Disciplinary Medicine between the two Institutions.

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

ARTICLE II: AREAS OF COOPERATION

Cooperation shall be carried out, subject to availability of funds and the approval of the competent authority of MGAC of DMIMS (DU) and **KLEU SBMKAM**, through such activities or programs as:

Exchange programs:

- Teachers
- PG scholars

Faculty and PG & UG students will be exchanged from both Universities every year for different programs like Workshops, Guest lectures, short time training courses, Seminars, short term research programs and project works etc. as agreed by both Universities from time to time.

Utilization of research facilities, Joint Research activities

- Faculty and students of both Universities will be allowed, with prior permission, to utilize the research facilities of the Universities by prescribed nominal fee. Both institutions will facilitate the students & faculty by providing access to facilities, guidance of concerned Faculty and Research staff.
- Both will promote and facilitate inter-institutional, interdisciplinary research and collaborative research projects by faculty and students of the institutions. Short term research projects, summer research projects etc will be allowed.

Multi-centric studies

To provide evidence based clinical research Multi-center clinical studies will be taken up. Faculty of both Universities will be allowed to projects on Collaborative multi-centric studies. Various laboratory facilities, expertise of faculty will be allowed for it.

Continuation of PG/PhD thesis activities

Students of both Universities will be allowed to have extension of their dissertation/ thesis activities utilizing facilities and expertise in these institutions.

Online meetings/On line Guest lectures

Innovative methods, Information Communication & technology will be used to have better interaction among faculty and students of Universities through Online guest lectures, group interactions through Skype etc. will be organized.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Knowledge sharing

Both Universities will share the knowledge through various academic activities, interaction of faculty, students, online discussions etc. They will allow partner Institution to utilize the databases, educational material, case presentations, practical manuals, dissertations etc.

Curriculum development

- Both universities will work in this area of Curriculum development by organizing workshops, brain storming sessions, skill development programs, CME programs collaboratively. They will work to create better teaching methodology, evaluation methods, feedback methods, multimedia utilization in teaching, and simulated practical for Ayurveda.
- Participation in seminars and academic developments
- Planning joint International Conferences and Workshops,
- Planning research publications in the journals published by each University
- Implementation of joint educational programs in each University within the identified areas
- Exchange of academic materials and other information
- The terms of such mutual cooperation and necessary budget for each specific program and activity that is implemented under the terms of this MoU. Each university will designate a Liaison Officer to develop and coordinate specific activities or programs.

ARTICLE III: FINANCIAL ARRANGEMENTS

- The financial arrangements to cover expenses for the identified research activities undertaken within the framework of this Memorandum of Understanding shall be mutually agreed upon by both the Parties on a case-by-case basis subject to availability of funds.

ARTICLE IV: PROTECTION OF INTELLECTUAL PROPERTY RIGHTS

(a) The protection of intellectual property rights shall be enforced in conformity with the national laws, rules and regulations.

(b) Notwithstanding anything in paragraph (a) above, the intellectual property rights in respect of any technological development, and any products and services development, carried out:

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

(i) Jointly by the parties or research results obtained through the joint activity effort by the Parties, shall be jointly owned by the Parties in accordance with the terms to be mutually agreed upon; and

(ii) Solely and separately by the Party or the research results obtained through the sole and separate effort of the Party, shall be solely owned by the Party concerned.

(iii) The terms and conditions in the execution of the research projects shall be decided on case to case basis.

ARTICLE V: CONFIDENTIALITY

A. Each Party undertakes to observe the confidentiality and secrecy of documents, information and other data received from, or supplied to, the other Party during the period of the implementation of this Memorandum of Understanding or any other agreements made pursuant to this Memorandum of Understanding;

B. Both Parties agree that the provisions of this Article shall continue to be binding between the Parties notwithstanding the termination of this Memorandum of Understanding.

ARTICLE VI: SETTLEMENT OF DISPUTES

Any difference or dispute between the Parties concerning the interpretation and/or implementation and/or application of any of the provision of this Memorandum of Understanding shall be settled amicably through mutual consultation and/or negotiation between the Parties. In case, the dispute occurred between both the parties and if the same is not resolved through negotiation or by adopting amicable measures, in that case the matter will be settled through Arbitration and the Arbitrator will be appointed with the mutual consent of both the parties.

ARTICLE VII: ENTRY INTO FORCE, DURATION AND TERMINATION

This understanding shall come into force and take effect from the date first written above and shall be valid for a period of FIVE (5) YEARS and may be renewed thereafter by the parties upon mutual consent.

This understanding may be terminated by either party by providing 90 (ninety) days written notice to the other party before the beginning of academic year, and the termination would be effective at the end of the notice period.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

And the termination of the Understanding shall be on the understanding that students/ faculty who have already enrolled in any of the courses / research programs as at the time of termination shall remain entitled to complete their respective courses/ research programs and be eligible to appear assessment conducted by the MGAC of DMIMS (DU) and **KLEU SBMKAM** conduced to obtain an award. The obligation of the parties shall continue to be in force during such period, notwithstanding any termination of the Understanding.

Now this MOU Witnesses as follows the Roles and Responsibilities of Either Party

a) **Common Responsibilities**

- Both institutes have to provide minimal accommodation for students/ faculty of other institute in their institute on nominal costs.
- Students/ faculty have to pay the prescribed fee for the facilities they have used.
- Universities have to facilitate for easy exchange programs and collaborative work. Administrative hurdles to be cleared at higher level by clear transparent methodology.
- Periodic meeting of co-ordinators should be arranged to have collaboration and co-operation among faculty of two universities.
- Both parties understand that all financial arrangements
- will have to be negotiated and will depend on the availability of funds.

b) **Roles & Responsibilities of KLE University and Shri BMK Ayurveda Mahavidyalya, Belagavi and MGAC of DMIMS (DU)**

- MGAC of DMIMS (DU) and **KLEU SBMKAM** will facilitate for collaborative activities in teaching, education and research. Both will arrange facilities for conducting activities including in-house and visiting members from academic institutes.
- MGAC of DMIMS (DU) and **KLEU SBMKAM** shall also arrange to appoint a Coordinator who shall be available at the centre where the programs being offered, in order to facilitate proper coordination between the MGAC of DMIMS (DU) and KLEU SBMKAM covering all aspects relating to conduct of training, research and all other activities coming within the ambit of conducting such programs.
- All students will be governed by the academic regulation of respective parent institutions. i.e. MGAC of DMIMS (DU) or KLEU SBMKAM, as specific to the course or program offered, which shall be provided by the MGAC of DMIMS (DU) or KLEU SBMKAM to the students at the start of the course/ program.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

- MGAC of DMIMS (DU) and KLEU SBMKAM shall maintain both in physical as well as in an electronic format (wherever possible or available) the details (including academic records) of all students/ faculty enrolled for the programs, and shall provide the same to MGAC of DMIMS (DU) and KLEU SBMKAM on request.
- KLEU SBMKAM will allow to utilize its facilities for education, teaching and research collaboration, where in the MGAC of DMIMS (DU) will allow the all facilities of the research available at MGAC premises and CRL of DMIMS. From both DMIMS (DU) and KLEU SBMKAM faculty will provide guidance time to time.

c) Miscellaneous:

- A coordination committee consisting of the following will monitor the academic and research programs and all related operational activities.

1. Vice Chancellor – DIMIMS (DU)
2. Vice Chancellor – KLEU (Chairman)
3. Registrar – DIMIMS (DU)
4. Registrar, KLE University
5. Two Nominees of DIMIMS (DU)- Members
6. Two nominees of KLEU - Members

d) Coordinators of each center

- At DMIMS (DU), the Registrar will oversee the implementation of the Memorandum of Understanding.
- At KLEU, Principal, Shri BMK Ayurveda Mahavidyalaya will oversee the implementation of the Memorandum of Understanding.

Any variation or amendment or addition of / to this Understanding shall be mutually agreed to in writing and executed by or on behalf of each of the parties, the MGAC of DMIMS (DU) and KLEU SBMKAM.

This Understanding represents the entire understanding as to the subject matter hereof and supersedes any prior understanding between the parties on the subjects matter hereof.

In witness whereof, the parties hereto have executed this understanding as of the date first above mentioned.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

In witness whereof, the parties hereto have executed this understanding as of the date first above mentioned.

Sealed & signed for and on behalf of

Principal
K.L.E.University's Shri B.M.Kankanawadi
Ayurveda Mahavidyalaya

PRINCIPAL
K.L.E. University's
Shri B. M. Kankanwadi
Ayurved Mahavidyalaya
Shahapur-BELAGAVI-03

Registrar,
KLE University,
Belguam

Registrar
K.L.E. UNIVERSITY
BELAGAVI

Sealed & signed for and on behalf of

Dean
College of Ayurveda
M.G.A.C.H.& R.Centre
SALOD (H.), WARDHA

PRINCIPAL

M. G. Salod (H) Wardha (M.S.)

Registrar
DMIMS(DU) Wardha

REGISTRAR
DMIMS (DU)
Sawangi (M.) Wardh-

Dr Meena S Deogade
Dr. Meena Deogade
MD Guide
Department of Dravyaguna
MGACH & RC,
Salod (H), Wardha

Dr. K. Siva Rama Prasad,
M.A, (Jyo) M.D, (Ay) (Osm)
H. O. D.
Department of Panchkarma
M. G. A. C. H. & R. C.
Salod (H), Wardha

Vice Dean (PG)

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Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
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SCHEDULE "A"

PROTOCOL

TITLE:

"A randomized, multi center, open label, two-treatment, two-period, two-sequence, multiple dose, crossover, pivotal steady state bioequivalence study of Everolimus 10 mg tablet, Manufactured by Teva Pharmaceuticals - Pliva Croatia Ltd., Prilaz baruna Filipovica 25, 10000 Zagreb Croatia vs. Afinitor®(Everolimus) 10 mg tablet of Novartis Pharmaceuticals Corporation, USA in advanced renal cell carcinoma (RCC) patients under fasting conditions."

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Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

addition to the Review Period in the event Sponsor so requests to enable Sponsor to secure patent or other proprietary protection ("Delay Period"). The Principal Investigator shall keep the proposed publication confidential until the Review Period concludes and, if elected by Sponsor, the Delay Period has expired. The Principal Investigator understands that, with respect to any proposed publication or presentation, good faith consideration will be given to Sponsor's comments with due regard for Sponsor's commercial and proprietary interests and at Sponsor's request, any Confidential Information will be deleted from such article or presentation. Notwithstanding the foregoing, unless otherwise permitted in writing by Sponsor / Veeda, the Principal Investigator shall not be permitted to publish Confidential Information. For the purposes of this provision, Confidential Information shall not include the results of the Study. Institution shall have no right to publish or present pursuant to this Agreement.

6.2 Multi-Center Studies. It is agreed and understood by Principal Investigator that Study is a multi-center study and an independent, joint publication is anticipated to be authored by investigators in the multi-center study, including Principal Investigator. Therefore, Principal Investigator agrees not to publish or present the results or any information derived from the study without prior approval from the sponsor.

7. TERM & TERMINATION

7.1 Termination by Sponsor/Veeda. Veeda or Sponsor may terminate this Agreement (i) immediately if the Study is terminated by regulatory authorities or in the interest of public health; or (ii) without cause at any time during the Term of this agreement on thirty (30) days prior written notice to Institution and Principal Investigator.

7.2 Effect of Termination. Termination or expiration of this Agreement shall not affect any rights or obligations which have accrued prior thereto. In the event of termination of this Agreement, Principal Investigator and Institution shall complete the Study for then-enrolled Subjects where required by accepted medical practice.

8. INDEMNIFICATION

8.1 Sponsor Indemnification. Sponsor shall indemnify Principal Investigator and Institution, (including Principal Investigator's and Institution's affiliates, contractors, agents, fellows, employees and servants) (collectively "Investigator Indemnitees") for any damages and liabilities, including reasonable attorney's fees incurred by Investigator Indemnitees as a result of any claim or lawsuit against them arising directly out of the performance of the Study drug pursuant to the Protocol ("Claims"); provided however Sponsor will not be responsible for and assumes no liability for any loss, claims, and/or demands to the extent arising from any of the following: the negligence or willful misconduct of an Investigator Indemnitees or any Investigator Indemnitees failure to adhere to (i) the terms of the Protocol and/or this Agreement including any amendments thereto; or (ii) applicable federal, provincial, or local laws; or (iii) the written instructions relative to the use of the Study Product.

8.2 Institution Indemnification. Institution shall indemnify, defend and hold harmless Sponsor and Veeda (including Sponsor's and Veeda's affiliates, contractors, agents, fellows, employees and servants) (collectively "Sponsor Indemnitees") from any and all losses, injuries, harm, costs or expenses, including without limitation, reasonable attorney's fees, incurred by Sponsor Indemnitees that arise from the negligence or willful misconduct by Investigator Indemnitees (as defined above in clause 8.1). Principal Investigator and Institution shall carry professional

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Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Indemnity Insurance and such other insurance required to indemnify under this clause, for the duration of this Agreement and for a reasonable period (which is not less than 1 year) after termination or expiration thereof. Principal Investigator and Institution shall provide the copy of insurance as and when required by Veeda or Sponsor.

8.3 Obligation to Notify. The foregoing agreement to indemnify is conditioned upon the obligation of the Indemnitee to:

(i) advise indemnifying party of any claim or lawsuit, in writing, within fifteen (15) days after Indemnitee has received notice of said claim or lawsuit, or within such other time frame so that indemnifying party's ability and rights to defend or settle such claim or lawsuit, as determined in Sponsor's sole discretion, are not prejudiced;

(ii) Assist indemnifying party and its representatives in the investigation and defense of any lawsuit and/or claim for which indemnification is provided; and

(iii) Not compromise or otherwise settle any such claim or lawsuit on behalf of indemnifying party without indemnifying party prior written consent.

8.4 Serious Adverse Event Reimbursement. Not withstanding any other terms contained in this Agreement, Sponsor will reimburse the Institution for any reasonable, necessary and properly documented medical expenses directly related to a Subject's Serious Adverse Event (as the term is defined in the Protocol, also referred to as an "SAE") that is because of the administration of the Study drug in accordance with the Protocol. Sponsor shall not be responsible for the reimbursement of SAE costs that are the result of a) the negligence, misconduct, lack of adherence to applicable law or breach of this Agreement by any agent/vendor or employee of the Principal Investigator or Institution

9. DEBARMENT

9.1 Debarment and Exclusion. Institution and Principal Investigator certify that they are not debarred or restricted from conducting clinical research and will not use in any capacity the services of any person debarred or restricted from conducting clinical research under applicable law with respect to services to be performed under this Agreement. Institution and Principal Investigator also certify that they are not excluded from any governmental health care program. Institution and Principal Investigator further certify that they are not subject to a government mandated corporate integrity agreement and has not violated any applicable anti-kickback or false claims laws or regulations. During the term of this Agreement and for three years after its termination, Principal Investigator and Institution will notify Veeda promptly in writing to the extent possible within two (2) business days if either of these certifications needs to be amended in light of new information or if Institution and/or Principal Investigator becomes aware of any material issues related to the medical licensure of any associated researchers. Institution and Principal Investigator will cooperate with Veeda and/or Sponsor regarding any responsive action necessary.

10. NOTICE

10.1 Notices. Except as otherwise provided herein, all notices, consents, or approvals required under this Agreement will be in writing delivered personally or delivered by facsimile, electronic mail, first class mail, or by a commercial overnight courier that guarantees next day delivery when

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Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

possible (in the case of notice by facsimile or electronic mail, a confirmation shall thereafter be transmitted to the addressee by first class mail or by a commercial overnight courier that guarantees next day delivery), addressed as follows:

If to Veeda:
Veeda Clinical Research Pvt. Ltd.
Address: Veeda Clinical Research Private Ltd. **Veeda House** "Vedant Complex" 4th Floor, Next to YMCA Club, Above Shivalik Hyundai Showroom, S. G. Highway, Vejalpur – 380051, Ahmedabad, Gujarat-INDIA
Attention: Dr. E. Venu Madhav
Phone: +91 79 30013000
Fax: +91 79 30013010

If to Principle Investigator:

Name	: Dr Maheshkumar V kalloli
Address	: KLES Dr. Prabhakar Kore Hospital & MRC, Nehru nagar, Belagavi 59010, Karnataka
Phone	: 09945014996
Fax	**: 0831-2493099**

If to Institution:

Name	: Dr. M. V. Jali
Designation	: MD & CE
Address	: KLES Dr. Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi 59010, Karnataka
Phone	: 0831 2470400
Fax	: 0831 2493099

11. Miscellaneous

11.1 Binding Obligations. Principal Investigator and Institution represent and certify that the terms of this Agreement are valid and binding obligations are not inconsistent with any other contractual and/or legal obligations they may have, or with the policies of company with which it is associated.

11.2 Publicity. To the extent permitted by law or regulation, no party shall disclose the existence or terms of this Agreement nor use the name of any other party, nor the names of other party's employees, in any publicity, advertising or announcement without the consenting party's prior written approval.

11.3 Independent Contractor. Principal Investigator's and Institution's relationship to Veeda and Sponsor under this Agreement is that of an independent contractor, Principal Investigator and Institution have no authority to bind or act on behalf of Veeda or Sponsor.

11.4 Assignment. Principal Investigator and Institution may not assign this Agreement to any other party, nor may it subcontract any of its services hereunder, without Veeda's and Sponsor's prior written consent. Any attempted assignment without Veeda's and Sponsor's prior written consent shall be null and void and shall, for the avoidance of doubt, constitute a material breach of this Agreement.

ATTESTED
Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

11.5 Sub-investigators. Principal Investigator and Institution hereby agree that as to any individuals identified on the applicable FDA Form 1572 or Investigator information and Agreement Form as sub-investigators for the Study, Principal Investigator and Institution shall ensure such individuals' compliance with the terms and conditions hereof.

11.6 Entire Agreement. This Agreement contains the entire understanding of the parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. This Agreement may be modified only by written agreement signed by the parties.

11.7 Governing Law. This agreement shall be governed by and interpreted in accordance with the Indian laws. Any disputes arising in connection with this Agreement shall be resolved through arbitration. The arbitrator shall be mutually decided among the parties. The arbitration shall be conducted under the Arbitration and Conciliation Act of 1996. The place of arbitration shall be Ahmedabad. Each party shall bear its own costs of the arbitration unless the arbitrator otherwise directs.

11.8 Survival. Notwithstanding termination of this Agreement for any reason, rights and obligations which by the terms of this Agreement survive termination thereof, shall remain in full force and effect including but not limited to Section 4 (Confidential Information), Section 5 (Intellectual Property) and Section 6 (Publication).

11.9 Severability. If any of the provisions or a portion of any provision, of this Agreement is held unenforceable or invalid by a court of competent jurisdiction, the validity and enforceability of the other portions of any such provision and/or the remaining provisions shall not be affected thereby.

11.10Conflict with Protocol. In the event of a conflict between the terms and conditions of this Agreement and those of the Protocol, the Protocol shall control in matters of science and the Agreement shall control in all other matters.

11.11Headings: Any headings, titles and captions used in this Agreement are for convenience and reference only. They do not purport to, and shall not be deemed to, limit or extend the scope or intent of the sections to which they pertain.

11.12 Veeda will assist the site to facilitate the execution of the study protocol with the procurement of the infusion pump and train the study staff on its functional operation for accurate dispensing of the study drug .

11.13 PI/Institute will be responsible for facilitating the availability of site level Phlebotomist dedicated for this study throughout the study duration.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date written above.

For, Veeda Clinical Research Pvt. Ltd.

Name: Dr. E. Venu Madhav
Title: COO

Date: 23 Jun 2016

For, Principle Investigator

Name: Dr. Mahesh Kumar Kalloli
Title: Principle Investigator

Date: 25 JUN 2016

For, Institute

Name: Dr. M. V. Jali
Title: MD & CE

Date: 30/6/2016

Witness:

Name: Dr Deepak Tumari
Contact Details: 9964403640

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

SCHEDULE "B"

STUDY BUDGET

All defined terms shall have the same meaning attributed to them in the Agreement unless otherwise defined herein.

Institution/Principal Investigator will be paid based upon the number of Subjects properly enrolled and the visits completed by the Subjects as legibly, completely and accurately recorded in the CRFs.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
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a) **Trial Budget:**

15-VIN-284	Screening	Period I						Period II						EOS	Total
Dr. Lokesh K N	**Visit 01**	**Day 0 & Day 01**	**Day 06**	**Day 11**	**Day 12**	**Day 13**	**Day 14**	**Day 15**	**Day 20**	**Day 25**	**Day 26**	**Day 27**	**Day 28**	**Day 29**	
Investigator Grant	5000	5000	4000	4000	4000	4000	7000	4000	4000	4000	4000	4000	7000	6000	66,000
Study Coordinator Grant	1000	500	500	500	500	500	2000	500	500	500	500	500	2000	1000	11,000
Investigations															
ECG	500													500	1,000
X-Ray	500														500
Local Lab: Bio Chemistry & Hematology								2500							2,500
Patient Housing		2000		2000	2000	2000	2000	2000		2000	2000	2000	2000	2000	22,000
Nursing Charges & Phlebotomy Charges	500	500	500	500	700	700	3000	500	500	500	700	700	3000	500	12,800
Admin Charge	200	200	200	200	200	200	200	200	200	200	200	200	200	200	2,800
Institutional Overhead (20 %)	1200	1100	900	900	900	900	1800	900	900	900	900	900	1800	1400	15,400
Patient Compensation	1000	2000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	2000	1000	16,000
Total Grant															**1,50,000**

Above budget is including all applicable taxes.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

ATTESTED

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

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

सत्यमेव जयते

Certificate No.	:	IN-KA89466949184183P
Certificate Issued Date	:	22-Feb-2017 12:27 PM
Account Reference	:	NONACC (FI)/ kaksfcl08/ BELGAUM27/ KA-BL
Unique Doc. Reference	:	SUBIN-KAKAKSFCL08278601196012 11P
Purchased by	:	KLES DR PRABHAKAR KORE HOSPITAL AND MRC BELAGAVI
Description of Document	:	Article 12 Bond
Description	:	AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	KLES DR PRABHAKAR KORE HOSPITAL AND MRC BELAGAVI
Second Party	:	ROTARY CLUB OF BELGAUM ROTARY DIST 3170 NBC MUMBAI
Stamp Duty Paid By	:	KLES DR PRABHAKAR KORE HOSPITAL AND MRC BELAGAVI
Stamp Duty Amount(Rs.)	:	200 (Two Hundred only)

Authorised Signatures
Aadhar Multi-Purpose Souhard Sahakari
Nyt. Shivabasav Nagar, BELGAVI

Please write or type below this line

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

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.

MEMORANDUM OF UNDERSTANDING

DATED THIS ____ DAY OF ____, 2017

BETWEEN

KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE, BELAGAVI

AND

ROTARY CLUB OF BELGAUM, BELAGAVI (ROTARY DISTRICT 3170)

AND

NATIONAL BURNS CENTRE (NBC) & ROTARY CLUB OF BOMBAY NORTH (RCBN)

THIS MEMORANDUM OF UNDERSTANDING is made and confirmed into at Belagavi on this _____day of_____ 2017.

BETWEEN

KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavihaving their office Nehru Nagar, Belagavi, represented by their duly authorised representative, Medical Director & Chief Executive, (hereinafter referred to as "KLESH");

AND

Rotary Club of Belgaum, Belagavi, (Rotary District 3170) an unregistered association of persons, represented by its Club President (hereinafter referred to as "RCB")

AND

(i) **National Burns Centre** a public charitable society registered under the Bombay Trusts Act, and having their office at National Burns Centre, Sector 13, Plot No.1, Samarth Ramdas Swami Marg, Airoli, Navi Mumbai- 400708 represented by their duly authorised representative, Dr. Sunil Keswani, (hereinafter referred to as "NBC"); and (ii) **Rotary Club of Bombay North,** an unregistered association of persons, represented by its Club President (hereinafter referred to as "RCBN") which together operate the RCBN Skin Bank as an unregistered association (hereinafter referred to as "RN") (which expression shall unless it be repugnant to the context or meaning thereof be deemed to mean and include the members of the Governing Council / Board of RN, their successors or successor the survivors or survivor of them and the heirs, executors and administrators of the last surviving member and his / her / assigns) of the First Part;

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Medical Director & Chief Executive
KLE... Hospital
Med... AGAVI

KLESH, RCB and RN are hereinafter collectively called the 'Parties",

AND WHEREAS KLESH has a 11 Bedded Burns Care facility serving over 100 Burns victims annually and has the necessary infrastructure and expertise in treating victims of Burns.

AND WHEREAS the RCB is a charitable organization bringing together business and professional leaders to provide philanthropic and humanitarian service, encourage high ethical standards in all vocations and help build goodwill and peace and is a part of the Rotary International.

WHEREAS RCBN has set up a skin bank known as RCBN Skin Bank at NBC situated at Plot No 1, Sector 13, Samarth Ramdas Swami Marg, Airoli, Navi Mumbai 400 708 in collaboration and with the guidance of Euro Skin Bank for promoting and spreading awareness of skin donation and is in the process of setting up skin banks in various places in India.

AND WHEREAS the RCB desires to set the Skin Bank/Skin Collection Centre through KLESH as part of its Community Service Project (CSP) and desires to participate in the Project.

AND WHEREAS KLES Hospital with the objective to reduce the intensity of suffering and the number of deaths due to burns, intends to participate in setting up of a skin bank within the city of Belagavi with the assistance from RCBN and NBC, in the space provided by KLESH within the KLES Dr. Prabhakar Kore Hospital premises. The purpose of such a skin bank/ skin collection centre as a part of "the Project" shall be harvesting of cadaver skin on call, processing, preservation of the skin and dispensing the skin to the burn victims being treated within, nearby Hospitals and elsewhere at a reasonable cost without any discrimination to any group, caste, colour, creed or place and to make available this service to the public at large as a HUMANITARIAN SERVICE.

AND WHEREAS the Parties have willingly agreed to participate in the collective Project and provide all resources and assistance to establish a skin bank to make it a success.

NOW THIS MEMORANDUM OF UNDERSTANDING WITNESSETH AND IT IS HEREBY AGREED AND UNDERSTOOD BY AND BETWEEN THE PARTIES HERE TO AS FOLLOWS:

1. The Project shall be implemented in accordance with the technical guidance from NBC/RCBN Skin Bank and the funds of $ 31500 for the implementation of the Project will be provided by RCB &through The Rotary Foundation. The project will be implemented as Global grant project no. 1746862 registered with Rotary Foundation and after the necessary sanction and disbursal of funds from the Rotary Foundation.
2. The Skin Bank/ Skin Collection Centre shall have the plaque in the following format

KLE ROTARY SKIN BANK/ SKIN COLLECTION CENTRE
in technical collaboration with RCBN Skin Bank and NBC
financed by Rotary Club of Belgaum under the Global Grants of the Rotary Foundation

3. The Parties have agreed to cooperate with each other in collectively executing the Project and to achieve the objectives of the Project and for this purpose the Parties shall constitute a joint committee comprising of three nominees of KLESH, one nominee of NBC and three nominees of RCB (hereinafter called the "Supervising Committee"). The Supervising Committee shall be responsible for taking all decisions relating to the Project. The Supervising Committee meetings should be conducted as and when required, but at least once every month to review the progress of the Project and to take necessary steps for the smooth establishment and functioning of a Skin Bank and reports of all aspects of its activities shall be recorded in the minutes of such meetings and provided to the Parties.

NATIONAL BURNS CENTRE

ATTESTED

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

Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

4. The Supervising Committee will supervise the setting up of the Skin Bank /Skin Collection Centre and monitor the functioning of Skin bank/Skin Collection Centre thereafter, in consultation with and under the supervision and guidance of RN.

5. The roles and responsibilities of the parties to this MOU are defined as follows:

5.1. KLESH: HOST

5.1.1. KLESHshall be responsible to maintain and operate a state of the art Skin Bank /Skin Collection Centre as per international guidelines with guidance from NBC/RCBN Skin Bank and maintain adequate records and report statistics of Beneficiaries periodically to RCB and RCBN.

5.1.2. KLESH shall provide and maintain a dedicated air-conditioned clean room space of about 1000 square feet with adequate lighting, furniture and partitions within KLES Hospital Premises.

5.1.3. KLESH shall procure all necessary clearances, approvals and/or permissions from the local, municipal, civil, government departments such as Tissue Bank License for the purpose of legitimate execution and functioning of Skin Bank/Skin Collection Centre.

5.1.4. KLESH shall maintain the dedicated skin harvest vehicle provided by RCB and will ensure that it shall be available 24 hours a day and for 365 days and provide alternative vehicle in case of its break down.

5.1.5. KLESH shall be responsible for recruitment, training and monitoring of dedicated human resources required for harvesting, processing, preservation, dispensing the cadaver skin and also the remuneration payable to the human resources including their salaries, fees, ESI, Provident Fund Contribution, Gratuity and all other statutory dues. The staff appointed shall be of KLESH only and they shall not have any relation or privity of contract with RCB/RCBN/NB.

5.1.6. KLESH shall ensure uninterrupted supply of all essential consumables, electricity, water, gas, telephone and anything else that may be required for the smooth functioning of Skin Bank.

5.1.7. KLESH will provide all their expertise and assistance to RCB in procuring all the necessary equipment as well as consumables.

5.1.8. KLESH shall maintain and keep all equipment provided by RCB for the Project in good working condition and shall enter into AMC contracts by paying charges for the maintenance of the equipment at the Skin Bank.

5.1.9. KLESH surplus to be reinvested for maintenance shall reinstate any equipment owned and provided by RCB for the Skin Bank after the expiry of its useful life or break down after its warranty period.

5.1.10. KLESH shall maintain a daily log record book and registries wherein, it shall record the calls for donation, requests, registered volunteers, details of skin donations, size of skin harvested, size of skin in store, details of beneficiaries in such format and periodically as may be mutually agreed amongst the Parties. Upon request, one copy of this shall be sent to RCB and the Donor every month for their records.

NATIONAL BURNS CENTRE

ATTESTED

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

Prof Dr V.A. KOTTIVALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

5.1.11. KLESH shall dispense skin from its Skin Collection Center at a very nominal fee on Non-Profit basis to make it affordable to all segments of public. KLES Rotary Skin Bank shall set up a separate Bank Account to secure the funds raised from dispensing of skin and donations received towards the Project. Such funds shall be exclusively used towards up keeping, expansion and promoting the benefits of the Skin Bank.

5.1.12. KLESH shall designate a Faculty member of Department of Plastic Surgery, as an In-Charge of the Skin Bank to ensure the smooth functioning of Skin Bankat any given point in time.

5.1.13. KLESHshall manage day to day activities of the centre.

5.1.14. KLESH along with RCB shall be responsible for creating awareness and creating publicity for the Skin Bank and the importance of skin donation in consultation with RCBN Skin Bank.

5.1.15. All the responsibilities of KLES Rotary Skin Bank under this MOU shall be at the expense of KLES Rotary Skin Bank Account.

5.2. RCB : ROTARY COMMUNITY SERVICE

5.2.1. RCB shall procure and deliver the Capital equipment and instruments as required for a full-fledged Skin Bank (hereinafter referred to as the "said equipment" and more particularly listed in Schedule 1 hereto). RCB shall take into account the recommendations made by KLES & NBC RN in respect of the equipment to be procured.

5.2.2. RCB shall be responsible for the installation of the said equipment as prescribed by NBC and RCBN Skin bank from time to time.

5.2.3. RCB shall provide a dedicated skin harvest vehicle spacious enough to harvest skin from cadaver on board and shall ensure that at all times the Skin Harvest Vehicle has the necessary capital instrumentation.

5.2.4. RCB shall be entitled to monitor the functioning of the Skin Bank and check the records, reports, impact on beneficiaries as well as the maintenance of the said equipment.

5.2.5. RCB shall support KLESH in creating public awareness about skin donation and promoting the usage of cadaver skin in burn care in the region using its Rotary Network.

5.3. RCBN & NBC: GUIDE

5.3.1. RN shall provide all the necessary guidance required during the establishment of the Skin Bank.

5.3.2. RCBN Skin Bank shall provide Standard Operating Procedures (SOPs) and Protocols to be adhered to by the Skin Bank as per International Guidelines.

5.3.3. RN shall train the human resources recruited and designated by KLESH to operate the Skin Bank.

NATIONAL BURNS CENTRE

ATTESTED

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

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

(5)

5.3.4. RN shall conduct periodic audits of the Skin Bank twice a year for the first two years and carry out an annual audit thereafter every year. The result of the audits shall be conveyed in a timely manner to the other parties. The expenses on local hospitality for the auditing will be provided by the skin bank. Travelling expenses will be borne by the auditing organization RN.

5.3.5. RN shall conduct yearly meetings with the entire Skin Harvesting Team and the Supervising Committee of the Skin Bank and give necessary technical assistance and guidance and share the experiences and research in skin harvesting, processing and storage with them. In the first year RN shall conduct meetings twice a year to Iron out teething problems.

5.3.6. RN shall be entitled to provide all the details in respect of the Skin Bank including contact details of members of KLESH and RCB involved with the Project on its website along with direct links to the websites of the Skin Bank, RCB and RCBN.

5.3.7. The Skin Bank/ Skin Collection Centre shall provide periodic reports every 3 months to RN in agreed formats.

6. KLESH shall be solely responsible for obtaining all statutory permissions and consents as may be required for harvesting of cadaver skin and neither NBC nor RCBN shall be held responsible for any non-compliance by KLESH in respect of obtaining permission and consent.

7. KLESH & RCB shall have the right to nominate the person who will inaugurate the Skin Bank on the inauguration date.

8. KLESHshall have the right but not an obligation to monitor and supervise the operations of the Skin Bank and also collect data and reports of the patients and other hospitals who receive support from the Skin Bank every quarter.

9. KLESH, RCB and RN shall organize a press meet to promote the importance of skin donation and creating a Skin Bank. All Parties will make all efforts to promote the message of skin donation. KLESH &RCB will have a complete right to carry out their PR activity before, during and after the inauguration of the Skin Bank. Any public announcement with regard to the Project, contents or subject matter of this MOU shall be made only with the mutual agreement of the Parties as to content and timing of such announcement.

10. KLESH shall permit visitors introduced by RCB and/or RN to showcase the Skin Bank as well as to inspect its functioning with prior appointment and without disturbing the operations of the Skin Bank.

11. All intellectual property rights belonging to each of the Parties as well as RCBN Skin Bank shall belong to each of them respectively and none of the Parties hereto shall utilize or misuse any such intellectual property of the others of them or claim any rights in respect thereof. It is agreed that wherever any names, trademarks or other intellectual property of the Parties hereto or RCBN Skin Bank is to be used by any one or more of the parties hereto for the Project, they will seek written permission of the party owning such name, trademark or other intellectual property before any such use.

NATIONAL BURNS CENTRE

ATTESTED

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

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

12. This MOU has been entered into with good faith by the Parties for providing service to burns victims with the intention to save more lives. NBC will make all efforts to provide good technical training to the KLESH technicians and help set up the Skin Bank using their expertise and RCB together with RN will use their respective organizations for facilitating the development of the Skin Bank and KLESH will use the Skin Bank to provide better treatment and outcomes to burns patients.

13. The Parties undertake not to operate the facility as a commercial enterprise and agree to provide the Skin Bank services on HUMANITARIAN CONSIDERATIONS only.

14. The tenure of this MOU shall be for a period of five years. Subsequently, upon evaluation, if the RN and KLESH& RCB are satisfied with functioning of the Skin Bank, this MOU will be renewed on such terms as may be mutually agreed upon at that time. Notwithstanding what is stated in this MOU if in the opinion of RN the Skin Bank is not running as per the standards suggested or laid down by RN then RN may at its discretion and without being subject to any liability terminate this MOU forthwith.

15. KLESHhereby indemnifies, and agrees to defend and hold harmless NBC, RCBN& RCB and their nominees from any and all actions, losses, claims, demands actions, causes of action, suits, costs, damages, expenses, compensation, penalties, liabilities and obligations of any kind (hereinafter collectively referred to as 'Loses') resulting from acts, misconduct or omissions of KLES Rotary Skin Bank or the **Supervising Committee**its agents or employees including but not limited to obtaining all statutory permissions and consents for harvesting, processing and storing of cadaver skin.

16. All disputes, differences and/ or claims arising out of this MOU or the construction, meaning or effect thereof or the rights, obligations and liabilities of the parties hereto or otherwise relating to the Skin Bank shall be referred to arbitration to be conducted in accordance with the Arbitration and Conciliation Act, 1996 or any statutory amendments or re-enactment thereof by appointing a Sole Arbitrator as mutually agreed upon between the parties and such Arbitration shall be held in Belagavi The Award of the Sole Arbitrator shall be final and binding.

17. This MOU shall be executed in three counterparts, each of which shall be deemed to be an original and each party to this MOU shall retain a counterpart. All three counterparts shall constitute one and the same MOU.

18. This MOU may be reviewed and renewed by mutual agreement of the parties to this MOU.

IN WITNESS WHEREOF the Parties hereto have set and subscribed their respective hands the names to this writing on the day and the year first hereinabove written.

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

ATTESTED

Prof Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

NATIONAL BURNS CENTRE

Signed and delivered by the
Within named **KLES Dr. P K Hospital & MRC, Belagavi**
Represented by:
1. Dr. M. V. Jali,
Medical Director& Chief Executive
KLES Dr. P K Hospital & MRC, Belagavi

Signatures:

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

Witnesses:

1. Dr. Rajesh Powar
   Chief Consultant
   Department of Plastic Surgery
   KLES Dr. P K Hospital & MRC, Belagavi

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

2. Mr. Vinay Bedre
   Administrator- Finance & Accounts
   KLES Dr. P K Hospital & MRC, Belagavi

Administrator / Finance & Accounts
KLES Dr. Prabhakar Kore Hospital &
MRC - BELGAUM.

Signed and delivered by the
Within named **Rotary Club of Belgaum**
Represented by its Trustee President
Dr. Satish Dhamankar
Rotary Club of Belgaum

Witnesses:

Signatures:

1. Dr. Mukund Udachankar
   Vice President
   Rotary Club of Belgaum

2. Mr. Sachin Bichu
   President Elect
   Rotary Club of Belgaum

Signed and delivered by the
Within named **National Burns Centre& Rotary Club of Bombay North**
Represented by:
Dr. Sunil Keswani

Witnesses:

Signatures:

1. Sangita Panda
   Res officer

2. Reshmi Varghese
   Research Associate

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

KLE UNIVERSITY'S
(Accredited 'A' Grade by NAAC)
SHRI B.M. KANKANAWADI AYURVEDA MAHAVIDYALAYA
(A Constituent Unit of K.L.E. University, Belgaum)
Shahapur, Belgaum - 590 003. Karnataka, India
Approved by Central Council of Indian Medicine, New Delhi & Dept. AYUSH

MOU

Ref:- BMK/1647/201617 Date: 6/3/17

To,

M/s. M.B. Life Sciences, Pvt. Ltd.,
54/8, Desh Bandhu Gupta Road
Karol Bagh,
New Delhi – 110 005.

Sub: Submission of Original MoU-reg.

Sir,

We are herewith sending the orginal copy of Memoradum of Understanding for two clinical trials / projects between KLE Univeristy's Shri B.M.K. Ayurveda Mahavidyalaya, Belagavi and M/s. M.B. Life Sciences Pvt. Ltd., New Delhi on 28.02.2017.

This is for your information.

Yours truly,

PRINCIPAL
K.L.E. University's
Shri B. M. Kankanwadi
Ayurved Mahavidyalaya
Shahapur-BELAGAVI-03

Encl: Two Original MoU

IMPARTING AYURVEDA EDUCATION SINCE 1933

Ph. No. : +91 831-2424886, Fax : +91 831-2424157.
E-mail : bmkayurveda@rediffmail.com Website : ayurveda.kleuniversity.edu.in www.kleayurveda.org,

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

K.L.E.UNIVERSITY'S

SHRI.B.M.K.AYURVED MAHAVIDYALAYA, SHAHAPUR, BELGAUM

Ref No: Nil

Date : 28.02.2017

RECEIPT

Received with thanks the sum of **Rs.1, 00,000/-** (Rupees, One Lakh only) through **NEFT to Syndicate Bank on Dt: 28.02.2017** towards **"The Clinical Trials of Vatsyana plus power capsules and contarapain oil and lep "** from M B Life Sciencies Pvt Ltd., New Delhi.

OFFICE SUPERINTENDENT
KLE University's
Shri B.M. Kankanwadi Ayurveda
Mahavidyalaya Shahapur
Belagavi.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

INDIA NON JUDICIAL

Government of National Capital Territory of Delhi

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सत्यमेव जयते

Certificate No.	:	IN-DL52945218183321P
Certificate Issued Date	:	28-Feb-2017 02:22 PM
Account Reference	:	IMPACC (IV)/ dl957503/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL95750306392090749558P
Purchased by	:	M B LIFE SCIENCES PVT LTD
Description of Document	:	Article 5 General Agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	M B LIFE SCIENCES PVT LTD
Second Party	:	KLE UNIVERSITY
Stamp Duty Paid By	:	M B LIFE SCIENCES PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

For MB Lifesciences Pvt. Ltd.,

Jitender Kumar

Director.

PRINCIPAL
K.L.E. University's
Shri B. M. Kankanwadi
Ayurved Mahavidyalaya
Shahapur-BELAGAVI-03

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

MEMORANDUM OF UNDERSTANDING

The memorandum understanding is concurred into this

BETWEEN

M/s. M.B.Life Sciences Pvt. Ltd., New Delhi, a company incorporated under the Indian Companies act, having its Registered Office at54/8, DeshBandhu Gupta Road, Karol Bagh, New Delhi, 110005, through its authorized signatory Mr. Jitender Kumar

Managing Director authorized by the Board Resolution dated- 28th February 2017, hereinafter referred to as the **company**, which expression shall unless repugnant to the context and meaning thereof include its heirs. successors of the one part.

AND

KLE.University'sShri.B.M.KankanawadiAyurvedMahavidyalaya – Medical Research Centre Shahapur, Belagavi, Karnataka-590003, India through its Principal Dr.B.Sreenivas Prasad hereinafter referred to as the **institute** which expression shall unless repugnant to the context and meaning thereof include its heirs, successors and assignees of the Second Part.

WHERE AS the company is engaged, interalia, in research and development of various Ayurveda Drugs.

AND WHERE AS the institute has fully established good research facilities and hospital facility for the clinical studies in the field of Ayurveda and Ayurvedic Drugs.

WHERE AS the company has developed Proprietary Ayurveda Preparations in its laboratory for the management of Male Impotency and wants a clinical assessment for its efficacy and safety in Male Impotency, to be done in the lab & hospital of the Institute, to which the Institute has agreed.

NOW, THERERFORE, in consideration of the representations, warranties, covenants and agreements set forth herein and other valuable consideration and subject to the terms and condition s set for the herein, the Lessor and the Lessee hereby agree as follows.

1. That the Institute has agreed to conduct a clinical assessment of the drug VATSYAYAN PLUSPower Capsule, development 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 details of the products, copy of certificate of analysis of used raw materials and ingredient pharmacology of used raw materials.
3. That the company has also agreed to utilize the result of the clinical study for the benefit of patients and undertakes that the company shall only be responsible /liable for any legal or other requirement arising out of the application of the project.
4. That the clinical study would require certain amount of expenditure as per details attached herewith in the project proposal (including financial) to which both the parties have agreed. Total amount of project is Rs. 5,83,800/- Only(Five Lakhs Eighty Three Thousand and Eight Hundred Only)in words.

For MB Lifesciences Pvt. Ltd.,
Jitender Kumar
Director.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

PRINCIPAL
K.L.E. University's
Shri B. M. Kankanwadi
Ayurved Mahavidyalaya
Shahapur-BELAGAVI-03

Put of the above proposed fixed expenditure of Rs.5,83,800 the company has agreed to make 10% non- refundable amount (Rs. 58,380/-) along with application which will be adjustable in total project cost. 50% (Rs.2,91,900/-) of payment will be made after ethical clearance as part of project institution, and 30%(Rs.1,75,140/-) payment will be made once the 50% of sample size is reached. Remaining 10% (Rs.58,380/-) of project cost should be paid after the completion of the project.

5. That the said trial shall be completed in the period of 12 months.
6. The Institute has agreed to provide trimonthlybasis 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 agreed between the parties that all rights arising and of research and clinical activities of the said drugs, including patent right shall vest with the company and the Institute shall never claim any right over the drugs time in future.
9. Important research findings arising out of the activities covered under this MOU will be published or presented at National/International Journals, Conferences with joint authorship of both of parties.
10. All notes and other communication required to be served on parties under the terms of the agreement shall be considered duly served if the same have been delivered to or posted by registered mail to:

    In case of M/S. M.B.Life Sciences Pvt. Ltd., New Delhi.
    Mr. Jitender Kumar,
    Director,
    M/S. M.B.Life Sciences Pvt. Ltd., New Delhi

    In case of KLEU's Shri.B.M.Kankanawadi Ayurveda Mahavidyalaya:

    Coordinator,
    Medical Research Centre,
    KLE University's Shri.B.M.Kankanawadi Ayurveda Mahavidyalaya,
    Shahapur-Belagavi-590003, Karnataka, India
    Fax:0831-2424157, Tel: 0831- 2486286
    Website: www.klebmk@gmail.edu.in,
    Email:mrcklebmk@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 the use the same as per the law. Hence in order to save the proprietary information/trade secret, both the parties has agreed as follows:
    - I. All rights to the proprietary information to the development product shall remain the sole property of the company.
    - II. The Institute undertakes to keep confidential all information provided by the company in the Institute whether in the drugs under trial of otherwise.
    - III. The Institute undertakes do not disclose to any third party about the present Agreement understanding.

For MB Lifesciences Pvt. Ltd.,
Jitender Kumar
Director.

PRINCIPAL
K.L.E. University's
Shri B. M. Kankanwadi
Ayurved Mahavidyalaya
Shahapur-BELAGAVI-03

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

12. None of the parties to this MOD shall make any public discloses in any form relating to this MOU without the prior written consent of the other party: provided, the party shall be permitted to make such disclosures to the Public or to Government agencies as the party shall deem necessary to comply with any applicable law, rule or regulation or to Goverment Reviews or approvals of the proposed business agreement disclosed on 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 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. This is the essence of this agreement.
16. Any dispute, difference or claim arising out of or in connection with the Agreement including the construction, validity, execution, performance, termination or breach hereof (a "Dispute") that is not settledwithin fifteen (15 business days of the date on which such dispute, difference or claim is raised, shall be referred to final and binding arbitration under the Indian Arbitration and Conciliation. All proceedings of such arbitration shall be in the English Language.
17. The courts of shall have the sole and exclusive jurisdiction to resolve any dispute if not solved amicably between the parties.

In witness whereof the parties hereof have signed in this agreement and the day month and year mentioned herein above:

PARTIES

For and on behalf of
M/s. M.B.Life Sciences Pvt. Ltd
54/8, DeshBandhu Gupta Road,
New Delhi - 110005

Mr. Jitender Kumar
Director, M.B.Life Sciences Pvt. Ltd

For MB Lifesciences Pvt. Ltd.,
Jitender Kumar
Director.

For and on behalf of
KLE.University's,Shri.B.M.Kankanawadi
Ayurveda Mahavidyalaya

Dr.B.S.Prasad
PRINCIPAL
K.L.E.University's
Shri B. M. Kankanawadi
Ayurved Mahavidyalaya
Shahapur-BELAGAVI-03

(1) Dr. Sukumar. Nandigondar

(2). Dr. Vedantam Girindhar
Girindhar 28/02/17

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

PAY - YOURSELF

KLE'S SHRI B.M. KANKANWADI
AYURVEDA MAHAVIDYALAYA BELAGAVI

A/C - 05382150000029

AMOUNT- 1,00,000/-

IFSC CODE - SYNB0000538

For MB Lifesciences Pvt. Ltd.

Authorised Signatory

NEFT -

N059170251874093

Acknowledgement HDFC BANK We understand your world

☐ RTGS / ☐ NEFT. (✓ the appropriate box).

Beneficiary Details

Name: KLE'S SHRI. B.M KANKANWADI AYURVEDA MAHAVIDYALAYA BELAGAVI

Account No.: 05382150000029

Bank: SYNDICATE BANK

IFSC Code: SYNB0000538

Date: 28/2/17

Time:

Cheque No.: 001147

Amount: 100000/-

Signature /Stamp by Bank Staff

HDFC BANK

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KAROL BAGH,NEW DELHI-110005,DELHI
RTGS / NEFT IFSC : HDFC0001560

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Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

PAY - YOURSELF

KLE'S SHRI B.M. KANKANWADI
AYURVEDA MAHAVIDYALAYA BELAGAVI

A/C - 053821500000029

AMOUNT- 1,00,000/-

IFSC CODE - SYNB0000538

For MB Lifesciences Pvt. Ltd.

Authorised Signatory

NEFT-
N059170251874093

Acknowledgement HDFC BANK We understand your world

☐ RTGS / ☐ NEFT. (✓ the appropriate box).

Beneficiary Details

Name: K'BEUS SHRI.B.M KANKANAWAD AYURVEDA MAHAVIDYALAYA BELAGAVI
Account No.: 053821500000029
Bank: SYNDICATE BANK
IFSC Code: SYNB0000538
Date: 28/2/17
Time:
Cheque No.: 001147
Amount: 100000/-

Signature /Stamp by Bank Staff

HDFC BANK
533,D B GUPTA ROAD
KAROL BAGH,NEW DELHI-110005,DELHI
RTGS / NEFT IFSC : HDFC0001560

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Weekly Holiday on SUNDAY

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Please sign above / कृपया यहाँ हस्ताक्षर क

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TESTED

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Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

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Government of National Capital Territory of Delhi

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सत्यमेव जयते

Certificate No.	:	IN-DL52944276492233P
Certificate Issued Date	:	28-Feb-2017 02:20 PM
Account Reference	:	IMPACC (IV)/ dl957503/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL95750306389928259144P
Purchased by	:	M B LIFE SCIENCES PVT LTD
Description of Document	:	Article 5 General Agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	M B LIFE SCIENCES PVT LTD
Second Party	:	KLE UNIVERSITY
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Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

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For MB Lifesciences Pvt. Ltd.,
Jitender Kumar
Director.

PRINCIPAL
K.L.E. University's
Shri B. M. Kankanwadi
Ayurved Mahavidyalaya
Shahapur-BELAGAVI-03

Statutory Alert:
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2. The onus of checking the legitimacy is on the users of the certificate.
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ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

MEMORANDUM OF UNDERSTANDING

The memorandum understanding is concurred into this

BETWEEN

M/s. M.B.Life Sciences Pvt. Ltd., New Delhi, a company incorporated under the Indian Companies act, having its Registered Office at54/8, DeshBandhu Gupta Road, Karol Bagh, New Delhi, 110005, through its authorized signatory Mr. Jitender Kumar(Director)

Managing Director authorized by the Board Resolution dated- 28th February 2017, hereinafter referred to as the **company**, which expression shall unless repugnant to the context and meaning thereof include its heirs. successors of the one part.

AND

KLE.University'sShri.B.M.KankanawadiAyurvedMahavidyalaya – Medical Research Centre Shahapur, Belagavi, Karnataka-590003, India through its Principal Dr.B.Sreenivas Prasad hereinafter referred to as the **institute** which expression shall unless repugnant to the context and meaning thereof include its heirs, successors and assignees of the Second Part.

WHERE AS the company is engaged, interalia, in research and development of various Ayurveda Drugs.

AND WHERE AS the institute has fully established good research facilities and hospital facility for the clinical studies in the field of Ayurveda and Ayurvedic Drugs.

WHERE AS the company has developed Proprietary Ayurveda Preparations in its laboratory for the management of Male Impotency and wants a clinical assessment for its efficacy and safety in Male Impotency, to be done in the lab & hospital of the Institute, to which the Institute has agreed.

NOW, THERERFORE, in consideration of the representations, warranties, covenants and agreements set forth herein and other valuable consideration and subject to the terms and condition s set for the herein, the Lessor and the Lessee hereby agree as follows.

1. That the Institute has agreed to conduct a clinical assessment of the drug Contrapain-Lep&Contrapain Oil, development 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 details of the products, copy of certificate of analysis of used raw materials and ingredient pharmacology of used raw materials.
3. That the company has also agreed to utilize the result of the clinical study for the benefit of patients and undertakes that the company shall only be responsible /liable for any legal or other requirement arising out of the application of the project.
4. That the clinical study would require certain amount of expenditure as per details attached herewith in the project proposal (including financial) to which both the parties have agreed. Total amount of project is Rs.4,05,600/- Only(Four Lakhs Five Thousand and six Hundred Only)in words.

For MB Lifesciences Pvt. Ltd.,

Jitender Kumar

Director.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

PRINCIPAL
K.L.E. University's
Shri B. M. Kankanwadi
Ayurved Mahavidyalaya
Shahapur-BELAGAVI-03

Put of the above proposed fixed expenditure of Rs.4,05,600/- the company has agreed to make 10% non- refundable amount (Rs.40,560/-) along with application which will be adjustable in total project cost. 50% (Rs.2,02,800/-) of payment will be made after ethical clearance as part of project institution, and 30%(Rs.1,21,680/-) payment will be made once the 50% of sample size is reached. Remaining 10% (Rs.40,560/-) of project cost should be paid after the completion of the project.

5. That the said trial shall be completed in the period of 12 months.
6. The Institute has agreed to provide trimonthlybasis 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 agreed between the parties that all rights arising and of research and clinical activities of the said drugs, including patent right shall vest with the company and the Institute shall never claim any right over the drugs time in future.
9. Important research findings arising out of the activities covered under this MOU will be published or presented at National/International Journals, Conferences with joint authorship of both of parties.
10. All notes and other communication required to be served on parties under the terms of the agreement shall be considered duly served if the same have been delivered to or posted by registered mail to:

    In case of M/S. M.B.Life Sciences Pvt. Ltd., New Delhi.
    Mr. Jitender Kumar,
    Director,
    M/S. M.B.Life Sciences Pvt. Ltd., New Delhi

    In case of KLEU's Shri.B.M.Kankanawadi Ayurveda Mahavidyalaya:

    Coordinator,
    Medical Research Centre,
    KLE University's Shri.B.M.Kankanawadi Ayurveda Mahavidyalaya,
    Shahapur-Belagavi-590003, Karnataka, India
    Fax:0831-2424157, Tel: 0831- 2486286
    Website: www.klebmk@gmail.edu.in,
    Email:mrcklebmk@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 the use the same as per the law. Hence in order to save the proprietary information/trade secret, both the parties has agreed as follows:
    - I. All rights to the proprietary information to the development product shall remain the sole property of the company.
    - II. The Institute undertakes to keep confidential all information provided by the company in the Institute whether in the drugs under trial of otherwise.
    - III. The Institute undertakes do not disclose to any third party about the present Agreement understanding.

For MB Lifesciences Pvt. Ltd.,
Jitender Kumar
Director.

PRINCIPAL
K.L.E. University's
Shri B. M. Kankanwadi
Ayurved Mahavidyalaya
Shahapur-BELAGAVI-03

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

12. None of the parties to this MOD shall make any public discloses in any form relating to this MOU without the prior written consent of the other party: provided, the party shall be permitted to make such disclosures to the Public or to Government agencies as the party shall deem necessary to comply with any applicable law, rule or regulation or to Government Reviews or approvals of the proposed business agreement disclosed on this MOU.
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 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. This is the essence of this agreement.
16. Any dispute, difference or claim arising out of or in connection with the Agreement including the construction, validity, execution, performance, termination or breach hereof (a "Dispute") that is not settledwithin fifteen (15 business days of the date on which such dispute, difference or claim is raised, shall be referred to final and binding arbitration under the Indian Arbitration and Conciliation. All proceedings of such arbitration shall be in the English Language.
17. The courts of shall have the sole and exclusive jurisdiction to resolve any dispute if not solved amicably between the parties.

In witness whereof the parties hereof have signed in this agreement and the day month and year mentioned herein above:

PARTIES

For and on behalf of
M/s. M.B.Life Sciences Pvt. Ltd
54/8, DeshBandhu Gupta Road,
New Delhi - 110005

Mr. Jitender Kumar
Director, M.B.Life Sciences Pvt. Ltd.

For MB Lifesciences Pvt. Ltd.,
Jitender Kumar
Director.

For and on behalf of
KLE.University's,Shri.B.M.Kankanawadi
Ayurveda Mahavidyalaya

Dr.B.S. Prasad
PRINCIPAL
K.L.E. University's
Shri B. M. Kankanwadi
Ayurved Mahavidyalaya
Shahapur-BELAGAVI-03

(1) Dr. Pradeep. L-G.

(2) Dr. Vedantam Giridhar
28/02/17

ATTESTED
Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

PAY - YOURSELF

KLE'S SHRI B.M. KANKANAWADI AYURVEDA MAHAVIDYALAYA BELAGAVI

A/C# - 053821500000029

AMOUNT- 1,00,000/-

IFSC CODE - SYNB0000538

For MB Lifesciences Pvt. Ltd.

Authorised Signatory

NEFT-

N059170251874093

Acknowledgement HDFC BANK

☐ RTGS / ☐ NEFT. (✓ the appropriate box).

Beneficiary Details

Name: KLE'S SHRI. B.M KANKANAWADI AYURVEDA MAHAVIDYALAYA BELAGAVI

Account No.: 053821500000029

Bank SYNDICATE BANK

IFSC Code: SYNB0000538

Date: 28/2/17

Time:

Cheque No.: 001147

Amount: 100000/-

Signature /Stamp by Bank Staff

HDFC BANK

533,D B GUPTA ROAD
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₹ 1,00,000/-

A/c No. खाता क्र. 14422560001235

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For MB LIFESCIENCES PRIVATE LIM

Authorised Signat

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SESHASAYDY CTS-2010 151216

ATTESTED

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Prof. Dr. V A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

PAY - YOURSELF

KLEU'S SHRI B.M. KANKANAWADI
AYURVEDA MAHAVIDYALAYA BELAGA

A/c - 0538215000029

AMOUNT - 1,00,000/-

IFSC CODE - SYNB0000538

For MB Lifesciences Pvt. Ltd.

Authorised Signatory

NEFT -
N059170251874093

Acknowledgement — HDFC BANK — We understand your world

☐ RTGS / ☐ NEFT. (✓ the appropriate box).

Beneficiary Details

Name: KLEU'S SHRI B.M KANKANAWAD AYURVEDA MAHAVIDYALAYA BELAGAU

Account No.: 0538215000029

Bank: SYNDICATE BANK

IFSC Code: SYNB0000538

Date: 28/2/17

Time:

Cheque No.: 001147

Amount: 1,00,000/-

Signature /Stamp by Bank Staff

HDFC BANK

53/3,D B GUPTA ROAD
KAROL BAGH,NEW DELHI-110005,DELHI
RTGS / NEFT IFSC : HDFC0001560

Preferred

Weekly Holiday on SUNDAY

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Valid for 3 months only

Pay yourself — Or Bearer / या धारक को

Rupees रुपये One lac Only — अदा करें ₹ 1,00,000/-

A/c No. खाता सं. 14422560001235

Payable at par through clearing/transfer at all branches of HDFC BANK LTD

For MB LIFESCIENCES PRIVATE LIMITE

Authorised Signatorie
Please sign above / कृपया यहाँ हस्ताक्षर क

⑈001147⑈ 110240188⑆ 003872⑈ 29

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

MoU

KLE UNIVERSITY'S
(Accredited 'A' Grade by NAAC)

SHRI B.M. KANKANAWADI AYURVEDA MAHAVIDYALAYA

(A Constituent Unit of K.L.E. University, Belgaum)
Shahapur, Belgaum - 590 003. Karnataka, India

Approved by Central Council of Indian Medicine, New Delhi & Dept. AYUSH

Ref:- BMK/1647/2016-17 Date:- 6/3/17

To,

M/s. M.B. Life Sciences, Pvt. Ltd.,
54/8, Desh Bandhu Gupta Road
Karol Bagh,
New Delhi – 110 005.

Sub: Submission of Original MoU-reg.

Sir,

We are herewith sending the orginal copy of Memoradum of Understanding for two clinical trials / projects between KLE Univeristy's Shri B.M.K. Ayurveda Mahavidyalaya, Belagavi and M/s. M.B. Life Sciences Pvt. Ltd., New Delhi on 28.02.2017.

This is for your information.

Yours truly,

PRINCIPAL
K.L.E. University's
Shri B. M. Kankanwadi
Ayurved Mahavidyalaya
Shahapur-BELAGAVI-03

Encl: Two Original MoU

IMPARTING AYURVEDA EDUCATION SINCE 1933

Ph. No. : +91 831-2486286, Fax : +91 831-2424157.
E-mail : bmkayurveda@rediffmail.com Website : ayurveda.kleuniversity.edu.in www.kleayurveda.org,

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

K.L.E.UNIVERSITY'S

SHRI.B.M.K.AYURVED MAHAVIDYALAYA, SHAHAPUR, BELGAUM

Ref No: Nil

Date : 28.02.2017

RECEIPT

Received with thanks the sum of **Rs.1, 00,000/-** (Rupees, One Lakh only) through **NEFT to Syndicate Bank on Dt: 28.02.2017** towards **"The Clinical Trials of Vatsyana plus power capsules and contarapain oil and lep "** from M B Life Sciencies Pvt Ltd., New Delhi.

OFFICE SUPERINTENDENT
KLE University's
Shri B.M. Kankanwadi Ayurveda
Mahavidyalaya Shahapur
Belagavi.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

INDIA NON JUDICIAL

Government of National Capital Territory of Delhi

e-Stamp

सत्यमेव जयते

Certificate No.	:	IN-DL52945218183321P
Certificate Issued Date	:	28-Feb-2017 02:22 PM
Account Reference	:	IMPACC (IV)/ dl957503/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL95750306392090749558P
Purchased by	:	M B LIFE SCIENCES PVT LTD
Description of Document	:	Article 5 General Agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	M B LIFE SCIENCES PVT LTD
Second Party	:	KLE UNIVERSITY
Stamp Duty Paid By	:	M B LIFE SCIENCES PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

For MB Lifesciences Pvt. Ltd.,

Jitender Kumar

Director.

PRINCIPAL
K.L.E. University's
Shri B. M. Kankanwadi
Ayurved Mahavidyalaya
Shahapur-BELAGAVI-03

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

MEMORANDUM OF UNDERSTANDING

The memorandum understanding is concurred into this

BETWEEN

M/s. M.B.Life Sciences Pvt. Ltd., New Delhi, a company incorporated under the Indian Companies act, having its Registered Office at54/8, DeshBandhu Gupta Road, Karol Bagh, New Delhi, 110005, through its authorized signatory Mr. Jitender Kumar

Managing Director authorized by the Board Resolution dated- 28th February 2017, hereinafter referred to as the company, which expression shall unless repugnant to the context and meaning thereof include its heirs. successors of the one part.

AND

KLE.University'sShri.B.M.KankanawadiAyurvedMahavidyalaya – Medical Research Centre Shahapur, Belagavi, Karnataka-590003, India through its Principal Dr.B.Sreenivas Prasad hereinafter referred to as the institute which expression shall unless repugnant to the context and meaning thereof include its heirs, successors and assignees of the Second Part.

WHERE AS the company is engaged, interalia, in research and development of various Ayurveda Drugs.

AND WHERE AS the institute has fully established good research facilities and hospital facility for the clinical studies in the field of Ayurveda and Ayurvedic Drugs.

WHERE AS the company has developed Proprietary Ayurveda Preparations in its laboratory for the management of Male Impotency and wants a clinical assessment for its efficacy and safety in Male Impotency, to be done in the lab & hospital of the Institute, to which the Institute has agreed.

NOW, THERERFORE, in consideration of the representations, warranties, covenants and agreements set forth herein and other valuable consideration and subject to the terms and condition s set for the herein, the Lessor and the Lessee hereby agree as follows.

1. That the Institute has agreed to conduct a clinical assessment of the drug VATSYAYAN PLUSPower Capsule, development 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 details of the products, copy of certificate of analysis of used raw materials and ingredient pharmacology of used raw materials.
3. That the company has also agreed to utilize the result of the clinical study for the benefit of patients and undertakes that the company shall only be responsible /liable for any legal or other requirement arising out of the application of the project.
4. That the clinical study would require certain amount of expenditure as per details attached herewith in the project proposal (including financial) to which both the parties have agreed. Total amount of project is Rs. 5,83,800/- Only(Five Lakhs Eighty Three Thousand and Eight Hundred Only)in words.

For MB Lifesciences Pvt. Ltd.,
ATTESTED Jitender Kumar

Director.

PRINCIPAL
K.L.E. University's
Shri B. M. Kankanwadi
Ayurved Mahavidyalaya
Shahapur-BELAGAVI-03

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Put of the above proposed fixed expenditure of Rs.5,83,800 the company has agreed to make 10% non- refundable amount (Rs. 58,380/-) along with application which will be adjustable in total project cost. 50% (Rs.2,91,900/-) of payment will be made after ethical clearance as part of project institution, and 30%(Rs.1,75,140/-) payment will be made once the 50% of sample size is reached. Remaining 10% (Rs.58,380/-) of project cost should be paid after the completion of the project.

5. That the said trial shall be completed in the period of 12 months.
6. The Institute has agreed to provide trimonthlybasis 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 agreed between the parties that all rights arising and of research and clinical activities of the said drugs, including patent right shall vest with the company and the Institute shall never claim any right over the drugs time in future.
9. Important research findings arising out of the activities covered under this MOU will be published or presented at National/International Journals, Conferences with joint authorship of both of parties.
10. All notes and other communication required to be served on parties under the terms of the agreement shall be considered duly served if the same have been delivered to or posted by registered mail to:

    In case of M/S. M.B.Life Sciences Pvt. Ltd., New Delhi.
    Mr. Jitender Kumar,
    Director,
    M/S. M.B.Life Sciences Pvt. Ltd., New Delhi

    In case of KLEU's Shri.B.M.Kankanawadi Ayurveda Mahavidyalaya:

    Coordinator,
    Medical Research Centre,
    KLE University's Shri.B.M.Kankanawadi Ayurveda Mahavidyalaya,
    Shahapur-Belagavi-590003, Karnataka, India
    Fax:0831-2424157, Tel: 0831- 2486286
    Website: www.klebmk@gmail.edu.in,
    Email:mrcklebmk@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 the use the same as per the law. Hence in order to save the proprietary information/trade secret, both the parties has agreed as follows:
    - I. All rights to the proprietary information to the development product shall remain the sole property of the company.
    - II. The Institute undertakes to keep confidential all information provided by the company in the Institute whether in the drugs under trial of otherwise.
    - III. The Institute undertakes do not disclose to any third party about the present Agreement understanding.

For MB Lifesciences Pvt. Ltd.,
Jitender Kumar
Director.

PRINCIPAL
K.L.E. University's
Shri B. M. Kankanwadi
Ayurved Mahavidyalaya
Shahapur-BELAGAVI-03

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

12. None of the parties to this MOD shall make any public discloses in any form relating to this MOU without the prior written consent of the other party: provided, the party shall be permitted to make such disclosures to the Public or to Government agencies as the party shall deem necessary to comply with any applicable law, rule or regulation or to Goverment Reviews or approvals of the proposed business agreement disclosed on 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:
    L 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 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. This is the essence of this agreement.
16. Any dispute, difference or claim arising out of or in connection with the Agreement including the construction, validity, execution, performance, termination or breach hereof (a "Dispute") that is not settledwithin fifteen (15 business days of the date on which such dispute, difference or claim is raised, shall be referred to final and binding arbitration under the Indian Arbitration and Conciliation. All proceedings of such arbitration shall be in the English Language.
17. The courts of shall have the sole and exclusive jurisdiction to resolve any dispute if not solved amicably between the parties.

In witness whereof the parties hereof have signed in this agreement and the day month and year mentioned herein above:

PARTIES
For and on behalf of
M/s. M.B.Life Sciences Pvt. Ltd
54/8, DeshBandhu Gupta Road,
New Delhi - 110005

Mr. Jitender Kumar
Director, M.B.Life Sciences Pvt. Ltd

For MB Lifesciences Pvt. Ltd.,
Jitender Kumar
Director.

For and on behalf of
KLE.University's,Shri.B.M.Kankanawadi
Ayurveda Mahavidyalaya

Dr.B. Prasad
PRINCIPAL
K.L.E. University's
Shri B. M. Kankanwadi
Ayurved Mahavidyalaya
Shahapur-BELAGAVI-03

(1) Dr. Sukumar. Nandigavar

(2). Dr. Vedantam Girindhar
Girindhar 28/02/17

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

PAY - YOURSELF

KLE'S SHRI B.M.KANKANAWADI
AYURVEDA MAHAVIDYALAYA BELAGAVI.

A/C - 05382150000029

AMOUNT - 1,00,000/-

IFSC CODE - SYNB0000538

For MB Lifesciences Pvt. Ltd.

Authorised Signatory

NEFT -

N059170251874093

Acknowledgement — HDFC BANK — We understand your world

☐ RTGS / ☐ NEFT. (✓ the appropriate box)

Beneficiary Details

Name: KLE'S SHRI. B.M KANKANAWADI AYURVEDA MAHAVIDYALAYA BELAGAVI

Account No.: 05382150000029

Bank: SYNDICATE BANK

IFSC Code: SYNB0000538

Date: 28/2/17

Time:

Cheque No.: 001147

Amount: 100000/-

Signature /Stamp by Bank Staff

HDFC BANK

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RTGS / NEFT IFSC : HDFC0001560

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A/c No: 14422560001235

Payable at par through clearing/local at all branches

For MB LIFESCIENCES PRIVATE LIMITE

Authorised Signatorie
Please sign above /कृपया यहां हस्ताक्षर क

SER/ASAIDV CTS-2010 151216

ATTESTED

⑈001147⑈ ⑆110240881⑆ 00387211⑈ 29

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

PAY - YOURSELF

KLE'S SHRI B.M. KANKANAWADI
AYURVEDA MAHAVIDYALAYA BELAGAVI

A/C - 05382150000029

AMOUNT- 1,00,000/-

IFSC CODE - SYNB0000538

For MB Lifesciences Pvt. Ltd.

Authorised Signatory

NEFT-

N059170251874093

Acknowledgement HDFC BANK We understand your world

☐ RTGS / ☐ NEFT. (✓ the appropriate box).

Beneficiary Details

Name: KLE'S SHRI. B.M KANKANAWADI AYURVEDA MAHAVIDYALAYA BELAGAVI

Account No.: 05382150000029

Bank: SYNDICATE BANK

IFSC Code: SYNB0000538

Date: 28/2/17

Time:

Cheque No.: 001147

Amount: 100000/-

Signature /Stamp by Bank Staff

HDFC BANK

53/3,0 B GUPTA ROAD
KAROL BAGH,NEW DELHI-110005,DELHI
RTGS / NEFT IFSC : HDFC0001580

Preferred

Weekly Holiday on SUNDAY

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Rupees रुपये One lac Only

अदा करें ₹ 1,00,000/-

A/c No: खाता सं. 14422560001235

For MB LIFESCIENCES PRIVATE LIMITE

Payable at par through clearinghouse at all branches of HDFC BANK

Authorised Signatorie
Please sign above / कृपया यहाँ हस्ताक्षर क

SCS-BANKOY CTS-2010 151216

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

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Government of National Capital Territory of Delhi

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सत्यमेव जयते

Certificate No.	:	IN-DL52944276492233P
Certificate Issued Date	:	28-Feb-2017 02:20 PM
Account Reference	:	IMPACC (IV)/ dl957503/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL95750306389928259144P
Purchased by	:	M B LIFE SCIENCES PVT LTD
Description of Document	:	Article 5 General Agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	M B LIFE SCIENCES PVT LTD
Second Party	:	KLE UNIVERSITY
Stamp Duty Paid By	:	M B LIFE SCIENCES PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

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For MB Lifesciences Pvt. Ltd.,
Jitender Kumar
Director.

PRINCIPAL
K.L.E. University's
Shri B. M. Kankanwadi
Ayurved Mahavidyalaya
Shahapur-BELAGAVI-03

Statutory Alert:
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ATTESTED
Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

MEMORANDUM OF UNDERSTANDING

The memorandum understanding is concurred into this

BETWEEN

M/s. M.B.Life Sciences Pvt. Ltd., New Delhi, a company incorporated under the Indian Companies act, having its Registered Office at54/8, DeshBandhu Gupta Road, Karol Bagh, New Delhi, 110005, through its authorized signatory Mr. Jitender Kumar(Director)

Managing Director authorized by the Board Resolution dated- 28th February 2017, hereinafter referred to as the **company**, which expression shall unless repugnant to the context and meaning thereof include its heirs. successors of the one part.

AND

KLE.University'sShri.B.M.KankanawadiAyurvedMahavidyalaya – Medical Research Centre Shahapur, Belagavi, Karnataka-590003, India through its Principal Dr.B.Sreenivas Prasad hereinafter referred to as the **institute** which expression shall unless repugnant to the context and meaning thereof include its heirs, successors and assignees of the Second Part.

WHERE AS the company is engaged, interalia, in research and development of various Ayurveda Drugs.

AND WHERE AS the institute has fully established good research facilities and hospital facility for the clinical studies in the field of Ayurveda and Ayurvedic Drugs.

WHERE AS the company has developed Proprietary Ayurveda Preparations in its laboratory for the management of Male Impotency and wants a clinical assessment for its efficacy and safety in Male Impotency, to be done in the lab & hospital of the Institute, to which the Institute has agreed.

NOW, THERERFORE, in consideration of the representations, warranties, covenants and agreements set forth herein and other valuable consideration and subject to the terms and condition s set for the herein, the Lessor and the Lessee hereby agree as follows.

1. That the Institute has agreed to conduct a clinical assessment of the drug Contrapain-Lep&Contrapain Oil, development 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 details of the products, copy of certificate of analysis of used raw materials and ingredient pharmacology of used raw materials.
3. That the company has also agreed to utilize the result of the clinical study for the benefit of patients and undertakes that the company shall only be responsible /liable for any legal or other requirement arising out of the application of the project.
4. That the clinical study would require certain amount of expenditure as per details attached herewith in the project proposal (including financial) to which both the parties have agreed. Total amount of project is Rs.4,05,600/- Only(Four Lakhs Five Thousand and six Hundred Only)in words.

For MB Lifesciences Pvt. Ltd.,
Jitender Kumar
Director.

PRINCIPAL
K.L.E. University's
Shri B. M. Kankanwadi
Ayurved Mahavidyalaya
Shahapur-BELAGAVI-03

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Put of the above proposed fixed expenditure of Rs.4,05,600/- the company has agreed to make 10% non- refundable amount (Rs.40,560/-) along with application which will be adjustable in total project cost. 50% (Rs.2,02,800/-) of payment will be made after ethical clearance as part of project institution, and 30%(Rs.1,21,680/-) payment will be made once the 50% of sample size is reached. Remaining 10% (Rs.40,560/-) of project cost should be paid after the completion of the project.

5. That the said trial shall be completed in the period of 12 months.
6. The Institute has agreed to provide trimonthlybasis 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 agreed between the parties that all rights arising and of research and clinical activities of the said drugs, including patent right shall vest with the company and the Institute shall never claim any right over the drugs time in future.
9. Important research findings arising out of the activities covered under this MOU will be published or presented at National/International Journals, Conferences with joint authorship of both of parties.
10. All notes and other communication required to be served on parties under the terms of the agreement shall be considered duly served if the same have been delivered to or posted by registered mail to:

In case of M/S. M.B.Life Sciences Pvt. Ltd., New Delhi.
Mr. Jitender Kumar,
Director,
M/S. M.B.Life Sciences Pvt. Ltd., New Delhi

In case of KLEU's Shri.B.M.Kankanawadi Ayurveda Mahavidyalaya:

Coordinator,
Medical Research Centre,
KLE University's Shri.B.M.Kankanawadi Ayurveda Mahavidyalaya,
Shahapur-Belagavi-590003, Karnataka, India
Fax:0831-2424157, Tel: 0831- 2486286
Website: www.klebmk@gmail.edu.in,
Email:mrcklebmk@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 the use the same as per the law. Hence in order to save the proprietary information/trade secret, both the parties has agreed as follows:
    - I. All rights to the proprietary information to the development product shall remain the sole property of the company.
    - II. The Institute undertakes to keep confidential all information provided by the company in the Institute whether in the drugs under trial of otherwise.
    - III. The Institute undertakes do not disclose to any third party about the present Agreement understanding.

For MB Lifesciences Pvt. Ltd.,
Jitender Kumar
Director.

PRINCIPAL
K.L.E. University's
Shri B. M. Kankanwadi
Ayurved Mahavidyalaya
Shahapur-BELAGAVI-03

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

12. None of the parties to this MOD shall make any public discloses in any form relating to this MOU without the prior written consent of the other party: provided, the party shall be permitted to make such disclosures to the Public or to Government agencies as the party shall deem necessary to comply with any applicable law, rule or regulation or to Government Reviews or approvals of the proposed business agreement disclosed on this MOU.
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 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. This is the essence of this agreement.
16. Any dispute, difference or claim arising out of or in connection with the Agreement including the construction, validity, execution, performance, termination or breach hereof (a "Dispute") that is not settledwithin fifteen (15 business days of the date on which such dispute, difference or claim is raised, shall be referred to final and binding arbitration under the Indian Arbitration and Conciliation. All proceedings of such arbitration shall be in the English Language.
17. The courts of shall have the sole and exclusive jurisdiction to resolve any dispute if not solved amicably between the parties.

In witness whereof the parties hereof have signed in this agreement and the day month and year mentioned herein above:

PARTIES

For and on behalf of
M/s. M.B.Life Sciences Pvt. Ltd
54/8, DeshBandhu Gupta Road,
New Delhi - 110005

Mr. Jitender Kumar
Director, M.B.Life Sciences Pvt. Ltd.

For MB Lifesciences Pvt. Ltd.,
Jitender Kumar
Director.

For and on behalf of
KLE.University's,Shri.B.M.Kankanawadi
Ayurveda Mahavidyalaya

Dr.B.Shripad Prasad
PRINCIPAL
K.L.E. University's
Shri B. M. Kankanwadi
Ayurved Mahavidyalaya
Shahapur-BELAGAVI-03

(1) Dr. Pradeep. L.G.

(2) Dr. Vedantam Giridhar
28/02/17

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

PAY - YOURSELF

KLE U'S SHRI B.M. KANKANAWADI AYURVEDA MAHAVIDYALAYA BELAGAVI

A/C - 053821500000029

AMOUNT - 1,00,000/-

IFSC CODE - SYNB0000538

For MB Lifesciences Pvt. Ltd.

Authorised Signatory

NEFT -

N059170251874093

Acknowledgement — HDFC BANK — We understand your world

☐ RTGS / ☐ NEFT. (✓ the appropriate box).

Beneficiary Details

Name: KLE'S SHRI. B.M KANKANAWADI AYURVEDA MAHAVIDYALAYA BELAGAVI

Account No.: 053821500000029

Bank: SYNDICATE BANK

IFSC Code: SYNB0000538

Date: 28/2/17

Time:

Cheque No.: 001147

Amount: 100000/-

Signature /Stamp by Bank Staff

HDFC BANK

533,D B GUPTA ROAD
KAROL BAGH,NEW DELHI-110005,DELHI
RTGS / NEFT IFSC : HDFC0001580

Preferred

Weekly Holiday dn SUND.

28 02 2017

Valid for 3 months only

Pay yourself

Or Bea

या धारक

Rupees रुपये One lac Only

अंका करें ₹ 1,00,000/-

A/c No. खाता क्र. 14422560001235

Brn: 1580 Fcr: 268
CA HDFC TRADE

Payable at par through clearing/transfer at all branches of HDFC BANK LTD.

For MB LIFESCIENCES PRIVATE LIM

Authorised Signatu

Please sign above / कृपया यहाँ हस्ता

SES/HAS/AJ/DY CTS-2010 151216

⑈001147⑈ ⑆025240188⑆ 00387 21⑈ 29

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

PAY - YOURSELF

KLE'S SHRI B.M. KANKANAWADI
AYURVEDA MAHAVIDYALAYA BELAGAVI

A/C - 053821500000029

AMOUNT- 1,00,000/-

IFSC CODE - SYNB0000538

For MB Lifesciences Pvt. Ltd.

Authorised Signatory

NEFT-

N059170251874093

Acknowledgement — HDFC BANK — We understand your world

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Name: KLE'S SHRI. B.M KANKANAWADI AYURVEDA MAHAVIDYALAYA BELAGAVI

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Signature /Stamp by Bank Staff

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593,D B GUPTA ROAD
KAROL BAGH,NEW DELHI-110005,DELHI
RTGS / NEFT IFSC : HDFC0001560

Preferred

Weekly Holiday on SUNDAY

28 02 2017

Valid for 3 months only

Pay yourself

Or Bearer
या धारक को

Rupees रुपये One lac Only

₹ 1,00,000/-

A/c No: 14422560001235

Payable at par through clearing houses of

For MB LIFESCIENCES PRIVATE LIMITE

Authorised Signatorie
Please sign above / कृपया ऊपर हस्ताक्षर क

SSS/ASWDJ/CTS-2010/151216

⑈001147⑈ ATTESTED ⑆0038721⑈ 29

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Memorandum of Understanding

Between

K.L.E University's College of Pharmacy, Bangalore

And

Nuwill Research and Innovations Private Limited, Bangalore

This MOU is made and signed and made effective on 30th May 2017 between the Department of Pharmaceutics, K.L.E University's College of Pharmacy (KLEUCP), with the principal Address at 2nd Block, Rajajinagar, Bangalore560 010, and Nuwill Research and Innovations Private Limited (NRIPL) with the address at No.640, Janardhana Towers, B Block, 3rd Floor, Bilekahalli, Bannerghatta Road, Bangalore 560076.

As per the agreement KLEUCP and NRIPL have entered into an agreement for the usage of Single Station Flow through Dissolution Tester USP IV (Make: Electrolab, Model: EFT-01) existing at the Department of Pharmaceutics, K.L.E University's College of Pharmacy, Bangalore.

Either parties agree to treat as confidential and not reveal to the third party without prior consent of the other party the information/data generated out of this MOU.

NRIPL has agreed upon to depute the technical personnel required to monitor the testing.

KLEUCP has agreed upon to provide the necessary operating assistance to perform the activity.

The charges for the consultancy services rendered by KLEUCP would be Rs. 3,000/- for a shift of 8 hours. The above prices will hold good for the current financial year.

Mr. Ashok Hegde
Vice President
Nuwill Research and Innovations Pvt. Ltd.
Bangalore

ATTESTED

Prof. Dr. V.A. KOTHIWALE
Registrar
...Education
...AGAVI

K. L. E. SOCIETY'S
INSTITUTE OF DENTAL SCIENCES
(Recognised by Dental Council of India & Affiliated to RGUHS Karnataka)
No. 20, Yeshwanthpur Suburb, II Stage, Tumkur Road, Bengaluru-560 022
Karnataka State, INDIA
ಕೆ. ಎಲ್. ಇ. ಸಂಸ್ಥೆಯ ದಂತ ವಿಜ್ಞಾನ ಮಹಾವಿದ್ಯಾಲಯ, ಬೆಂಗಳೂರು
E-mail : principal.kledblore@gmail.com Website : www.kledentalbengaluru.com

MEMORANDUM OF UNDERSTANDING

This memorandum of understanding (MoU) is signed on 25/07/2017

Between:

1. KLES Institute of Dental Sciences. No 20,Yeshwantpur Suburb,Tumkur Road Bengaluru-560022 here in after referred to as "KLESIDS", being represented by Dr.Srivatsa.G as its Principal and Authorized Signatory

AND

2.KLE University's College of Pharmacy, 2nd Block, Rajajinagar, Bengaluru – 10 India here in referred to as KLEUAP being represented by Dr Hippargi as its principal and Authorized Signatory.

FOR

Exchange of resource person and utilization of KLE University's College of Pharmacy infrastructure for research purposes

The MOU being laid down herein on mutually agreed broad framework of understanding for running of the program.

1. PREAMBLE:

1.1. KLEDC EDUCATION INSTITUTION, No 20,Yeshwantpur Suburb,Tumkur Road Bengaluru-560022 operating since 1992 and has been mainly concentrating in the areas of healthcare and education related to medical and dental science.

1.2. KLE University's College of Pharmacy, 2nd Block, Rajajinagar, Bengaluru – 10 established since 1992 and has been mainly concentrating in education related to pharmacy.

1.3. The objective of the MOU is to DO RESEARCH ON MUTUALE[illegible]

2. CONDITIONS:

2.1. Both the Parties have held discussions and have agreed to collaborate

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

1.5. Purpose

The purpose of this MOU is to clearly identify the roles and responsibilities of each party as they come together to carry out the research project.

Funding:

MOU is not a commitment of funds

Duration

This MOU is at-will and may be modified by mutual consent of authorized officials. This MOU shall become effective upon signature by the authorized officials from the and will remain in effect until modified or terminated by any one of the partners by mutual consent. In the absence of mutual agreement by the authorized officials from this MOU shall end on end date of partnership.

Partner Name	KLE's INSTITUTE OF DENTAL SCIENCES
Partner representative	Dr SRIVATSA G.
Position	PRINCIPAL
Address	NO 26, YESHWANTPUR SUBURB, BANGALORE - 22
Telephone	080 2347 4137
E-mail	principal.kleblore@gmail.com
Partner Name	KLE UNIVERSITY'S COLLEGE OF PHARMACY
Partner representative	Dr HIPPARGI
Position	PRINCIPAL
Address	3rd BLOCK, RAJAJINAGAR, BANGALORE
Telephone	
E-mail	

Date:
(Partner signature)
(Partner name, organization, position)

Date: 5/7/2017
(Partner signature)
(Partner name, organization, position)

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

सत्यमेव जयते

Certificate No.	:	IN-KA30675282783506P
Certificate Issued Date	:	09-May-2017 04:10 PM
Account Reference	:	NONACC (FI)/ kaksfcl08/ BELGAUM3/ KA-BL
Unique Doc. Reference	:	SUBIN-KAKAKSFCL08099345705712225P
Purchased by	:	PRINC KLEU HOMEOPATHIC MEDICAL COLLEGE AND HOSP
Description of Document	:	Article 12 Bond
Description	:	M O U
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	PRINC KLEU HOMEOPATHIC MEDICAL COLLEGE AND HOSP
Second Party	:	DIRECTOR,KLE CENTENARY CHARITABLE HOSPITAL YALLUR
Stamp Duty Paid By	:	PRINC KLEU HOMEOPATHIC MEDICAL COLLEGE AND HOSP
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

USER / SUPERVISOR
Shri Beereshwar Co-op Credit Society Ltd., Examba (Multi - State)
BRANCH BELAGAVI.

NOTARY
Shri B. A. NAIK
BELAGAVI
Revenue Talluka
Reg. No. Law
102/LCL/2016
Ex. Dt. 13-09-21
GOVT. OF KARNATAKA

Please write or type below this line... Reg At Sl. No. 427/2017

Memorandum of Understanding

This is An Agreement for the exposure of the students in the clinical field and to understand the depth of operative surgery and operative Gynecology and Obstetrics as well as management in clinical illnesses.

Between

Principal, KLE University Homeopathic Medical College, & Hospital Belgaum, (Party A)

And

Dr. S.C. Dharawd, Director (C S). KLE Centenary Charitable Hospital Yellur Road Belagavi (Party B)

No of corrections nil

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
Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

I. Purpose and Scope.

The purpose of this Memorandum of Understanding (MoU) is to clearly identify the roles and responsibilities of each party as they relate to providing exposure of the students in BHMS Course and MD(Hom)courses in the clinical field and to understand the depth o operative surgery and operative Gynecology and Obstetrics as well as management in clinical illness.

Both Party A and Party B should ensure that educational activities are conducted in compliance with all requirements for provision of clinical exposure to the Homoeopathic Medical Students as per curriculum of BHMS and MD(Hom) and requirement laid down by the Central Council of Homoeopathy (minimum standards requirement of Homoeopathic Colleges and attached Hospitals) regulations2013.

II. MoU Term

The term o this MoU Agreement is the period within which the project responsibilities of this agreement shall be performed. The terms commences from 10.03.2017.

III. Party B Responsibilities

Party B shall undertake the following activities during the during of the MoU term

1.Ensure adherence of party A to at least 2hours per day clinical classes for batch wise students and six hours in two sift pr day for batch wise internees will be allowed by the Party B for clinical teaching and training as laid down in regulation.

2. Review and approve al documentation evidencing Party A ` s performance of services per regulations and monitor Party B` compliance with the MoU.

3. Provide training and technical assistances to Party A by providing exposure of the students in BHMS Course and MD (Hom) courses in the clinical field and to understand the depth of operative surgery and operative Gynecology and Obstetrics.

4.Not more than three months should allowed in any department for internees rotation period may be cut short as per requirement of Hospital authorities subject to prior approval writing from party A.

5. Party B will not create any restriction with regard to teaching and training programme. Teaching and training programme will be in accordance with curriculum as laid down by the Central Council of Homoeopathy.

6. Party B. will not be responsible for transportation of students .

7. Party B has the right to take action against any students for committing/breach of any discipline and decorum of Party B with information and consultation of Party A of his /her guilt.

8. Ensure that Party A`s Scope of work activities do not suffer for ensuring provision of curriculum requirement under the regulation.

IV Party A Responsibilities

Party A shall undertake the following activities during the duration of the MoU term.

1. Teaching and Training should be guided by the teaching staff of Party A.

2. Party A will ensure presence of Students / Internees a per the programme drawn under mutual understanding of both the party.

3. Party A will be responsible for transportation of the students /internee from respective college premises to the Party B premises.

No of corrections

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

4. Party A will ensure to replace or make good of any damages made to Party B by the students /Internee done during the period of teaching and training.

5. Party A will ensure that all student/Internee attending the teaching and training at Party B Hospital are under the guidance and supervision of in charge teaching faculty deputed by Party A.

6.Party A will ensure that Student /Internee attending the teaching and training programme at Super Specialty Hospital of Party B to, assist in the clinical and related activities of Party B.

7. Party A will follow all relevant laws and regulations regarding documentation , reporting use etc. in accordance with the provision of Hospital as well as regulations of the Central Council of Homoeopathy.

V. Parties A and B Agree to the Following Provision :

1.Documentation Approval and Acknowledgements .

All the activities of teaching and training will be suitably documented for record.

2.Special Terms and Conditions.

Party A and Party B shall follow all relevant and applicable regulations as specified in their respective area of application.

VI. Funding

1. Party A will ensure that all expenses related to students/internee teaching and training are borne and managed and themselves and will not create any liability of Party B.

2.Party B shall only provide time and pace for teaching and training programme for students/internee and will not charge for the services rendered by them.

VII. Modification and Termination.

1.This agreement may be cancelled or terminated without cause by either party by giving (30) calendar days advance written notice to the other party. Such notification shall state the effective date of termination or cancellation and include any final performance and/or payment invoicing instructions/requirements.

2.Any and al amendments must be made in writing and must be agreed to and executed by the parties before becoming effective.

VIII. Effective Date and Signature.

This MoU shall be effective upon the signature of Party A and Party B authorized official. It shall be in force from **10/03/2017 till 10/03/2022**

Indicate agreement with this MoU by their signatures.

Signatures and dates.

NOTARY Shri B. A. Nandi BELAGAVI Revenue Taluka Reg. No. Law 102/LCL/2016 Ex. Dt. 13-03-21 GOVT. OF KARNATAKA

Authorized signature from Party A)	(Authorized signature from arty B)
Dr. M.A. Udachankar.	Dr. S.C. Dharwad,
Principal, KLEU'S HMC	Director (CS) KLE Centenary Charitable Hospital Yellur Road
(name of Party A signatory)	(name of Part B signatory)
Date 10.3.2017	Date. 10.3.2017

Identified by

No of corrections. 1.

12 MAY 2017

B. A. NANDI, BA,LL.B. (Spl)
ATTESTOR & NOTARY, BELAGAVI
Reg At SL. No. 427/2017.

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

World Health Organization

COVERING LETTER
LETTRE D'ACCOMPAGNEMENT

Global Procurement and Logistics
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*	
WHO Reference	2019/928926-0
Purchase Order	202319732
Unit Reference	A65913

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

TECHNICAL SERVICES AGREEMENT (TSA)

Re: To conduct activities for WHO ACTION-1 and ACTION-2 Trials.

We are enclosing the Technical Services Agreement between the World Health Organization and PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM (JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM), KARNATAKA, in the amount of INR 11,773,153.21 (Eleven Million Seven Hundred Seventy-Three Thousand One Hundred Fifty-Three), for conducting the above-mentioned work. We also enclosed three attachment(s) referenced in the Agreement.

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

For any technical or scientific questions related to this Agreement, please contact the responsible technical officer, Olufemi Taiwo OLADAPO, 234 0 37 783403, oladapoo@who.int.

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

WHO Global Service Centre

Cc: WHO Representative; India

Concerne: To conduct activities for WHO ACTION-1 and ACTION-2 Trials.

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 11,773,153.21 (Eleven Million Seven Hundred Seventy-Three Thousand One Hundred Fifty-Three), vous permettant de mener à bien le travail susmentionné. Veuillez également trouver three pièces jointes mentionnées dans l'Accord.

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

Pour toutes questions à caractère scientifique ou technique ayant trait à cet Accord, veuillez contacter le responsible technique Olufemi Taiwo OLADAPO, 234 0 37 783403, oladapoo@who.int.

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

Centre de Soutien Administratif Mondial de l'OMS

Cc: Représentant de l'OMS, India

9/7/2019

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

World Health Organization

Global Procurement and Logistics
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Reference	2019/928926-0
Purchase Order	202319732
Unit Reference	A65913

TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

The WORLD HEALTH ORGANIZATION hereby agrees to provide to
L'ORGANISATION MONDIALE DE LA SANTÉ s'engage par la présente à fournir à
INSTITUTION:

PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM
(JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM)
KARNATAKA
PRINCIPAL INVESTIGATOR
Karnataka
India

Principal Investigator: DR.Shivaprasad Goudar
Telephone:
Fax:
Email/Courriel:

The Amount of/*Un Montant de*: INR 11,773,153.00 (Eleven Million Seven Hundred Seventy-Three Thousand One Hundred Fifty-Three)
In respect of/*en vue de:* To conduct activities for WHO ACTION-1 and ACTION-2 Trials.

For the period financed by this Agreement — *From/De* : 10-JUL-2019
***Période du projet** financée par le présent accord* — *To/A* : 31-OCT-2019

Summary of work/ *Description sommaire des travaux:*

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

A65913 (ACTION 1)
A65916 (ACTION 2)

See attached protocol

2. Contribution of the Institution and/or other sources for the project (Staff, equipment, supplies, etc. excluding general facilities). The Institute will provide all facilities, equipment and personnel not covered by this Agreement.
Contribution de l'Institution ou de tout autre organisme à l'exécution du projet (personnel, matériel, fournitures, etc, à l'exclusion des services d'ordre général). L'institution s'engage à fournir les locaux, équipement et personnels non couverts par cet accord.

Financial Arrangements/ *Dispositions financiers:*

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

	Deliverable/ Résultat	Due Date/ *Date Remise*	%	Currency Amount/ *Montant en Devise*
1	Upon signature	12-JUL-2019	100.00	11,773,153.21
2	Financial Report	31-OCT-2019	0.00	0.00
3	Technical report	31-OCT-2019	0.00	0.00

2. INR 0.00 will be used by WHO for the purchase of equipment and supplies to be ordered by the Institution as soon as practicable, but not beyond 31 December of the year following the end of the Agreement period as indicated above at which time any uncommitted balance will revert to WHO.

INR 0.00 *seront affectés par l'OMS à l'achat de matériels et de fournitures à commander par l'Institution dès que possible, mais au plus tard avant le 31 décembre de l'année suivant la fin de la période susmentionnée d'exécution de l'accord, étant entendu qu'à ce moment tout solde non engagé fera retour à l'OMS.*

Annexes

The following annexes form an integral part of this Agreement/ *Les annexes listées ci-dessous font partie intégrante de cet accord:*

Annex	File Description/Description de fichier
1	2019/928926 | Contractual - Budget Breakdown |
2	2019/928926 | Contractual - Terms of Reference |
3	2019/928926 | Contractual - Terms of Reference |

9/7/2019

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

General
The parties accept the "General Conditions" overleaf, which constitute an integral part of this Agreement. The Institution certifies the correctness of the banking

Généralités
Les parties acceptent les "Conditions générales" reproduites au verso, lesquelles font partie intégrante du présent accord. L'Institution certifie l'exactitude des

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

88

World Health Organization

Global Procurement and Logistics
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Reference	2019/928926-0
Purchase Order	202319732
Unit Reference	A65913

TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

Instructions provided on Page 1.
All necessary arrangements to comply with national regulations relating to this project and relevant to the Institution's responsibilities shall have been under-taken by the Institution; failure to do so will nullify this Agreement. The responsibility of the World Health Organization is limited only to the financial support as specified in this Agreement.

Instructions bancaires indiquées à la page 1.
Toutes les dispositions relevant des responsabilités de l'Institution et nécessaires à la mise en conformité de ce Projet avec la réglementation nationale, devront avoir été prises par l'Institution, faute de quoi l'accord sera nul. La responsabilité de l'Organisation Mondiale de la Santé se limite au soutien financier spécifié dans le présent accord.

ON BEHALF OF WHO/ *POUR L'OMS*

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

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

Responsible Divisional Director
Directeur de division responsable

Peter Joseph SALAMA
Executive Director
HQ/HIA ADGO Health Systems and Innovation

Authorized Signatory:
Signataire autorisé:

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

Processed by:
Traité par:

Kiranjeet Kaur
Senior Procurement Assistant
HQ/GSC Global Service Centre
09-JUL-2019

PRINCIPAL INVESTIGATOR/ *CHERCHEUR PRINCIPAL*

Principal Investigator or Technical Officer responsible for the project.
Chercheur Principal ou membre du personnel technique responsable de l'exécution du projet.

Signature : .....
DR.Shivaprasad Gouder 9/7/2019

ON BEHALF OF THE INSTITUTION/ *POUR L'INSTITUTION*

Responsible Administrative Authority*
*Autorité administrative responsable**

Signature : .....
Name/*nom* : Dr. N. S. Mahantashetti
Division : PRINCIPAL
Date JAWAHARLAL NEHRU MEDICAL COLLEGE
BELAGAVI-590010
09/07/2019

KAHER J.N. MEDICAL COLLEGE BELAGAVI

* An official of the Institution - other than the Principal Investigator - fully empowered to enter into contracting arrangements on behalf of the Institution./*Un responsable de l'Institution autre que le Chercheur principal - ayant pleins pouvoirs pour passer un contrat au nom de l'Institution.*

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

World Health Organization

TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

Global Procurement and Logistics
Block 3510
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MALAYSIA
psc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Reference	2019/928926-0
Purchase Order	202319732
Unit Reference	A65913

GENERAL CONDITIONS

The following are the general conditions relating to this Agreement concerning WHO support for research or other technical services. The purpose of such support is to assist an Institution to undertake, for WHO, investigations on a particular problem or other work which has been agreed upon by the Institution and WHO. If the support to be provided under this Agreement is a sub-grant under a principal grant to WHO, this Agreement shall be subject to WHO receiving the full amount of the principal grant. In the event WHO does not receive the full amount of the principal grant, WHO shall be entitled to either cancel this Agreement or adjust the amount to be provided hereunder (at WHO's sole discretion and without incurring any liability towards the Institution).

1. INSTITUTION AND PRINCIPAL INVESTIGATOR
1.1 The Institution and the Principal Investigator (or Responsible Technical Officer), who must be an employee of the Institution, shall be jointly responsible for all the technical and administrative aspects of the work referred to in this Agreement.
1.2 The Institution is required to notify WHO immediately of knowledge that the Principal Investigator will cease or ceases to be an employee of the Institution or is no longer continuing the responsibilities covered by this Agreement. Under such circumstances WHO has the right to:
(a) terminate this Agreement; or
(b) agree to continue the project under a new Principal Investigator proposed by the Institution and approved by WHO.

2. FINANCIAL ARRANGEMENTS
2.1 Payments shall be made into the bank account(s) of the Institution as specified in this Agreement and in accordance with the schedule of payments contained therein. If, after the submission of the final financial report referred to in paragraph 4.4 below, there remains an unused balance of funds with the Institution, this balance shall be due to WHO. In the event of this Agreement being terminated under any circumstances, the Institution shall refund to WHO the balance of uncommitted funds. The funds provided under this Agreement shall be expended only in accordance with its terms.
2.2 The funds transferred to the Institution under this Agreement may not be used to meet any form of emoluments, travel costs or any other reimbursements of expenditure to a staff member of WHO.
2.3 Unless otherwise provided in this Agreement, the funds transferred to the Institution hereunder may not be used to cover:
(a) normal administrative and overhead expenses of the Institution;
(b) cost of maintenance, repair, running or insurance of existing equipment and machinery belonging to the Institution;
(c) cost of construction of new buildings or alterations and modifications of existing buildings and premises; or
(d) salary support of the Principal Investigator.

3. EQUIPMENT AND SUPPLIES; PROCUREMENT
3.1 Unless otherwise agreed, and subject to subparagraph 3.2 below, any equipment and supplies acquired under this Agreement shall become the property of the Institution. The Institution and the Principal Investigator shall be jointly responsible for the proper safeguard, maintenance and care of all equipment and supplies acquired under this Agreement.
3.2 Notwithstanding subparagraph 3.1 above, the Institution shall transfer ownership of any equipment and supplies acquired under this Agreement to WHO, if so requested by WHO, upon termination or expiry of this Agreement. In such cases the Institution shall dispatch the equipment and supplies to any destination chosen by WHO, the cost of which will be borne by WHO.
3.3 To the extent the Institution needs to purchase any goods and/or services in connection with its performance of this Agreement, the Institution shall ensure that such goods and/or services shall be procured in accordance with the principle of best value for money. "Best value for money" means the responsive offer that is the best combination of technical specifications, quality and price.

4. REPORTS; AUDIT
The Institution shall submit technical and financial reports to WHO on the work as required, or at least annually, in accordance with the following provisions:
4.1 Technical reports shall be prepared by the Principal Investigator and forwarded through and countersigned by the authorized official of the Institution or his authorized representative. Each annual report shall summarize the results of the project and give in sufficient detail its positive and negative findings so that the value of the work can be assessed.
4.2 Financial reports shall be forwarded after being jointly certified by the Institution' s chief financial officer and the Principal Investigator, using form WHO 782. The reports must show the use of the funds provided by WHO compared with the original budget expenditure pattern agreed between the Institution and WHO.
4.3 WHO may request a financial and/or operational review or audit of the project and related activities, to be conducted by WHO and/or parties authorized by WHO, and the Institution undertakes to facilitate such review or audit. This review or audit may be carried out at any time during the implementation of the work performed under this Agreement, or within five years of completion of the work hereunder. The Institution shall make available, without restriction, to WHO and/or parties authorized by WHO:
(a) the Institution's books, records and systems (including all relevant financial and operational information) relating to the project and related activities; and
(b) reasonable access to the Institution's premises and personnel.
In order to facilitate financial reporting and audit, the Institution shall ensure that accurate and systematic accounts and records are kept in respect of the project and related activities. The Institution shall provide satisfactory explanations to all queries arising in connection with the aforementioned audit and access rights.
WHO may request the Institution to provide complementary information about the project and related activities that is reasonably available, including the findings and results of an audit (internal or external) conducted by the Institution and related to Such funds may be used only to support investigations where
(a) the rights and welfare of the subjects involved in the research are adequately protected,
(b) freely given informed consent has been obtained,
(c) the balance between risk and potential benefits involved has been assessed and deemed acceptable by a panel of independent experts appointed by the Institution and
(d) any special national requirements have been met.
8.2 Regulatory Requirements
It is the responsibility of the Institution and the Principal Investigator to comply with the relevant national regulations pertaining to research involving human subjects.
8.3 Protection of Subjects
Without prejudice to obligations under applicable laws, the Institution shall make appropriate arrangements to eliminate or mitigate the consequences to subjects or their families in the case of death, injury or illness resulting from the conduct of research referred to in paragraph 8.1. Such arrangements shall, to the extent feasible, include medical treatment and financial relief. The Institution and Principal Investigator undertake to protect the confidentiality of the information relating to the possible identification of subjects involved in the research involving human subjects conducted under the auspices of this Agreement.

9. RESEARCH INVOLVING THE USE OF LABORATORY ANIMALS
The Institution undertakes that living vertebrate animals, required for use as laboratory animals for the research to be carried out under this Agreement, shall be handled in accordance with generally accepted principles for the humane treatment of such animals and the avoidance of unnecessary suffering.

10. RESEARCH SAFETY
It is the responsibility of the Institution to establish and implement policies and practices to assure and provide for the safety of its employees, the public, and the environment during the conduct of the research to be carried out under this Agreement. If the supported research involves the use of dangerous biological agents, the Institution shall establish and implement an appropriate safety plan.

11. COMPLIANCE WITH WHO POLICIES
By entering into this Agreement, the Institution and Principal Investigator acknowledge that they have read, and hereby accept and agree to comply with, the WHO Policies (as defined below). In connection with the foregoing, the Institution and Principal Investigator shall take appropriate measures to prevent any violations of the standards of conduct (as described in the WHO Policies) by employees of the Institution and any other persons engaged by the Institution and/or Principal Investigator to perform any services under this Agreement. Without limiting the foregoing, the Institution and Principal Investigator shall each promptly report to WHO, in accordance with the terms of the applicable WHO Policies, any actual or suspected violations of any WHO Policies of which the Institution and/or Principal Investigator become aware. For purposes of this Agreement, the term "WHO Policies" means collectively:
(a) the WHO Code of Ethics and Professional Conduct;
(b) the WHO Policy on Sexual Exploitation and Abuse Prevention and Response;
(c) the WHO Code of Conduct for Responsible Research;
(d) the WHO Policy on Whistleblowing and Protection Against Retaliation; and
(e) the UN Supplier Code of Conduct, in each case, as amended from time to time and which are publicly available on the WHO website at the following links: http://www.who.int/about/finances-accountability/procurement/en/ for the UN Supplier Code of Conduct and at http://www.who.int/about/ethics/en/ for the other WHO Policies.

12. ZERO TOLERANCE FOR SEXUAL EXPLOITATION AND ABUSE
WHO has zero tolerance towards sexual exploitation and abuse in this regard, and without limiting any other provisions contained herein:
- the Institution warrants that it will:
(a) take all reasonable and appropriate measures to prevent sexual exploitation or abuse as described in the WHO Policy on Sexual Exploitation and Abuse Prevention and Response by any of its employees and any other persons engaged by it to perform any services under this Agreement; and
(b) promptly report to WHO and respond to, in accordance with the terms of the Policy, any actual or suspected violations of the Policy of which the Institution becomes aware; and
- The Principal Investigator warrants that he/she will
(a) not engage in any conduct that would constitute sexual exploitation or abuse as described in the WHO Policy on Sexual Exploitation and Abuse Prevention and Response; and
(b) promptly report to WHO, in accordance with the terms of the Policy, any actual or suspected violations of the Policy of which the Principal Investigator becomes aware.

13. TOBACCO- AND ARMS-RELATED DISCLOSURE
The Institution is required to disclose relationships it may have with the tobacco and/or arms industry through completion of the WHO Tobacco / Arms Disclosure Statement. The Institution undertakes not to permit work under this Agreement to commence until WHO has assessed the disclosed information and confirmed to the Institution in writing that the work can commence.

14. ANTI-TERRORISM AND UN SANCTIONS; FRAUD AND CORRUPTION
14.1 The Institution and Principal Investigator warrant for the entire duration of this Agreement that:
(a) they are not and will not be involved in, or associated with, any person or entity associated with terrorism, as designated by any UN Security Council sanctions regime; that they will not make any payment or provide any other support to any such person or entity; and that they will not enter into any employment or

7/7/2019

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the Project and/or related activities
4.4The final technical and financial reports must be submitted within 90 days after the expiry of this Agreement.

5. RELATIONSHIP AND RESPONSIBILITY OF PARTIES
The relationship of the Institution to WHO shall be that of an independent contractor. The employees of the Institution are not entitled to describe themselves as staff members of WHO. The Institution shall be solely responsible for the manner in which work on the project is carried out and accordingly shall assume full liability for any damage arising from research or other technical services under this Agreement. No liability shall attach to WHO, its advisers, agents or employees.

6. USE OF RESULTS, EXPLOITATION OF RIGHTS.
6.1 The results of the project funded under this Agreement may be freely used or disclosed by either party provided that, without the consent of the other party, no use may be made for commercial purposes and confidentiality shall be maintained with respect to results that may be eligible for protection by proprietary rights. The Institution shall provide WHO with the results, in the form of relevant know how and other information, and to the extent feasible, tangible products.
6.2 The industrial or commercial exploitation of any intellectual property rights, including the ownership of know-how, arising from the project shall be designed to achieve, in so far as circumstances permit, the following objectives in the following order of priority:
(a) the general availability of the products of creative activity;
(b) the availability of those products to the public health sector on preferential terms, particularly in developing countries;
(c) the grant to each party of additional benefits, including royalties, account being taken of the relative value of each party's financial, intellectual and other contribution to the research.
6.3 The rights referred to in paragraph. 6.2 shall belong to the Institution, or to the Principal Investigator if the Institution and WHO so agree. To the extent that the former do not intend to exercise them, the rights shall be promptly transferred to WHO, if it so requests. Each party shall provide the other with its full cooperation to permit the effective exercise of the rights. The party in which the corresponding rights are vested may file applications for industrial property protection, promptly furnishing copies of the applications and other patent documents to the other party. All rights other than the right to file applications shall be exercised in accordance with an agreement which shall be negotiated in good faith between the Institution and WHO.

7. PUBLICATIONS
7.1 Subject to any proprietary rights of WHO and/or third parties collaborating with WHO, the work supported by WHO under this Agreement may be published by the Institution and/or the Principal Investigator. In order to avoid prejudicing proprietary rights, the Institution or the Principal Investigator shall transmit to WHO for its review the material intended to be published at least 60 working days before a proposed publication is submitted to any editor, publisher, referee or meeting organizer. In the absence of any objection by WHO within that 60 working day period concerning prejudice to its proprietary rights, the publication may proceed.
7.2 Any publication by the Institution or the Principal Investigator of the work supported by WHO under this Agreement shall be published in accordance with the WHO policy on open access, which is available at the following link: http://www.who.int/about/policy/oa/.
7.3 In any publication by the Institution or the Principal Investigator relating to the results of the project, the responsibility for the direction of the work shall not be ascribed to WHO. Unless WHO advises otherwise, all publications shall include a notice indicating that the underlying investigation received financial support from WHO. Two off-prints or copies of each publication shall be sent to WHO unless another number is stipulated. WHO funds may not be used for publication costs unless specifically authorized.

8. RESEARCH INVOLVING HUMAN SUBJECTS
8.1 Ethical Aspects
It is the responsibility of the Institution and the Principal Investigator to safeguard the rights and welfare of human subjects involved in research supported in whole or in part by funds from WHO, in accordance with the appropriate national code of ethics or legislation, if any, and in the absence thereof, the Helsinki Declaration and any subsequent amendments.

subcontracting relationship with any such person or entity; and
(b) They shall not engage in any illegal, corrupt, fraudulent, collusive or coercive practices (including bribery, theft and other misuse of funds) in connection with the execution of this Agreement.
14.2 The Institution and Principal Investigator shall take all necessary precautions to prevent the financing of terrorism and/or any illegal corrupt, fraudulent, collusive or coercive practices (including bribery, theft and other misuse of funds) in connection with the execution of this Agreement.
14.3 Any funds used by the Institution and/or Principal Investigator for the promotion of any terrorist activity or any illegal, corrupt, fraudulent, collusive or coercive practice shall be repaid to WHO without delay.

15. BREACH OF ESSENTIAL TERMS
The Institution and Principal Investigator acknowledge and agree that each of the provisions in Sections 11, 12, 13 and 14 hereof constitutes an essential term of this Agreement, and that in case of breach of any of these provisions, WHO may, in its sole discretion, decide to:
(a) terminate this Agreement and/or any other contract concluded by WHO with the Institution and/or Principal Investigator, immediately upon written notice to them, without any liability for termination charges or any other liability of any kind; and/or
(b) exclude the Institution and/or Principal Investigator from participating in any ongoing or future tenders and/or entering into any future contractual or collaborative relationships with WHO.
WHO shall be entitled to report any breach of such provisions to WHO's governing bodies, other UN agencies, and/or donors.

16. PUBLICITY; USE OF WHO NAME AND EMBLEM
16.1 The Institution and the Principal Investigator shall not refer to the relationship of WHO to the project, or to products or processes connected with the project, in any statement or material of an advertising or promotional nature, including but not limited to any statements or materials issued for commercial purposes or with a view to financial benefit.
16.2 Without WHO's prior written approval, the Institution and/or the Principal Investigator shall not, in any statement or material of an advertising or promotional nature, refer to this Agreement or to the Institution's and/or Principal Investigator's relationship with WHO, or otherwise use the name (or any abbreviation thereof) or emblem of the World Health Organization.

17. PUBLICATION OF AGREEMENT
Subject to considerations of confidentiality, WHO may acknowledge the existence of this Agreement to the public and publish and/or otherwise publicly disclose the name of the Institution and/or Principal Investigator, the Institution's country of incorporation, general information with respect to the work supported under this Agreement, and this Agreement's value. Such disclosure will be made in accordance with WHO's Information Disclosure Policy and shall be consistent with the terms of this Agreement.

18. SURVIVING PROVISIONS
Those provisions of this Agreement that are intended by their nature to survive its expiration or earlier termination shall continue to apply.

19. SETTLEMENT OF DISPUTES
Any matter relating to the interpretation or application of this Agreement which is not covered by its terms shall be resolved by reference to Swiss law. Any dispute relating to the interpretation or application of this Agreement shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or, in the absence of agreement, with the Rules of Arbitration of the International Chamber of Commerce. The parties shall accept the arbitral award as final.

20. PRIVILEGES AND IMMUNITIES
Nothing contained in or relating to this Agreement shall be deemed to constitute a waiver of any of the privileges and immunities enjoyed by WHO under national or international law, and/or as submitting WHO to any national court jurisdiction.

9/7/2019

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Registrar
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World Health Organization

TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

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CONDITIONS GENERALES

Les conditions générales énoncées ci-après s'appliquent au présent Accord sur l'appui de l'OMS aux recherches ou autres services techniques. Cet appui vise à aider une institution à entreprendre pour le compte de l'OMS, des investigations portant sur un problème particulier ou des travaux convenus entre l'Institution et l'OMS. Si l'appui au titre du présent Accord provient d'une subvention principale accordée à l'OMS, le présent Accord est conclu sous réserve que le montant total de la subvention principale soit payé à l'OMS. Dans l'éventualité où l'OMS ne recevrait pas le montant total de la subvention principale, l'OMS se réserve le droit d'annuler le présent Accord ou d'ajuster le montant de l'appui à l'Institution (à la seule discrétion de l'OMS et sans encourir aucune responsabilité vis-à-vis de l'Institution).

1. INSTITUTION ET CHERCHEUR PRINCIPAL
1.1 L'Institution et le Chercheur principal (ou l'Administrateur technique responsable), lequel doit être employé par l'Institution, sont conjointement responsables de l'ensemble des aspects techniques et administratifs des travaux visés par le présent Accord.
1.2 L'Institution est tenue d'aviser immédiatement l'OMS lorsqu'elle apprend que le Chercheur principal va cesser, ou a cessé, d'être employé par elle, ou bien qu'il ne continue pas à exercer les fonctions visées par le présent Accord. En pareil cas, l'OMS peut:
(a) soit résilier le présent Accord;
(b) soit accepter de poursuivre le projet sous la conduite d'un nouveau Chercheur principal proposé par l'Institution et approuvé par l'OMS.

2. DISPOSITIONS FINANCIERES
2.1 Des versements seront faits au(x) compte(s) bancaire(s) de l'Institution comme il est stipulé dans le présent Accord et conformément au calendrier qui y figure. Si, après communication du rapport financier final mentionné plus loin au paragraphe 4.4, il apparaît que l'Institution détient un solde non utilisé, ce solde reste payable à l'OMS. En cas de résiliation du présent Accord, quelles qu'en soient les circonstances, l'Institution restituera à l'OMS les sommes non encore engagées. Les sommes fournies en vertu du présent Accord ne pourront être dépensées que conformément aux dispositions dudit Accord.
2.2 Les fonds versés à l'Institution en vertu du présent Accord ne peuvent être utilisés pour verser des émoluments quelconques à un fonctionnaire de l'OMS, couvrir ses frais de voyage ou lui rembourser toute autre dépense.
2.3 Sauf dispositions contraires du présent Accord, les fonds versés à l'Institution en vertu des présentes ne peuvent être utilisés pour couvrir:
(a) les dépenses administratives et les frais généraux normaux de l'Institution;
(b) le coût de l'entretien, de la réparation, de l'exploitation ou de l'assurance de matériels ou d'appareils existants qui appartiennent à l'Institution;
(c) le coût de la construction de nouveaux bâtiments, ou de la transformation ou de la modification de bâtiments et locaux existants; ou
(d) le versement d'un complément de traitement au Chercheur principal.

3. MATERIEL ET FOURNITURES; ACHAT
3.1 Sauf convention contraire, et sous réserve des dispositions de l'alinéa 3.2 ci-après, tout matériel et toutes fournitures obtenus en vertu du présent Accord sera la propriété de l'Institution. L'Institution et le Chercheur principal seront conjointement responsables du bon état de conservation, de la maintenance et de l'entretien de tout matériel et de toutes fournitures acquis en application du présent Accord.
3.2 Nonobstant les dispositions de l'alinéa 3.1 ci-dessus et si l'OMS en fait la demande, l'Institution transférera à celle-ci, lors de la résiliation ou de l'expiration du présent Accord, les droits de propriété afférents à tout matériel et à toutes fournitures acquis au titre dudit Accord. L'Institution expédiera alors ce matériel et ces fournitures vers toute destination que lui aura indiquée l'OMS, les frais d'expédition étant à la charge de cette dernière.
3.3 Dans la mesure où l'Institution doit acheter des biens et/ou des services dans le cadre de l'exécution du présent Accord, elle devra veiller à ce que l'achat de ces biens et/ou services soit effectué sur la base du principe du meilleur rapport qualité-prix. On entend par « meilleur rapport qualité-prix » l'offre qui présente la meilleure combinaison du point de vue des spécifications techniques, de la qualité et du prix.

4. RAPPORTS ; AUDIT
L'Institution soumettra à l'OMS des rapports techniques et financiers concernant ses travaux, chaque fois qu'il y a lieu et au moins une fois par an, selon les modalités suivantes :
4.1 Les rapports techniques seront établis par le Chercheur principal, envoyés sous couvert du responsable de l'Institution ou de son représentant l'un et l'autre dûment autorisés, et contresignés par eux. Chaque rapport annuel résumera les résultats du projet et en exposera les conclusions positives ou négatives de façon assez détaillée pour permettre d'apprécier la valeur des travaux.
4.2 Les rapports financiers devront être envoyés, après avoir été visés conjointement par le Chef des Services financiers de l'Institution et par le Chercheur principal. Les rapports devront indiquer l'utilisation des fonds provenant de l'OMS au regard des prévisions de dépenses initiales dont avaient convenu l'Institution et l'OMS.
4.3 L'OMS peut demander qu'un examen ou un audit de type financier et opérationnel du projet et des activités y afférentes, soit effectué par l'OMS et/ou par des parties autorisées par l'OMS, et l'Institution s'engage à faciliter cet examen ou cet audit. Cet examen ou cet audit peut être effectué à tout moment pendant la mise en œuvre du projet au titre du présent Accord, ou dans les cinq ans suivant son achèvement. L'Institution permettra à l'OMS et/ou aux parties autorisées par celle-ci, sans restriction :
(a) de consulter ses livres, archives et systèmes (y compris l'ensemble des

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(a) les droits et le bien-être des sujets impliqués sont protégés comme il convient;
(b) le consentement libre et éclairé des intéressés a été obtenu;
(c) un groupe d'experts indépendants désignés par l'Institution ont pesé les risques et les avantages potentiels et ont jugé qu'ils s'équilibraient de manière acceptable; et
(d) toute exigence particulière de la réglementation nationale a été satisfaite.
8.2 Dispositions réglementaires
Il incombe à l'Institution et au Chercheur principal de respecter la réglementation nationale relative aux recherches impliquant l'étude de sujets humains.
8.3 Protection des sujets d'expérience
Sans préjudice des obligations qui lui incombent aux termes des lois en vigueur, l'Institution prendra des dispositions appropriées en vue d'éliminer ou d'atténuer les conséquences des expériences pour les sujets ou leur famille en cas de décès, de traumatisme ou de maladie résultant de la conduite des recherches mentionnées au paragraphe 8.1. Ces dispositions comprendront, dans la mesure du possible, un traitement médical et un dédommagement financier. L'Institution et le Chercheur principal s'engagent à protéger le caractère confidentiel des informations qui pourraient permettre d'identifier les sujets impliqués dans les études effectuées en vertu du présent Accord.

9. RECHERCHES IMPLIQUANT L'UTILISATION D'ANIMAUX DE LABORATOIRE
L'Institution s'engage à veiller à ce que les animaux vertébrés vivants qu'il sera nécessaire d'utiliser comme animaux de laboratoire pour des recherches entreprises en vertu du présent Accord soient traités conformément aux principes généralement admis destinés à assurer un traitement humain des animaux et à leur épargner toute souffrance inutile.

10. SECURITE DES RECHERCHES
Il incombe à l'Institution d'établir et d'appliquer des politiques et pratiques visant à préserver et garantir la sécurité de ses employés, celle du public et de de l'environnement pendant le déroulement des recherches qui seront effectuées au titre du présent Accord. Si les travaux impliquent l'utilisation de substances biologiques dangereuses, l'Institution établira et appliquera un plan de sécurité approprié.

11. RESPECT DES POLITIQUES DE L'OMS
En signant le présent Accord, l'Institution et le Chercheur principal reconnaissent avoir lu les politiques de l'OMS (telles que définies ci-après) et, par les présentes, acceptent ces politiques et conviennent de s'y conformer. En lien avec ce qui précède, l'Institution et le Chercheur principal prendront les mesures appropriées afin de prévenir et répondre à toute violation des normes de conduite, telles que décrites dans les politiques de l'OMS, par les employés de l'Institution ou toute autre personne que l'Institution et/ou le Chercheur principal aura engagée en vue de fournir un quelconque service au titre du présent Accord. Sans limiter la portée de ce qui précède, l'Institution et le Chercheur principal signaleront immédiatement à l'OMS, conformément aux dispositions des politiques de l'OMS applicables, toute violation réelle ou présumée dont ils ont connaissance concernant toute politique de l'OMS. Aux fins du présent Accord, l'expression « politiques de l'OMS » désigne, collectivement :
(a) le Code d'éthique et de déontologie de l'OMS,
(b) la Politique de l'OMS relative à la prévention et à la lutte contre l'exploitation et les abus sexuels,
(c) le Code de conduite pour une recherche responsable,
(d) la Politique de l'OMS sur le signalement des actes répréhensibles et la protection contre les représailles et
e) le Code de conduite des fournisseurs des Nations Unies, y compris leurs modifications éventuelles et qui sont publiquement accessibles sur le site Internet de l'OMS aux liens suivants : http://www.who.int/about/finances-accountability/procurement/en/ (pour ce qui est du Code de conduite des fournisseurs des Nations Unies) et http://www.who.int/about/ethics/en/ (pour ce qui est des autres politiques de l'OMS).

12. TOLERANCE ZERO POUR L'EXPLOITATION ET LES ABUS SEXUELS
L'OMS applique la tolérance zéro en matière d'exploitation et d'abus sexuels. À cet égard, et sans limiter la portée de toute autre disposition du présent Accord :
- l'Institution garantit:
(a) qu'elle prendra toutes les mesures raisonnables et appropriées pour prévenir tout acte d'exploitation ou d'abus sexuels tels que décrits dans la Politique de l'OMS relative à la prévention et à la lutte contre l'exploitation et les abus sexuels, par l'un quelconque de ses employés et toute autre personne engagée par elle en vue de fournir un quelconque service au titre du présent Accord ; et
(b) qu'elle signalera immédiatement à l'OMS et donnera suite à toute violation réelle ou présumée de cette Politique dont elle a connaissance, conformément aux dispositions de la Politique; et
- le Chercheur principal garantit:
(a) qu'il n'adoptera aucun comportement qui relèverait de l'exploitation ou l'abus sexuels tels que décrits dans la Politique de l'OMS relative à la prévention et à la lutte contre l'exploitation et les abus sexuels, et
(b) qu'il signalera immédiatement à l'OMS toute violation réelle ou présumée de la Politique dont il a connaissance, conformément aux dispositions de la Politique.

13. DECLARATION RELATIVE A L'INDUSTRIE DU TABAC/DE L'ARMEMENT
L'Institution est tenue de déclarer ses éventuelles relations avec l'industrie du tabac et/ou de l'armement en remplissant la déclaration requise par l'OMS relative à l'industrie du tabac/de l'armement. Elle s'engage à ne pas autoriser le commencement des travaux tant que l'OMS n'a pas évalué les informations

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TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

informations financières et opérationnelles pertinentes) relatifs au projet et aux activités y afférentes; et
(b) d'avoir un accès raisonnable à ses locaux et à son personnel.
Afin de faciliter l'établissement de rapports financiers et la réalisation d'un audit financier, l'Institution tiendra des comptes et des registres exacts et systématiques concernant le projet et les activités y afférentes. L'Institution fournira des explications satisfaisantes en réponse à toutes les questions découlant de l'audit et des droits d'accès susmentionnés.
L'OMS pourra demander à l'Institution de lui communiquer des informations complémentaires concernant le projet et les activités y afférentes qui sont raisonnablement à sa disposition, y compris les conclusions et les résultats d'un audit (interne ou externe) effectué par l'Institution et relatif au projet et/ou aux activités y afférentes.
4.4 Les rapports techniques et financiers finaux devront être présentés dans les 90 jours suivant l'expiration du présent Accord.

5. RELATIONS ENTRE LES PARTIES ET LEURS RESPONSABILITES
L'Institution agira à l'égard de l'OMS en tant qu'entrepreneur indépendant; ses employés ne pourront se prévaloir de la qualité de membres du personnel de l'OMS. L'Institution sera seule responsable de la façon dont s'exécute le projet et, partant, assumera l'entière responsabilité de tout dommage résultant de recherches ou d'autres services techniques visés par le présent Accord. Aucune responsabilité ne pourra incomber à l'OMS, ses conseillers, agents ou employés.

6. UTILISATION DES RESULTATS, EXPLOITATION DES DROITS
6.1 Les résultats du projet financé en vertu du présent Accord pourront être librement utilisés ou divulgués par l'une ou l'autre partie. Toutefois, à défaut du consentement de l'autre partie, les résultats ne pourront être utilisés à des fins commerciales et, s'ils sont susceptibles d'être protégés par des droits de propriété, ils conserveront leur caractère strictement confidentiel. L'Institution communiquera à l'OMS les résultats des recherches, sous forme de savoir-faire et autres informations pertinents et, dans la mesure du possible, lui fournira des produits concrets.
6.2 L'exploitation industrielle ou commerciale de tout droit de propriété intellectuelle, y compris les droits qui s'attachent au savoir-faire, découlant du projet, devra permettre, dans toute la mesure du possible, d'atteindre les objectifs suivants énoncés par ordre de priorité:
(a) mise à la disposition générale de tous les produits de l'activité créatrice;
(b) leur mise à la disposition auprès du secteur de la santé publique, à des conditions préférentielles, en particulier dans les pays en développement;
(c) octroi à chaque partie d'avantages additionnels, y compris sous formes de royalties, compte tenu de la valeur relative de ses contributions financières, intellectuelles et autres.
6.3 Les droits mentionnés plus haut au paragraphe 6.2 seront la propriété de l'Institution, ou du Chercheur principal si l'Institution et l'OMS en conviennent ainsi. Dans la mesure où l'Institution n'entend pas les exercer, les droits seront promptement transmis à l'OMS, si celle-ci le demande. Chaque partie coopérera pleinement avec l'autre pour lui permettre d'exercer effectivement ses droits. La partie détentrice des droits pourra déposer des demandes de propriété industrielle et devra alors remettre à l'autre partie copie de ces dépôts et des autres documents relatifs au brevet. Tous les droits autres que celui de déposer des demandes s'exercent aux termes d'un accord qui sera négocié de bonne foi entre l'Institution et l'OMS.

7. PUBLICATIONS
7.1 Sous réserve des droits de propriété de l'OMS et/ou de tiers qui collaborent avec elle, les travaux financés par l'OMS au titre du présent Accord peuvent être publiés par l'Institution et/ou le Chercheur principal. Afin d'éviter de porter atteinte à des droits de propriété, l'Institution ou le Chercheur principal transmettra à l'OMS, pour examen, le document qu'il est prévu de publier, au moins 60 jours ouvrables avant qu'une proposition de publication ne soit présentée à un quelconque éditeur, maison d'édition, arbitre scientifique ou organisateur d'une réunion. Si l'OMS ne formule aucune objection pendant ces 60 jours ouvrables concernant une violation de ses droits de propriété, la publication peut avoir lieu.
7.2 Toute publication, par l'Institution ou le Chercheur principal, des travaux financés par l'OMS au titre du présent Accord sa fera conformément à la politique de l'OMS en matière de libre accès, qui peut être consultée à l'adresse suivante: http://www.who.int/about/policy/fr/ .
7.3 Dans aucune de ses publications concernant les résultats du projet, l'Institution ou le Chercheur principal n'attribuera à l'OMS la responsabilité de la direction des travaux. Sauf instructions contraires de l'OMS, toutes les publications comporteront une note indiquant que les recherches qui sont à l'origine des résultats ont reçu un appui financier de l'OMS. A moins qu'un autre chiffre n'ait été stipulé, deux exemplaires ou tirages de chaque publication seront envoyés à l'OMS. Sauf autorisation expresse, les fonds de l'OMS ne pourront être utilisés pour couvrir les coûts de publication.

8. RECHERCHES IMPLIQUANT L'ETUDE DE SUJETS HUMAINS
8.1 Aspects éthiques
Il incombe à l'Institution et au Chercheur principal de s'assurer qu'au cours des travaux financés totalement ou en partie par l'OMS et impliquant l'étude de sujets humains, les droits et le bien-être de ces derniers soient protégés conformément au code éthique ou à la législation appropriés du pays, ou, à défaut, à la Déclaration d'Helsinki et aux amendements qui pourraient lui être ultérieurement apportés. Les fonds ne peuvent être utilisés pour financer des recherches que si les conditions suivantes sont remplies:
communiquées et confirmé par écrit à l'Institution que ces travaux peuvent commencer.

14. ANTI-TERRORISME ET SANCTIONS DE L'ONU; FRAUDE ET CORRUPTION
14.1 L'Institution et le Chercheur principal garantissent, pour toute la durée du présent Accord :
(a) qu'ils ne sont ni ne seront impliqués à l'égard de, ni associés à, aucune personne ou entité que le régime de sanctions du Conseil de sécurité des Nations Unies a désignée comme étant associée au terrorisme, qu'ils ne feront aucun paiement à, ou ne soutiendront d'aucune autre manière, à une telle personne ou entité, et qu'ils ne concluront aucune relation d'emploi ni de sous-traitance avec une telle personne ou entité; et
(b) qu'ils ne prendront part à aucune pratique illégale, de corruption, de fraude, de collusion ou de coercition (y compris pots de vin, vol ou autre utilisation abusive de fonds) en lien avec l'exécution du présent Accord.
14.2 L'Institution et le Chercheur principal prendront toutes les précautions nécessaires pour empêcher le financement du terrorisme et/ou toute pratique illégale, de corruption, de fraude, de collusion ou de coercition (y compris, pots de vin, vol ou autre utilisation abusive de fonds) en lien avec l'exécution du présent Accord.
14.3 Toute somme que l'Institution et/ou le Chercheur principal utiliseraient pour promouvoir une quelconque activité terroriste ou une quelconque pratique illégale, de corruption, de fraude, de collusion ou de coercition sera remboursée à l'OMS sans délai.

15. VIOLATION DE CLAUSES ESSENTIELLES
L'Institution et le Chercheur principal reconnaissent et acceptent que chacune des dispositions des sections 11, 12, 13 et 14 des présentes constitue une clause essentielle du présent Accord et qu'en cas de manquement à l'une quelconque de ces dispositions, l'OMS peut, à sa seule discrétion, décider :
(a) de résilier immédiatement le présent Accord, et/ou tout autre contrat conclu par l'OMS avec l'Institution et/ou le Chercheur principal, moyennant une notification écrite adressée à ceux-ci, sans être redevable d'aucune pénalité au titre d'une telle résiliation et sans que sa responsabilité ne soit engagée d'une quelconque manière que ce soit; et/ou
(b) d'exclure l'Institution et/ou le Chercheur principal de toute participation à des appels d'offres en cours ou à venir et/ou de toute relation contractuelle ou de collaboration future avec l'OMS.
L'OMS sera en droit de rapporter toute violation de ces dispositions à ses organes directeurs, aux autres organismes des Nations Unies et/ou aux donateurs.

16. PUBLICITE ; UTILISATION DU NOM ET DE L'EMBLEME DE L'OMS
16.1 L'Institution et le Chercheur principal ne pourront faire mention, dans un quelconque écrit ou déclaration à caractère publicitaire ou promotionnel, y compris, sans s'y limiter, ceux qui sont diffusés à des fins commerciales, ou en vue d'un avantage financier, du lien existant entre l'OMS et le projet ou les produits ou procédés en découlant.
16.2 Ni l'Institution ni le Chercheur principal n'auront le droit, dans une déclaration ou support à caractère publicitaire ou promotionnel, de faire référence au présent Accord ou à leur relation avec l'OMS, ni d'utiliser d'une autre manière le nom (ou toute abréviation de celui-ci) et/ou l'emblème de l'Organisation mondiale de la Santé, sans l'autorisation écrite préalable de l'OMS.

17. PUBLICATION DE L'ACCORD
Sous réserve de considérations relatives à la confidentialité, l'OMS a le droit de divulguer l'existence du présent Accord et de publier, et/ou rendre public d'une autre manière, le nom de l'Institution et/ou du Chercheur principal, le pays d'enregistrement de l'Institution, des informations générales concernant les travaux financés au titre des présentes et la valeur du présent Accord. Cette divulgation se fera conformément à la politique de l'OMS sur la divulgation des informations et aux dispositions du présent Accord.

18. DISPOSITIONS RESTANT EN VIGUEUR APRES LA FIN DE L'ACCORD
Les dispositions du présent Accord qui sont, de par leur nature, destinées à survivre à l'expiration ou à la résiliation anticipée de l'Accord continueront de s'appliquer.

19. REGLEMENT DES DIFFERENDS
Toute question concernant l'interprétation ou l'application du présent Accord que les dispositions de ce dernier ne permettent pas de résoudre doit être résolue par référence au droit suisse. Tout différend relatif à l'application ou à l'interprétation du présent Accord qui n'aurait pu être résolu à l'amiable, fera l'objet d'une conciliation. En cas d'échec de celle-ci, le différend sera réglé par arbitrage. Les modalités de l'arbitrage seront convenues entre les parties ou, en l'absence d'accord, seront déterminées selon le Règlement d'arbitrage de la Chambre de commerce internationale. Les parties reconnaissent que la sentence arbitrale sera finale.

20. PRIVILEGES ET IMMUNITES
Aucun des termes du présent Accord ni rien qui s'y rapporte ne sera considéré comme constituant une renonciation à quelque privilège ou immunité que ce soit dont jouit l'OMS en vertu du droit national ou international et/ou interprété comme une soumission de l'OMS à la compétence d'une quelconque juridiction nationale.

ATTESTED

9/7/2019

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

World Health Organization

COVERING LETTER
LETTRE D'ACCOMPAGNEMENT

Global Procurement and Logistics
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*	
WHO Reference	2017/716530-0
Purchase Order	201737246
Unit Reference	

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

TECHNICAL SERVICES AGREEMENT (TSA)

Re: To conduct preparatory activities for WHO ACTION-1 and ACTION-2 Trials. To initiate participant recruitment for WHO ACTION-1 Trial. To initiate participant recruitment for WHO ACTION-2 Trial (pending receipt of all necessary approval

We are enclosing the Technical Services Agreement between the World Health Organization and PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM (JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM), KARNATAKA, in the amount of INR 28,889,270.16 (Twenty-Eight Million Eight Hundred Eighty-Nine Thousand Two Hundred Seventy), for conducting the above-mentioned work. We also enclosed five attachment(s) referenced in the Agreement.

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

For any technical or scientific questions related to this Agreement, please contact the responsible technical officer, Joshua VOGEL, vogeljo@who.int.

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

WHO Global Service Centre

Cc: WHO Representative, India

Concerne: To conduct preparatory activities for WHO ACTION-1 and ACTION-2 Trials. To initiate participant recruitment for WHO ACTION-1 Trial. To initiate participant recruitment for WHO ACTION-2 Trial (pending receipt of all necessary approval

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 28,889,270.16 (Twenty-Eight Million Eight Hundred Eighty-Nine Thousand Two Hundred Seventy), vous permettant de mener à bien le travail susmentionné. Veuillez également trouver five pièces jointes mentionnées dans l'Accord.

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

Pour toutes questions à caractère scientifique ou technique ayant trait à cet Accord, veuillez contacter le responsible technique Joshua VOGEL, vogeljo@who.int.

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

Centre de Soutien Administratif Mondial de l'OMS

Cc: Représentant de l'OMS, India

12/5/2017
Research Co- Ordinator
JNMC - Women's & Children's
Health Research Unit,
J.N. Medical College, BELAGAVI.

J.N. MEDICAL COLLEGE * BELAGAVI *

12/5/2017
Principal
JNMC, BELAGAVI

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

World Health Organization

Global Procurement and Logistics
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Reference	2017/716530-0
Purchase Order	201737246
Unit Reference	

TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

The WORLD HEALTH ORGANIZATION hereby agrees to provide to
L'ORGANISATION MONDIALE DE LA SANTÉ s'engage par la présente à fournir à
INSTITUTION:

PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM
(JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM)
KARNATAKA
PRINCIPAL INVESTIGATOR
Karnataka
India

Principal Investigator: DR.Shivaprasad Goudar
Telephone:
Fax:
Email/Courriel:

The Amount of/*Un Montant de*: INR 28,889,270.00 (Twenty-Eight Million Eight Hundred Eighty-Nine Thousand Two Hundred Seventy)
In respect of/*en vue de:* To conduct preparatory activities for WHO ACTION-1 and ACTION-2 Trials. To initiate participant recruitment for WHO ACTION-1 Trial. To initiate participant recruitment for WHO ACTION-2 Trial (pending receipt of all necessary approval

For the period financed by this Agreement — From/*De* : 15-MAY-2017
***Période du projet** financée par le présent accord* — To/*A* : 31-JUL-2018

Summary of work/ *Description sommaire des travaux:*

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

A65913 (ACTION 1)
A65916 (ACTION 2)

See attached protocol

2. Contribution of the Institution and/or other sources for the project (Staff, equipment, supplies, etc. excluding general facilities).
The Institute will provide all facilities, equipment and personnel not covered by this Agreement.
Contribution de l'Institution ou de tout autre organisme à l'exécution du projet (personnel, matériel, fournitures, etc, à l'exclusion des services d'ordre général). L'Institution s'engage à fournir les locaux, équipement et personnels non couverts par cet accord.

Financial Arrangements/ *Dispositions financiers:*

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

	Deliverable/ Résultat	Due Date/ *Date Remise*	%	Currency Amount/ *Montant en Devise*
1	Upon signature	22-MAY-2017	100.00	28,889,270.16
2	Financial Report	31-JUL-2018	0.00	0.00
3	Technical report	31-JUL-2018	0.00	0.00

2. INR 0.00 will be used by WHO for the purchase of equipment and supplies to be ordered by the Institution as soon as practicable, but not beyond 31 December of the year following the end of the Agreement period as indicated above at which time any uncommitted balance will revert to WHO.

INR 0.00 *seront affectés par l'OMS à l'achat de matériels et de fournitures à commander par l'Institution dès que possible, mais au plus tard avant le 31 décembre de l'année suivant la fin de la période susmentionnée d'exécution de l'accord, étant entendu qu'à ce moment tout solde non engagé fera retour à l'OMS.*

Annexes

The following annexes form an integral part of this Agreement/ *Les annexes listées ci-dessous font partie intégrante de cet accord:*

Annex	File Description/Description de fichier
1	2017/716530 | Contractual - Statement of Work |
2	2017/716530 | Contractual - Statement of Work |
3	2017/716530 | Contractual - Budget Breakdown | Budget ACTION 1 AND 2
4	2017/716530 | Contractual - Terms of Reference |
5	2017/716530 | Contractual - Statement of Work |

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

12/5/2017
Research Co-Ordinator
JNMC Women's & Children Health Research Unit
J.N. Medical College, BELAGAVI

J.N. MEDICAL COLLEGE ★ BELAGAVI ★

12/5/2017
Principal
JNMC, BELAGAVI

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

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World Health Organization

Global Procurement and Logistics
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Reference	2017/716530-0
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Unit Reference	

TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

General

The parties accept the "General Conditions" overleaf, which constitute an integral part of this Agreement. The institution certifies the correctness of the banking instructions provided on Page 1.

All necessary arrangements to comply with national regulations relating to this project and relevant to the Institution's responsibilities shall have been under-taken by the Institution; failure to do so will nullify this Agreement. The responsibility of the World Health Organization is limited only to the financial support as specified in this Agreement.

Généralités

Les parties acceptent les "Conditions générales" reproduites au verso, lesquelles font partie intégrante du présent accord. L'institution certifie l'exactitude des instructions bancaires indiquées à la page 1.

Toutes les dispositions relevant des responsabilités de l'Institution et nécessaires à la mise en conformité de ce Projet avec la réglementation nationale, devront avoir été prises par l'institution, faute de quoi l'accord sera nul. La responsabilité de l'Organisation Mondiale de la Santé se limite au soutien financier spécifié dans le présent accord.

ON BEHALF OF WHO/ *POUR L'OMS*

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

Joshua Vogel
Technical Officer
HQ/RHR - Reproductive Health and Research

Responsible Divisional Director
Directeur de division responsable

Flavia BUSTREO
Asst Director-General
HQ/FWA FWC ADGO Office of the Assistant DG

Authorized Signatory:
Signataire autorisé:

Mr Motohiro Ogita
Coordinator
Global Procurement and Logistics
(WHO/GMG/GSC/GPL)

Motohiro Ogita
Coordinator
HQ/GSC Global Service Centre
06-MAY-2017

PRINCIPAL INVESTIGATOR/ *CHERCHEUR PRINCIPAL*

Principal Investigator or Technical Officer responsible for the project.
Chercheur Principal ou membre du personnel technique responsable de l'exécution du projet.

Signature : 12/5/2017
DR.Shivaprasad Goudar

ON BEHALF OF THE INSTITUTION/ *POUR L'INSTITUTION*

Responsible Administrative Authority*
*Autorité administrative responsable**

Signature : .....
Name/*nom* : DR.N.S.MAHANTSHETTI
Division : Principal, JNMC, Belgaum
Date : 12/05/2017

MEDICAL COLLEGE ★ BELAGAVI ★

Principal
JNMC, BELAGAVI

* An official of the Institution - other than the Principal Investigator - fully empowered to enter into contracting arrangements on behalf of the Institution/*Un responsable de l'Institution autre que le Chercheur principal - ayant pleins pouvoirs pour passer un contrat au nom de l'Institution.*

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

World Health Organization

TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

Global Procurement and Logistics
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MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Reference	2017/716530-0
Purchase Order	201737246
Unit Reference	

GENERAL CONDITIONS

The following are the general conditions relating to this Agreement concerning WHO support for research or other technical services. The purpose of such support is to assist an Institution to undertake, for WHO, investigations on a particular problem or other work which has been agreed upon by the Institution and WHO.

1 INSTITUTION AND PRINCIPAL INVESTIGATOR
1.1 The Institution and the Principal Investigator (or Responsible Technical Officer), who must be an employee of the Institution, shall be jointly responsible for all the technical and administrative aspects of the work referred to in this Agreement.
1.2 The Institution is required to notify WHO immediately of knowledge that the Principal Investigator will cease or ceases to be an employee of the Institution or is no longer continuing the responsibilities covered by this Agreement. Under such circumstances WHO has the right to:
a. cancel this Agreement or
b. agree to continue the project under a new Principal Investigator proposed by the Institution and approved by WHO.

2. FINANCIAL ARRANGEMENTS
2.1 Payments shall be made to the bank account(s) of the Institution as specified in this Agreement and in accordance with the schedule of payments contained therein. If, after the submission of the final financial report referred to in paragraph 4.3 below, there remains an unused balance of funds with the Institution, this balance shall be due to WHO. In the event of this Agreement being cancelled under any circumstances, the Institution shall refund to WHO the balance of uncommitted funds. The funds provided under this Agreement shall be spent only in accordance with its terms.
2.2 The funds transferred to the Institution under this Agreement may not be used to meet any form of emoluments, travel costs or any other reimbursements of expenditure to a staff member of WHO.
2.3 Unless otherwise provided in this Agreement the funds may not be used to cover:
a. normal administrative and overhead expenses of the Institution;
b. cost of maintenance, repair, running or insurance of existing equipment and machinery belonging to the Institution;
c. cost of construction of new buildings or alterations and modifications of existing buildings and premises;
d. salary support of the Principal Investigator.

3. EQUIPMENT AND SUPPLIES
3.1 Unless otherwise agreed, and subject to subparagraph 3.2 below, any equipment acquired under this Agreement shall become the property of the Institution. The Institution and the Principal Investigator shall be jointly responsible for the proper safeguard, maintenance and care of all equipment acquired under this Agreement.
3.2 Notwithstanding subparagraph 3.1 above, the Institution shall transfer ownership of any equipment acquired under this Agreement to WHO, if so requested by WHO, upon termination or expiry of this Agreement. In such cases the Institution shall dispatch the equipment to any destination chosen by WHO, the cost of which will be borne by WHO.

4. REPORTS
The Institution shall submit technical and financial reports to WHO on the work as required, or at least annually, in accordance with the following provisions:
4.1 Technical reports shall be prepared by the Principal Investigator and forwarded through and countersigned by the authorized official of the Institution or his authorized representative. Each annual report shall summarize the results of the project and give in sufficient detail its positive and negative findings so that the value of the work can be assessed.
4.2 Financial reports shall be forwarded after being jointly certified by the Institution's Chief Financial Officer and the Principal Investigator, using form WHO 782. The reports must show the use of the funds provided by WHO compared with the original budget expenditure pattern agreed between the Institution and WHO.
4.3 All Financial and Technical reports are subject to audit by WHO, including examination of supporting documentation and relevant accounting entries in the Institution's books. In order to facilitate such reporting and audit, the Institution shall ensure that accurate and systematic accounts and records are kept in respect of the project. The final Technical and Financial reports must be submitted within 90 days after the expiry of this Agreement.

5. RELATIONSHIP AND RESPONSIBILITY OF PARTIES
The relationship of the Institution to WHO shall be that of an independent contractor. The employees of the Institution are not entitled to describe themselves as staff members of WHO. The Institution shall be solely responsible for the manner in which work on the project is carried out and accordingly shall assume full liability for any damage arising from research or other technical services under this Agreement. No liability shall attach to WHO, its advisers, agents or employees.

6. USE OF RESULTS, EXPLOITATION OF RIGHTS, AND PUBLICATION
6.1 The results of the project funded under this Agreement may be freely used or disclosed by either party provided that, without the consent of the other party, no use may be made for commercial purposes and confidentiality shall be maintained with respect to results that may be eligible for protection by proprietary rights. The Institution shall provide WHO with the results, in the form of relevant know how and other information, and to the extent feasible, tangible products.
6.2 The industrial or commercial exploitation of any intellectual property rights, including the ownership of know-how, arising from the project shall be designed to achieve, in so far as circumstances permit, the following objectives in the following order of priority:
a. the general availability of the products of creative activity;
b. the availability of those products to the public health sector on preferential terms, particularly in developing countries;
c. the grant to each party of additional benefits, including royalties, account being taken of the relative value of each party's financial, intellectual and other contribution to the research.
6.3 The rights referred to in para. 6.2 shall belong to the Institution, or to the Principal Investigator if the Institution and WHO so agree. To the extent that the former do not intend to exercise them, the rights shall be promptly transferred to WHO, if it so requests. Each party shall provide the other with its full cooperation to permit the effective exercise of the rights. The party in which the corresponding rights are vested may file applications for industrial property protection, promptly furnishing copies of the applications and other patent documents to the other party. All rights other than the right to file applications shall be exercised in accordance with an agreement which shall be negotiated in good faith between the Institution and WHO.
6.4 In any publication by the Institution or the Principal Investigator relating to the results of the project, the responsibility for the direction of the work shall not be ascribed to WHO. Unless WHO advises otherwise, all publications shall include a notice indicating that the underlying investigation received financial support from WHO. Two off-prints or copies shall be sent to WHO unless another number is stipulated. WHO funds may not be used for publication costs unless specifically authorized.

7. RESEARCH INVOLVING HUMAN SUBJECTS
7.1 Ethical Aspects
It is the responsibility of the Institution and the Principal Investigator to safeguard the rights and welfare of human subjects involved in research supported in whole or in part by funds from WHO, in accordance with the appropriate national code of ethics or legislation, if any, and in the absence thereof, the Helsinki Declaration and any subsequent amendments. Such funds may be used only to support investigations where (a) the rights and welfare of the subjects involved in the research are adequately protected, (b) freely given informed consent has been obtained, (c) the balance between risk and potential benefits involved has been assessed and deemed acceptable by a panel of independent experts appointed by the Institution and (d) any special national requirements have been met.
7.2 Regulatory Requirements
It is the responsibility of the Institution and the Principal Investigator to comply with the relevant national regulations pertaining to research involving human subjects.
7.3 Protection of Subjects
Without prejudice to obligations under applicable laws, the Institution shall make appropriate arrangements to eliminate or mitigate the consequences to subjects or their families in the case of death, injury or illness resulting from the conduct of research referred to in paragraph 7.1. Such arrangements shall, to the extent feasible, include medical treatment and financial relief. The Institution and Principal Investigator undertake to protect the confidentiality of the information relating to the possible identification of subjects involved in the research involving human subjects conducted under the auspices of this Agreement.

8. RESEARCH INVOLVING THE USE OF LABORATORY ANIMALS
The Institution undertakes that living vertebrate animals, required for use as laboratory animals for the research to be carried out under this Agreement, shall be handled in accordance with generally accepted principles for the humane treatment of such animals and the avoidance of unnecessary suffering.

9. RESEARCH SAFETY
It is the responsibility of the Institution to establish and implement policies and practices to assure and provide for the safety of its employees, the public, and the environment during the conduct of the supported research. If the supported research involves the use of dangerous biological agents, the Institution shall establish and implement an appropriate safety plan.

10. PUBLICITY
The Institution and the Principal Investigator shall not refer to the relationship of WHO to the project, or to products or processes connected with the project, in any statement or material of a publicity or promotional nature issued for commercial purposes, or with a view to financial benefit.

11. SETTLEMENT OF DISPUTES
Any matter relating to the interpretation or application of this Agreement which is not covered by its terms shall be resolved by reference to Swiss law. Any dispute relating to the interpretation or application of this Agreement shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or, in the absence of agreement, with the Rules of Arbitration of the International Chamber of Commerce. The parties shall accept the arbitral award as final.

12. PRIVILEGES AND IMMUNITIES
Nothing contained in or relating to this Agreement shall be deemed to constitute a waiver of any of the privileges and immunities enjoyed by WHO and/or as submitting WHO to any national court jurisdiction.

12/5/2017
Research Co- Ordinator
JNMC - Women's & Children's Health Research Unit
J.N. Medical College, BELAGAVI.

J.N. MEDICAL COLLEGE ★ BELAGAVI ★

12/5/2017
Principal
JNMC, BELAGAVI

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

World Health Organization

TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

Global Procurement and Logistics
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Reference	2017/716530-0
Purchase Order	201737246
Unit Reference	

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 déposées 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 est 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

Research Co-Ordinator
JNMC - Women's & Children's Health
J.N. Medical College, BELAGAVI.

Technical Services Agreement

J.N. MEDICAL COLLEGE BELAGAVI

12/5/2017
Principal
JNMC, BELAGAVI

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

World Health Organization

TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

Global Procurement and Logistics
Block 3510
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63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Reference	2017/716530-0
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Unit Reference	

informations pertinentes et, dans la mesure du possible, lui fournira des produits concrets.
6.2 L'exploitation industrielle ou commerciale de tout droit de propriété

renonciation à quelque privilège ou immunité que ce soit dont jouit l'OMS et/ou comme constituant une soumission de l'OMS à la compétence d'un quelconque tribunal national.

12/5/2017
Research Co- Ordinator
JNMC - Women's & Children's
Health Research Unit,
J.N. Medical College, BELAGAVI.

J.N. MEDICAL COLLEGE ★ BELAGAVI ★

12/5/2017
Principal
JNMC, BELAGAVI

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

World Health Organization

COVERING LETTER
LETTRE D'ACCOMPAGNEMENT

Global Procurement and Logistics
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WHO Reference/ *Référence OMS*

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Purchase Order	201940772
Unit Reference	

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

TECHNICAL SERVICES AGREEMENT (TSA)

Re: Original TSA: PO 201737246
This additional amount is required to complete the tasks under the original TSA.
To conduct preparatory activities for WHO ACTION-1 and ACTION-2 Trials. To initiate participant recruitment for WHO ACTION-1 Trial

We are enclosing the Technical Services Agreement between the World Health Organization and PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM (JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM), KARNATAKA, in the amount of INR 2,803,640.00 (Two Million Eight Hundred Three Thousand Six Hundred Forty), for conducting the above-mentioned work. We also enclosed five attachment(s) referenced in the Agreement.

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

For any technical or scientific questions related to this Agreement, please contact the responsible technical officer, Joshua VOGEL, vogeljo@who.int.

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

WHO Global Service Centre

Cc: WHO Representative, India

Concerne: Original TSA: PO 201737246
This additional amount is required to complete the tasks under the original TSA.
To conduct preparatory activities for WHO ACTION-1 and ACTION-2 Trials. To initiate participant recruitment for WHO ACTION-1 Trial

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 2,803,640.00 (Two Million Eight Hundred Three Thousand Six Hundred Forty), vous permettant de mener à bien le travail susmentionné. Veuillez également trouver five pièces jointes mentionnées dans l'Accord.

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

Pour toutes questions à caractère scientifique ou technique ayant trait à cet Accord, veuillez contacter le responsible technique Joshua VOGEL, vogeljo@who.int.

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

Centre de Soutien Administratif Mondial de l'OMS

Cc: Représentant de l'OMS, India

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

World Health Organization

Global Procurement and Logistics
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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:

The Amount of/*Un Montant de*: INR 2,803,640.00 (Two Million Eight Hundred Three Thousand Six Hundred Forty)
in respect of/*en vue de:* Original TSA: PO 201737246
This additional amount is required to complete the tasks under the original TSA.
To conduct preparatory activities for WHO ACTION-1 and ACTION-2 Trials. To initiate participant recruitment for WHO ACTION-1 Trial

For the period financed by this Agreement — From/*De* : 16-FEB-2018
***Période du projet** financée par le présent accord* — To/*A* : 30-JUN-2018

Summary of work/ *Description sommaire des travaux:*

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

Please see PO 201737246.
This additional amount (44'075 USD) is required to complete the tasks under the original TSA.

A65913 (ACTION 1)
A65916 (ACTION 2)

See attached protocol

2. Contribution of the Institution and/or other sources for the project (Staff, equipment, supplies, etc. excluding general facilities).
The Institute will provide all facilities, equipment and personnel not covered by this Agreement.
Contribution de l'Institution ou de tout autre organisme à l'exécution du projet (personnel, matériel, fournitures, etc, à l'exclusion des services d'ordre général). L'Institution s'engage à fournir les locaux, équipement et personnels non couverts par cet accord.

Financial Arrangements/ *Dispositions financiers:*

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

	Deliverable/ Résultat	Due Date/ *Date Remise*	%	Currency Amount/ *Montant en Devise*
1	Upon signature	22-FEB-2018	100.00	2,803,640.00
2	Financial Report	30-JUN-2018	0.00	0.00
3	Technical report	30-JUN-2018	0.00	0.00

2. INR 0.00 will be used by WHO for the purchase of equipment and supplies to be ordered by the Institution as soon as practicable, but not beyond 31 December of the year following the end of the Agreement period as indicated above at which time any uncommitted balance will revert to WHO.

INR 0.00 *seront affectés par l'OMS à l'achat de matériels et de fournitures à commander par l'Institution dès que possible, mais au plus tard avant le 31 décembre de l'année suivant la fin de la période susmentionnée d'exécution de l'accord, étant entendu qu'à ce moment tout solde non engagé fera retour à l'OMS.*

Annexes

The following annexes form an integral part of this Agreement/ *Les annexes listées ci-dessous font partie intégrante de cet accord:*

Annex	File Description/Description de fichier	
1	2018/791908	Contractual - Budget Breakdown
2	2018/791908	Contractual - Statement of Work
3	2018/791908	Contractual - Statement of Work
4	2018/791908	Contractual - Statement of Work
5	2018/791908	Contractual - Terms of Reference

In the event that the terms of the annexes contain any provisions which are contrary to the terms of this Agreement, the terms of this Agreement shall take precedence/ *En cas de contradiction entre les termes apparaissant sur les*

ATTESTED

Prof. Dr. V.A.KOTHIWALE
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TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

annexes et ceux de l'Accord, les dispositions de l'Accord prévaudront dans tous les cas.

General
The parties accept the "General Conditions" overleaf, which constitute an integral part of this Agreement. The Institution certifies the correctness of the banking instructions provided on Page 1.
All necessary arrangements to comply with national regulations relating to this project and relevant to the Institution's responsibilities shall have been under-taken by the Institution; failure to do so will nullify this Agreement. The responsibility of the World Health Organization is limited only to the financial support as specified in this Agreement.

Généralités
Les parties acceptent les "Conditions générales" reproduites au verso, lesquelles font partie intégrante du présent accord. L'Institution certifie l'exactitude des instructions bancaires indiquées à la page 1.
Toutes les dispositions relevant des responsabilités de l'Institution et nécessaires à la mise en conformité de ce Projet avec la réglementation nationale, devront avoir été prises par l'Institution, faute de quoi l'accord sera nul. La responsabilité de l'Organisation Mondiale de la Santé se limite au soutien financier spécifié dans le présent accord.

ON BEHALF OF WHO/ *POUR L'OMS*

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

Joshua Vogel
Technical Officer
HQ/RHR - Reproductive Health and Research

Responsible Divisional Director
Directeur de division responsable

Ian ASKEW
Director
HQ/RHR - Reproductive Health and Research

Authorized Signatory:
Signataire autorisé:

Mr Motohiro Ogita
Coordinator
Global Procurement and Logistics
(WHO/GMG/GSC/GPL)

Fauziah Binti Ahmad
National Professional Officer (Procurement)
HQ/GSC Global Service Centre
02-MAR-2018

PRINCIPAL INVESTIGATOR/ *CHERCHEUR PRINCIPAL*

Principal Investigator or Technical Officer responsible for the project.
Chercheur Principal ou membre du personnel technique responsable de l'exécution du projet.

Signature : .....
Dr Shivaprasad Goudar
20/03/2018

ON BEHALF OF THE INSTITUTION/ *POUR L'INSTITUTION*

Responsible Administrative Authority*
*Autorité administrative responsable**

Signature : .....
Name/*nom* : Dr. (mrs) N.S. Mahantshetti
Division : Principal
Date : 20/03/2018

* An official of the Institution - other than the Principal Investigator - fully empowered to enter into contracting arrangements on behalf of the Institution./*Un responsable de l'Institution autre que le Chercheur principal - ayant pleins pouvoirs pour passer un contrat au nom de l'Institution.*

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

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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

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

World Health Organization

TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

Global Procurement and Logistics
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Reference	2018/791908-0
Purchase Order	201940772
Unit Reference	

CONDITIONS GENERALES

Les conditions générales énoncées ci-après s'appliquent au présent Accord sur l'appui de l'OMS aux recherches ou autres services techniques. Cet appui vise à aider une institution à entreprendre pour le compte de l'OMS, des investigations portant sur un problème particulier ou des travaux convenus entre l'Institution et l'OMS.

1. INSTITUTION ET CHERCHEUR PRINCIPAL
1.1 L'Institution et le Chercheur principal (ou l'Administrateur technique responsable), lequel doit être employé par l'Institution, sont conjointement responsables de l'ensemble des aspects techniques et administratifs des travaux visés par le présent Accord.
1.2 L'Institution est tenue d'aviser immédiatement l'OMS lorsqu'elle apprend que le Chercheur principal va cesser, ou a cessé, d'être employé par elle, ou bien qu'il ne continue pas à exercer les fonctions visées par le présent Accord. En pareil cas, l'OMS peut:
a. soit annuler le présent Accord;
b. soit accepter de poursuivre le projet sous la conduite d'un nouveau Chercheur principal proposé par l'Institution et approuvé par l'OMS.

2. DISPOSITIONS FINANCIERES
2.1 Des versements seront faits au(x) compte(s) bancaire(s) de l'Institution comme il est stipulé dans le présent Accord et conformément au calendrier qui y figure. Si, après communication du rapport financier final mentionné plus loin au paragraphe 4.3, il apparaît que l'Institution 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 utilisèront 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

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
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104

Global Procurement and Logistics
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
psc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Reference	2018/791908-0
Purchase Order	201940772
Unit Reference	

informations pertinentes et, dans la mesure du possible, lui fournira des produits concrets.
6.2 L'exploitation industrielle ou commerciale de tout droit de propriété

renonciation à quelque privilège ou immunité que ce soit dont jouit l'OMS et/ou comme constituant une soumission de l'OMS à la compétence d'un quelconque tribunal national.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

FDP Research Subaward Agreement
Amendment (Number 1)

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

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

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

Subaward Period of Performance:		Amount Funded This Action:	Subaward No:
Start Date: Dec 9, 2017	End Date: Nov 30, 2019	$ 46,910.00	080-70000-S28101

Effective Date of Amendment:	Total Amount of Federal Funds Obligated to Date:	Subject to FFATA:	Automatic Carryover:
Dec 1, 2018	$ 102,098.00	(•) Yes ( ) No	(•) Yes ( ) No

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

ACTION:

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

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

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

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

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

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Notice of Award

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

Federal Award Date: 11/21/2018

FOGARTY INTERNATIONAL CENTER

Grant Number: 5R21TW010609-02
FAIN: R21TW010609

Principal Investigator(s):
RICHARD J DERMAN, MD

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

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

Award e-mailed to: resadmin@jefferson.edu

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

Dear Business Official:

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

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

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

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

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

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Sincerely yours,

BRUCE R BUTRUM
Grants Management Officer
FOGARTY INTERNATIONAL CENTER

Additional information follows

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

FDP Cost Reimbursement Research Subaward Agreement

Pass-through Entity (PTE): Thomas Jefferson University		Subrecipient: Jawaharlal Nehru Medical College, KLE	
PTE Principal Investigator (PI): Richard Derman, M.D.		Subrecipient Principal Investigator (PI): Dr. Shivaprasad S. Goudar	
PTE Federal Award No: 1R21TW010609-01	FAIN: R21TW010609	Federal Awarding Agency: NIH	
Federal Award Issue Date: Dec 11, 2017	Total Amount of Federal Award to PTE $ $ 199,846.00	CFDA No: 93.989	CFDA Title: International Research and Research Training
Project Title: Breastfeeding Education Support Tool for Baby (BEST4Baby)			
Subaward Period of Performance: Start: Dec 9, 2017 End: Nov 30, 2018		Amount Funded This Action: $ ~~46,910.00~~ $ 55,188 (TC-2)	Subaward No. 080-70000-S28101
Estimated Project Period (if incrementally funded): Start: Dec 9, 2017 End: Nov 30, 2019		Incrementally Estimated Total: $ $ 102,098.00	Is this Award R & D [x] Yes or [ ] No
Check all that apply [✓] Reporting Requirements (Attachment 4) [✓] Subject to FFATA (Attachment 3B) [ ] Cost Sharing (Attachment 5)			

Terms and Conditions

1) PTE hereby awards a cost reimbursable subaward, as described above, to Subrecipient. The statement of work and budget for this subaward are (check one) [ ] as specified in Subrecipient's proposal dated or [✓] as shown in Attachment 5. In its performance of subaward work, Subrecipient shall be an independent entity and not an employee or agent of PTE.

2) PTE shall reimburse Subrecipient not more often than monthly for allowable costs. All invoices shall be submitted using Subrecipient's standard invoice, but at a minimum shall include current and cumulative costs (including cost sharing), subaward number, and certification, as required in 2 CFR 200.415 (a). Invoices that do not reference PTE Subaward number shall be returned to Subrecipient. Invoices and questions concerning invoice receipt or payments should be directed to the appropriate party's Financial Contact, as shown in Attachments 3A. (Invoices should be submitted electronically)

3) A final statement of cumulative costs incurred, including cost sharing, marked "FINAL" must be submitted to PTE's Financial Contact, as shown in Attachments 3A, NOT LATER THAN 60 days after subaward end date. The final statement of costs shall constitute Subrecipient's final financial report.

4) All payments shall be considered provisional and subject to adjustment within the total estimated cost in the event such adjustment is necessary as a result of an adverse audit finding against the Subrecipient. PTE reserves the right to reject an invoice, in accordance with 2 CFR 200.305.

5) Matters concerning the technical performance of this subaward should be directed to the appropriate party's Principal Investigator as shown in Attachments 3A and 3B. Technical reports are required as shown above, "Reporting Requirements."

6) Matters concerning the request or negotiation of any changes in the terms, conditions, or amounts cited in this subaward agreement, and any changes requiring prior approval, should be directed to the appropriate party's Administrative Contact, as shown in Attachments 3A and 3B. Any such changes made to this subaward agreement require the written approval of each party's Authorized Official, as shown in Attachments 3A and 3B.

7) Substantive changes made to this subaward agreement require the written approval of each party's Authorized Official as shown in Attachments 3A and 3B. The PTE may issue non-substantive changes to the Period of Performance (check one) [ ] Bilaterally, or [✓] Unilaterally. Unilateral modifications shall be considered valid 14 days after receipt unless otherwise indicated by Subrecipient

8) Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, or directors, to the extent allowed by law.

9) Either party may terminate this subaward with thirty days written notice to the appropriate party's Administrative Contact, as shown in Attachments 3A and 3B. PTE shall pay Subrecipient for termination costs as allowable under Uniform Guidance, 2 CFR 200, or 45 CFR Part 75 Appendix IX, "Principles for Determining Costs Applicable to Research & Development under Grants and Contracts with Hospitals, as applicable.

10) No-cost extensions require the approval of the PTE. Any requests for a no-cost extension should be addressed to and received by the Administrative Contact, as shown in Attachments 3A, not less than 30 days prior to the desired effective date of the requested change.

11) The Subaward is subject to the terms and conditions of the PTE Award and other special terms and conditions, as identified in Attachment 2.

12) By signing this Research Subaward Agreement Subrecipient makes the certifications and assurances shown in Attachments 1 and 2.

13) Research Terms & Conditions – RESERVED

By an Authorized Official of Pass-through Entity:	By an Authorized Official of Subrecipient:
Name: Timothy Schailey Date: 1/19/18	Name: Dr N S Mahantashetti Date: Jan 13, 2018
Title: Director, Office of Research Administration	Title: Principal, J N Medical College, Belagavi

FDP Version 3.27.15

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Notice of Award

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

Federal Award Date: 12/11/2017

FOGARTY INTERNATIONAL CENTER

Grant Number: 1R21TW010609-01
FAIN: R21TW010609

Principal Investigator(s):
RICHARD J DERMAN, MD

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

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

Award e-mailed to: resadmin@jefferson.edu

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

Dear Business Official:

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

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

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

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

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

Sincerely yours,

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

RTI International
Global Supply Chain
PO Box 12194, 3040 Cornwallis Road
Research Triangle Park, NC 27709-2194

RTI INTERNATIONAL

Master Service Agreement 888-18-04-05
Subaward Number 3-312-0216193-65162L
Modification Number 1

Supplier Information	Task Order Information	
Jawaharlal Nehru Medical College KLEU Research Foundation Belgaum – 590 010 Belgaum – 590 010, India	Subaward Amount	$1,566,189.00
	Funded Amount	$1,241,107.00
	Period of Performance	12/15/2017 - 10/31/2020
	Subaward Type	Fixed Price
	Effective Date of Mod	November 14, 2018

Description of Modification:

This modification:

- Increases the Subaward Ceiling amount by $49,226.00 from $1,516,963.00 to $1,566,189.00.
- Increases the Subaward Funded amount by $647,495.00 from $593,612.00 to $1,241,107.00.

Appendix A: Special Contract Requirements (SCRs)*;is amended as per the attached;*
Appendix D: Statement of Work/Budget *is amended as per the attached;*

[X] See Attachment

EXCEPT AS MODIFIED BY THIS AND ANY PRIOR MODIFICATIONS, ALL TERMS AND CONDITIONS OF THE SUBAWARD REMAIN IN FULL FORCE AND EFFECT.

In accepting this Subaward, the Subrecipient certifies that neither it nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from participation in this type of transaction by any Federal department or agency. Any change in the debarred or suspended status of the Subrecipient during the life of this Subaward must be reported immediately to RTI. The Subrecipient agrees to incorporate the Debarment and Suspension certification into any lower-tier subcontract or subaward that they may enter into as a part of this Subaward. Subcontractor hereby certifies, to the best of its knowledge and belief, that no federal appropriated funds have been paid or will be paid to any person for influencing or at attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress on its behalf in connection with the awarding of this subcontract. In accordance with FAR 52.203-12, Subcontractor attests any required disclosures have been made as of the date of award of this subcontract and will be made for any subsequent applicable lobbying activity.

Supplier Personnel:	RTI Personnel:-
Administrative Contact: Shivaprasad Goudar +91 944 812 6371 Project Manager: Shivaprasad Goudar +91 944 812 6371	Supply Chain Compliance Specialist: Jackie Williams 919-541-5876 Project Manager: Beth McClure 919-316-3773
Signature:	Signature: Jackie Williams (Digitally signed by Jackie Williams, DN: cn=Jackie Williams, o=RTI University, ou=SSES, email=jackiewilliams@rti.org, c=US, Date: 2019.03.28 10:07:58 -05'00')
Typed Name: SHIVAPRASAD GOUDAR.	Typed Name: Jackie Williams
Title: RESEARCH COORDINATOR.	Title: Supply Chain Specialist
29/1/2019	

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Appendix A: Special Contract Requirements (SCRs)

SCR 1. Type of Subaward/Funding (Fixed Amount Subaward) *is deleted in its entirety and replaced with the following:*

A. This is a Firm Fixed Amount Subaward in the amount of **$1,566,189.00**, for the completion of all the work requirements found in Attachment 2: Statement of Work/Budget. Upon completion and RTI acceptance of the work specified herein, the Subrecipient will submit invoice(s) in accordance with the Payment Schedule set forth below. In addition to any other available remedies, if, in the opinion of RTI, Subrecipient fails to perform in accordance with the terms of the MSA or this Subaward, the RTI Subaward Administrator may refuse or limit approval of any invoices for payment, and may cause payments to Subrecipient to be reduced or withheld until such time as RTI determines that Subrecipient has met the performance terms as established by both the MSA and this Subaward.

B. The Subaward is funded in the amount of **$1,241,107.00**. Accordingly, the Limitation of Funds/Costs clause set forth in the Master Serve Agreement ("MSA") shall apply to the management of this funding allocation. RTI shall bear no legal liability or financial obligation beyond the funded amount stipulated in this paragraph.

C. This Subcontract is incrementally funded in accordance with a projected schedule set forth in this paragraph. The Subcontract is established with a base period and if exercised by RTI's client; two potential Option Periods as shown in table below.

Year	Period of Performance	Ceiling	Funded
Base Year	12/15/2017 – 8/31/2018	$593,612.00	$593,612.00
Option Year 1	9/1/2018 – 8/31/2019	$647,495.00	$647,495.00
Option Year 2	9/1/2019 – 8/31/2020	$325,082.00	$0.00
Total		**$1,566,189.00**	**$1,241,107.00**

SCR 2. Payment Schedule (Fixed Amount Subaward) *is deleted in its entirety and replaced with the following:*

The Subrecipient shall provide the services/supplies set forth in Attachment 2: Statement of Work/Budget, and will invoice RTI for a total fixed amount of **$1,566,189.00** upon the completion and submission of all deliverables as described in the Statement of Work.

SCR 3. Invoice Instructions *is deleted in its entirety and replaced with the following:*

Invoice and payment instructions, which may be amended from time to time after this Agreement's execution, are set forth at the following link: www.rti.org/files/invoice-payment.pdf. Additionally, Supplier shall submit an invoice summary page as incorporated herein with each invoice submission. Supplier may use its own invoice summary format if such is substantially similar to the template provided in this Subcontract/Subaward.

SCR 9. Debarment and Suspension *is hereby appended with the following:*

In accepting this Subcontract Modification, the Subcontractor certifies that neither it nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from participation in this type of transaction by any Federal department or agency. Any change in the debarred or suspended status of the Subcontractor during the life of this Subcontract must be reported immediately to RTI. The Subcontractor agrees to incorporate the Debarment and Suspension certification into any lower-tier subcontract that they may enter into as a part of this Subcontract.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Research Triangle Institute
RTI International, Global Supply Chain
PO Box 12194, 3040 Cornwallis Road
Research Triangle Park, NC 27709-2194

RTI INTERNATIONAL

Subaward Number 3-312-0216193-65162L

Subrecipient Information

Jawaharlal Nehru Medical College
KLEU Research Foundation,
Belgaum – 590 010
Belgaum – 590 010 India

Subrecipient Size and Socio-Economic Status:

*If a Small Business**, check ALL that apply and enter appropriate NAICS Number*. NAICS:* _____

- ☐ Small Business Concern (SB)
- ☐ Small Disadvantaged Business, [Including Black-, Asian Pacific-, Subcontinent Asian-, Native-, Hispanic American-owned SBs or active 8(a)]
- ☐ Woman-Owned SB
- ☐ Veteran-Owned SB
- ☐ Service-Disabled Veteran-Owned SB
- ☐ HUBZone (Historically Underutilized Business Zone) certified SB
- ☐ Alaska Native Corporation and Indian Tribe

If not a Small Business, check one.

☐ Large ☒ Non-Profit ☐ Foreign/Other (including Govt) ☐

*North American Industry Classification System (NAICS) online search: www.census.gov/eos/www/naics. **Small Business definitions and size standards are available in the Federal Acquisition Regulation 52.219-8 and 13 CFR Part 121; HUBZone SB must be certified by SBA (www.sam.gov and www.sba.gov/size). Under 15 U.S.C. 645(d), any person who misrepresents its size status shall (1) be punished by a fine, imprisonment, or both; (2) be subject to administrative remedies; and (3) be ineligible for participation in programs conducted under the authority of the Small Business Act. ***Historically Black Colleges and University (HBCU) or Minority Institutions (MI).

Subaward Information

Subaward Amount	$1,516,963
Funded Amount	$593,612
Period of Performance	12/15/17 - 10/31/20
Subaward Type	Fixed Price
Purchase Order Number	65162L
Taxpayer ID Number	

DPAS Rating:
Not Applicable

Prime Award Info:
Bill & Melinda Gates Foun Grant OPP1169824

KLE Academy of Higher Education and Research's JN Medical College Belagavi (KLE) Study of Cause of Death among Preterm Births: Asia

CFDA Number (if applicable): n/a

This Subaward is between Research Triangle Institute, under the trade name RTI International (hereinafter referred to as RTI), a nonprofit organization, and Jawaharlal Nehru Medical College, acting as an independent contractor and not as an agent of RTI, (referred to throughout as "Subrecipient"). Subrecipient agrees to deliver all items and perform all services in accordance with the following Subaward Appendices:

- Appendix A: Special Contract Requirements
- Appendix B: Standard Subaward Terms and Conditions
- Appendix C: Grant Flow Down Provisions
- Appendix D: Statement of Work/Budget
- Appendix E: Invoice Summary Template

This Subcontract embodies the entire agreement between RTI and Subrecipient and supersedes all other agreements either written or oral. Officials signing this Subaward certify that they have legal authority to enter into binding agreements on behalf of their organizations.

In accepting this Subaward, the Subrecipient certifies that neither it nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from participation in this type of transaction by any Federal department or agency. Any change in the debarred or suspended status of the Subrecipient during the life of this Subaward must be reported immediately to RTI. The Subrecipient agrees to incorporate the Debarment and Suspension certification into any lower-tier subaward or Subcontract that they may enter into as a part of this Subaward.

Subrecipient Contractual Personnel:		**RTI Contractual Personnel:**	
Shivaprasad Goudar	+91 944 812 6371	Jackie Williams	919-541-5876
Project Manager:		**Project Manager:**	
Shivaprasad Goudar	+91 944 812 6371	Beth McClure	919-316-3773
Signature:		Signature:	
Typed Name: SHIVAPRASAD GOUDAR.		Typed Name:	Jackie Williams
Title: RESEARCH COORDINATOR		Title:	Supply Chain Compliance Specialist
Date: 1/12/2018		Date:	1/11/2018

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

RTI International
Global Supply Chain
PO Box 12194, 3040 Cornwallis Road
Research Triangle Park, NC 27709-2194

RTI INTERNATIONAL

Master Service Agreement 888-19-04-06
Subaward Number 3-312-0216193-65162L
Modification Number 2

Supplier Information	Task Order Information	
Jawaharlal Nehru Medical College KLEU Research Foundation Belgaum – 590 010 Belgaum – 590 010, India	Subaward Amount	$1,567,338.00
	Funded Amount	$1,567,338.00
	Period of Performance	12/15/2017 - 10/31/2020
	Subaward Type	Fixed Price
	Effective Date of Mod	February 6, 2020

Description of Modification:

This modification:

- Increases the Subaward's Ceiling amount by $1,149.00 from $1,566,189.00 to $1,567,338.00
- Increases the Subaward's Funded amount by $326,231.00 from $1,241,107.00 to $1,567,338.00

Appendix A: Special Contract Requirements *(SCRs) as per the attached;*
Appendix D: Statement of Work/Budget *Is amended as per the attached;*

[X] See Attachment

EXCEPT AS MODIFIED BY THIS AND ANY PRIOR MODIFICATIONS, ALL TERMS AND CONDITIONS OF THE SUBAWARD REMAIN IN FULL FORCE AND EFFECT.

In accepting this Subaward, the Subrecipient certifies that neither it nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from participation in this type of transaction by any Federal department or agency. Any change in the debarred or suspended status of the Subrecipient during the life of this Subaward must be reported immediately to RTI. The Subrecipient agrees to incorporate the Debarment and Suspension certification into any lower-tier subcontract or subaward that they may enter into as a part of this Subaward. Subcontractor hereby certifies, to the best of its knowledge and belief, that no federal appropriated funds have been paid or will be paid to any person for influencing or at attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress on its behalf in connection with the awarding of this subcontract. In accordance with FAR 52.203-12, Subcontractor attests any required disclosures have been made as of the date of award of this subcontract and will be made for any subsequent applicable lobbying activity.

Supplier Personnel:	RTI Personnel:
Administrative Contact: Shivaprasad Goudar +91 944 812 6371	Supply Chain Compliance Specialist: Jackie Williams 919-541-5876
Project Manager: Shivaprasad Goudar +91 944 812 6371	Project Manager: Beth McClure 919-316-3773, x3773
Signature:	Signature:
Typed Name: Dr Shivaprasad S. Goudar	Typed Name: Jackie Williams
Title: Research Coordinator.	Title: Sr. Supply Chain Specialist
Date: February 14, 2020	Date:

REV 06/2018

RTI International is a trade name of Research Triangle Institute

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

KLE University's, J N Medical College
Women's and Children's Health Research Unit

COST REIMBURSABLE RESEARCH SUBCONTRACT

"WHO ACTION Trials (ACTION I and ACTION II)"

This contract Agreement for

"The WHO ACTION (Antenatal CorticosTeroids for Improving Outcomes in preterm Newborns) Trials:"

1. WHO ACTION-I TRIAL - A65913: A multi-country, multi-centre, two-arm, parallel, double-blind, placebo-controlled, randomized trial of antenatal corticosteroids for women at risk of imminent birth in the early preterm period in hospitals in low-resource countries to improve newborn outcomes.

2. WHO ACTION-II TRIAL - A65916: A multi-country, multi-centre, two-arm, parallel, double-blind, placebo-controlled, randomized trial of antenatal corticosteroids for women at risk of imminent birth in the late preterm period in hospitals in low-resource countries to improve newborn outcomes. in Bagalkot Sub-site, India hereafter referred to as the "WHO ACTION Trials" is entered into in order to specify the terms and conditions under which the KLE University's, Women's and Children's Health Research Unit, J N Medical College, (hereinafter referred to as "JNMC") and S N Medical College (hereinafter referred to as "SNMC") will participate in the conduct of a project supported by the World Health Organization (WHO) (hereinafter referred to as "Sponsor").

General Information:
Title: Research Subcontract in between Jawaharlal Nehru Medical College, Belagavi and S Nijalingappa Medical College, Bagalkot for the **"WHO ACTION TRIALS"**

Award Title: This Hospital-based Trial Contract (the "Contract"), effective as of July 01, 2017 (the "Effective Date") is by and between WHO and Jawaharlal Nehru Medical College located at Belagavi 590010 in Karnataka, India ("JNMC"), represented by its employee Dr Shivaprasad Goudar, MD (the "Principal Investigator").

Prime Award: WHO Reference - 2017/716530-0,
Purchase Order - 201737246
Reg. File -
Unit Reference -
Principal Investigator Name: Dr Shivaprasad S Goudar (JNMC)
Facility Director Name: Dr Ashalata Mallapur (SNMC)

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

WHEREAS, JNMC and SNMC wish to enter into a subcontract wherein SNMC will provide certain services to JNMC in JNMC's performance of the contract with World Health Organization (WHO);

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

WHEREAS, SNMC agrees to abide by all of the terms and conditions of the Sponsor- World Health Organization (WHO) agreement;

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

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

Definitions:

1. "JNMC" means the Jawaharlal Nehru Medical College, which has its principal office in Belagavi, India
2. "WHO" means World Health Organization.
3. "SNMC" means S.Nijalingappa Medical College, which has its principal office in Bagalkot, India, and which pursuant to the Protocol, agrees to provide data entry, data management, and data quality control services and to dedicate an employee to serve as a Co-Investigator (as defined below) for the Community-based Trial.

Article I. Scope of Work

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

Article II. Period of Performance

The period of this Agreement shall be from July 1, 2017 to December 31, 2019 unless extended by written amendment to this Agreement.

Article III. Estimated Cost

JNMC agrees to pay SNMC an amount not to exceed Rs.72,49,503=00 for the work described in Article I. Payment will be made upon receipt of SNMC's invoices.

WHO does not pay any indirect cost as per the **Prime Award to JNMC, hence JNMC will not pay** any indirect to SNMC for the conduct of the **"WHO ACTION Trials" study.**

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

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

For the administration of this contract, SNMC will open an independent account at a branch of Syndicate Bank in Bagalkot in the name of Principal, S N Medical College, Bagalkot for the "WHO

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

ACTION Trials"

Which shall be operated by the Administrative Representative of SNMC i.e. The Principal of SNMC.

ArticleIV. Authorized Representatives
The authorized representatives of JNMC and SNMC for technical and administrative matters shall be:

S N Medical College, Bagalkot	**J N Medical College, Belagavi**
Technical Representative:	*Technical Representative:*
Dr Ashalata Mallapur,	Dr Shivaprasad S Goudar
Administrative Representative:	*Administrative Representative:*
Dr Ashok Mallapur	Dr.N S Mahantshetti
Principal	Principal

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

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

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

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

Article VII. Additional General Provisions
The following general provisions shall apply to this Agreement:

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

B. Billing
JNMC shall reimburse the SNMC 's payment within forty (40) days after receipt of an acceptable invoice and after inspection and acceptance of the research deliverables provided in accordance with the terms and conditions of this Agreement.
SNMC agrees that bills and invoices for fees or other compensation for services or expenses shall cite the Title: **"WHO ACTION Trials"**

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

ATTESTED

Dr V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed to be University)

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

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

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

Dr Shivaprasad S Goudar
Principal Investigator, WHO ACTION Trials,
KLE University's Women's and Children's Health Research Unit
J N Medical College
Nehru Nagar,
Belagavi, 590010
sgoudar@jnmc.edu

C. Audit

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

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

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

D. Equipment

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

E. Indemnification

Each party hereby assumes any and all risk of personal injury and property damage attributable to the negligent acts or omissions of that party and the officers, employees and agents thereof. SNMC will assure that persons subcontracting with or otherwise acting or engaged to act at the instance of SNMC in furtherance of SNMC fulfilling its obligations under this Agreement will assume such risk with respect to the willful or negligent acts or omissions of their personnel. SNMC shall provide professional liability

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,

coverage for its employees discharging services as per the provisions of this contract and accident insurance coverage for all equipment/material procured for conducting the trial as specified in Attachment B.

F. Amendments

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

G. Governance

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

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

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

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

H. Termination

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

I. Publications

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

J. Arbitration

If any dispute arises in between JNMC and SNMC the same should be referred to Chancellor, KLE University and Chairman, KLE Society, Belagavi and Chancellor & President, Basaveshwara Vidyavardhak Sangh, Bagalkot and the decision of the Arbitrators shall be final and the same shall be binding on the both the parties.

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

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

ATTESTED

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

This Contract includes the following Appendices (incorporated herein):
Attachment A: Cover Letter for TAS issued for Clinical Trial, Technical Services Agreement
Attachment B: WHO ACTION Trials Protocols (ACTION-I Trial and ACTION-II Trial)
Attachment C: Budget Sheet for SNMC

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

Jawaharlal Medical College (JNMC)

By: _____

Name: Dr N S Mahantshetti

Title: Principal

Date: 22/8/17
DD /MM /YYYY

Sri Nijalingappa Medical College (SNMC)

By: _____

Name: Dr Ashok Mallapur

Title: Principal

Date: 12/09/2017
DD /MM /YYYY

Principal Investigator

By: _____

Name: Dr Shivaprasad S Goudar

Title: Professor Department of PHYSIOLOGY

Date: 24/08/2017
DD /MM /YYYY

By: _____

Name: Dr Ashalata Mallapur

Title: Professor and Head, Department of OBGYN

Date: 12 09 2017
DD /MM /YYYY

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

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

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

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

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

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

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

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

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

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

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

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

ATTESTED
Prof. Dr. V.A. KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

incorporated herein by this reference. In consideration of the covenants and conditions contained in this Agreement ("the Agreement"), and other good and valuable consideration, the adequacy and receipt of which are acknowledged, JNMC and JJMMC agree as follows:

Definitions:

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

Article I. Scope of Work provided in Attachment A

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

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

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

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

Article II. Period of Performance

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

Article III. Estimated Cost

JNMC agrees to pay JJMMC an amount not to exceed Rs. 2,061,554 for the work described in Article I which includes 15% Indirect costs payable to JJMMC.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar

and Research, BELAGAVI

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

JNMC will also reimburse JJMMC towards Screening, reimbursements of data captions, cost of IDI, FGD & transcription of IDI and FGDs will be directly paid by JNMC .
JJMMC will extend credit facility to the site investigators towards expenditures by investigations and sample collection as requested by the Site Principal Investigator until reimbursement is processed by JNMC. JNMC will process all Invoices within 45 days of receipt of the Invoices.

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

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

The Project funds will be transferred to JJMMC

INSTITUTION ACCOUNT DETAILS

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

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

ATTESTED

Prof. Dr. V.A KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

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

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

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

ArticleIV. Authorized Representatives

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

JJM Medical College, Davangere,Karnataka

Technical Representative:
Dr Gowdar Guruprasad,
Administrative Representative:
Dr S B Murugesh
Dean & Principal

J N Medical College, Belgaum

Technical Representative:
Dr Shivaprasad S Goudar
Administrative Representative:
Dr.N S Mahantshetti
Principal

Article V. Reports

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

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

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

ATTESTED

Prof. Dr. V.A.KOTHIWALE

Article VI. General Provisions

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

Article VII. Additional General Provisions

The following general provisions shall apply to this Agreement:

A. Allowable Costs

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

B. Billing

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

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

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

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

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

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

ATTESTED
ATTESTED
Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

C. Audit

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

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

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

D. Equipment

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

E. Indemnification

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

F. Amendments

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

G. Governance

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

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

ATTESTED

Prof Dr V.A.KOTHIWALE

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

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

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

H. Termination

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

I. Publications

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

J. Arbitration

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

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

This Contract includes the following Appendices (incorporated herein):

Attachment A:

Attachment B:

Attachment C:

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

Jawaharlal Medical College (JNMC)

By: _____

Name: Dr N S Mahantshetti

Title: Principal

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

JJM Medical College, Davangere, Karnataka (JJMMC)

By: _____

Name: Dr. S B Murugesh

Title: Dean & Principal

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

Principal Investigator

By: _____

Name: Dr Shivaprasad S Goudar

Title: Professor Department of PHYSIOLOGY

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

By: _____

Name: Gowdar Guruprasad

Title: Professor and Head, Neonatology

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

ATTESTED

Prof Dr V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Bapuji Educational Association®

J.J.M. MEDICAL COLLEGE

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

DAVANGERE-577 004, KARNATAKA, INDIA.

To, Ref. No: JJMMC/5289/2018-19 Date: 03.01.2019

Dr.Shamanur Shivashankarappa MLA
Chairman,
Bapuji Educational Association,
Davangere

Respected sir,

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

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

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

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

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

We seek your kind Permission and Guidance for the same.

Kindly oblige and do the needful.

Thanking You

Yours Faithfully

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

Dr.S.B.Murugesh
Principal
JJMMC
Davangere

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

FDP Research Subaward Agreement
Amendment (Number 1)

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

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

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

Subaward Period of Performance:	Amount Funded This Action:	Subaward No:
Start Date: Dec 9, 2017 End Date: Nov 30, 2019	$ 46,910.00	080-70000-S28101

Effective Date of Amendment:	Total Amount of Federal Funds Obligated to Date:	Subject to FFATA:	Automatic Carryover:
Dec 1, 2018	$ 102,098.00	(•) Yes ( ) No	(•) Yes ( ) No

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

ACTION:

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

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

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

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

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

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Attachment 1

Notice of Award

EXPLORATORY/DEVELOPMENT GRANT **Federal Award Date:** 11/21/2018

Department of Health and Human Services
National Institutes of Health

FOGARTY INTERNATIONAL CENTER

Grant Number: 5R21TW010609-02
FAIN: R21TW010609

Principal Investigator(s):
RICHARD J DERMAN, MD

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

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

Award e-mailed to: resadmin@jefferson.edu

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

Dear Business Official:

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

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

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

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

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

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Sincerely yours,

BRUCE R BUTRUM
Grants Management Officer
FOGARTY INTERNATIONAL CENTER

Additional information follows

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

FDP Cost Reimbursement Research Subaward Agreement

Pass-through Entity (PTE): Thomas Jefferson University		Subrecipient: Jawaharlal Nehru Medical College, KLE	
PTE Principal Investigator (PI): Richard Derman, M.D.		Subrecipient Principal Investigator (PI): Dr. Shivaprasad S. Goudar	
PTE Federal Award No: 1R21TW010609-01	FAIN: R21TW010609		Federal Awarding Agency: NIH
Federal Award Issue Date: Dec 11, 2017	Total Amount of Federal Award to PTE $ $ 199,846.00	CFDA No: 93.989	CFDA Title: International Research and Research Training
Project Title: Breastfeeding Education Support Tool for Baby (BEST4Baby)			
Subaward Period of Performance: Start: Dec 9, 2017 End: Nov 30, 2018		Amount Funded This Action: $ ~~$46,810.00~~ $55,188 (R.S)	Subaward No. 060-70000-S28101
Estimated Project Period (if incrementally funded): Start: Dec 9, 2017 End: Nov 30, 2019		Incrementally Estimated Total: $ $ 102,098.00	Is this Award R & D ☒ Yes or ☐ No
Check all that apply ☑ Reporting Requirements (Attachment 4)	☑ Subject to FFATA (Attachment 3B)		☐ Cost Sharing (Attachment 5)

Terms and Conditions

1) PTE hereby awards a cost reimbursable subaward, as described above, to Subrecipient. The statement of work and budget for this subaward are (check one) ☐ as specified in Subrecipient's proposal dated or ☑ as shown in Attachment 5. In its performance of subaward work, Subrecipient shall be an independent entity and not an employee or agent of PTE.

2) PTE shall reimburse Subrecipient not more often than monthly for allowable costs. All invoices shall be submitted using Subrecipient's standard invoice, but at a minimum shall include current and cumulative costs (including cost sharing), subaward number, and certification, as required in 2 CFR 200.415 (a). Invoices that do not reference PTE Subaward number shall be returned to Subrecipient. Invoices and questions concerning invoice receipt or payments should be directed to the appropriate party's Financial Contact, as shown in Attachments 3A. (Invoices should be submitted electronically)

3) A final statement of cumulative costs incurred, including cost sharing, marked "FINAL" must be submitted to PTE's Financial Contact, as shown in Attachments 3A, NOT LATER THAN 60 days after subaward end date. The final statement of costs shall constitute Subrecipient's final financial report.

4) All payments shall be considered provisional and subject to adjustment within the total estimated cost in the event such adjustment is necessary as a result of an adverse audit finding against the Subrecipient. PTE reserves the right to reject an invoice, in accordance with 2 CFR 200.305.

5) Matters concerning the technical performance of this subaward should be directed to the appropriate party's Principal Investigator as shown in Attachments 3A and 3B. Technical reports are required as shown above, "Reporting Requirements."

6) Matters concerning the request or negotiation of any changes in the terms, conditions, or amounts cited in this subaward agreement, and any changes requiring prior approval, should be directed to the appropriate party's Administrative Contact, as shown in Attachments 3A and 3B. Any such changes made to this subaward agreement require the written approval of each party's Authorized Official, as shown in Attachments 3A and 3B.

7) Substantive changes made to this subaward agreement require the written approval of each party's Authorized Official as shown in Attachments 3A and 3B. The PTE may issue non-substantive changes to the Period of Performance (check one) ☐ Bilaterally, or ☑ Unilaterally. Unilateral modifications shall be considered valid 14 days after receipt unless otherwise indicated by Subrecipient.

8) Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, or directors, to the extent allowed by law.

9) Either party may terminate this subaward with thirty days written notice to the appropriate party's Administrative Contact, as shown in Attachments 3A and 3B. PTE shall pay Subrecipient for termination costs as allowable under Uniform Guidance, 2 CFR 200, or 45 CFR Part 75 Appendix IX, "Principles for Determining Costs Applicable to Research & Development under Grants and Contracts with Hospitals, as applicable.

10) No-cost extensions require the approval of the PTE. Any requests for a no-cost extension should be addressed to and received by the Administrative Contact, as shown in Attachments 3A, not less than 30 days prior to the desired effective date of the requested change.

11) The Subaward is subject to the terms and conditions of the PTE Award and other special terms and conditions, as identified in Attachment 2.

12) By signing this Research Subaward Agreement Subrecipient makes the certifications and assurances shown in Attachments 1 and 2.

13) Research Terms & Conditions – RESERVED

By an Authorized Official of Pass-through Entity:	By an Authorized Official of Subrecipient:
Name: Timothy Schailey	Name: Dr N S Mahantashetti
Date: 1/10/18	Date: Jan 13, 2018
Title: Director, Office of Research Administration	Title: Principal, J N Medical College, Belagavi

FDP Version 3.27.15

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Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Notice of Award

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

Federal Award Date: 12/11/2017

FOGARTY INTERNATIONAL CENTER

Grant Number: 1R21TW010609-01
FAIN: R21TW010609

Principal Investigator(s):
RICHARD J DERMAN, MD

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

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

Award e-mailed to: resadmin@jefferson.edu

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

Dear Business Official:

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

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

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

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

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

Sincerely yours,

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

'This Memorandum of understanding for clinical study has been agreed upon & signed on this date 12 Apr 2017 by the following thereto, as under:

Part 1:

1. Dr. Swapnali Mahadik
   Project Head, being the authorized signatory of
   M/s Target Institute of Medical Education & Research
   205, B Wing, Blue Diamond Society, Nayagaon,
   Dahisar (W), Mumbai - 68, a registered Partnership Firm
   (Hereafter referred to as 'TIMER')

Part 2:

2. Dr. B S Prasad
   Principal
   KLEU'S SHRI B M K AYURVED MAHAVIDYALAYA
   BELAGAVI, KARNATAKA 590003
   (Hereafter referred to as 'KLEUBMK')

To undertake a clinical study entitled ""A Randomized, Multi-center, Double blind, Placebo controlled, Prospective Clinical study to Evaluate The Efficacy and Safety of AYUBES CAPSULE as an Add-on therapy to Oral Hypoglycemic Agents (OHA) in Type 2 Diabetic Patients" Clinical Study Protocol No. AYUBES/DM/WELX/2017, Version 1.0, 25th Mar 2017.

Now, whereas M/s. Welex Laboratories Pvt. Ltd. have entrusted the work of conducting clinical trials on Ayubes Capsules as multicenter study to M/s. Target Institute of Medical Education and Research, Mumbai and as whereas 'TIMER' has approached and discussed with 'KLEUBMK' to undertake the clinical trials as referred above as per Protocol No. AYUBES/DM/WELX/2017, Version 1.0, 25th Mar 2017.

Now the terms of this M.O.U. witness as under –

1. The Objectives of the study shall be –

The objective of the study is to evaluate the efficacy and safety of Ayubes Capsules as an Add-on therapy to Oral Hypoglycemic Agent (OHA) in Type 2 Diabetic Patients

For CITIZENCREDIT CO-OP. BANK LTD., Y.C. COLONY, Borivali Branch
Authorised Signatory
CITIZENCREDIT CO-OP. BANK LTD., Y.C. COLONY, BORIVLI (W), MUMBAI-400 103. D-5/STP(V)/C.R.1009/06/ 06/208-211

INDIA STAMP DUTY Rs.0000100 03532 158813

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PRINCIPAL
K.L.E. University's
Shri B. M. Kankanwadi Ayurved Mahavidyalaya
Khanapur-BELAGAVI-03

2. Study outcomes of the study shall be -

1. Primary Outcome:

1. Assessment of change in dose of OHAs over a period of three months
2. Assessment of change in Quality of life of patient over three months of treatment

2. Secondary outcomes:

1. Assessment of monthly changes in fasting & postprandial plasma glucose levels over three months of study treatment
2. Assessment of changes in post treatment HbA1C % (Glycosylated Hemoglobin) value
1. Assessment of changes in post treatment serum Insulin level
2. Assessment of clinical symptoms of Type 2 DM i.e. Polydypsia, Polyphasia, Polyurea, & Fatigue at every visit till completion of the study
3. Global assessment for overall improvement by subject and investigator at the end of 3 months of study treatment
4. Assessment of tolerability of study drugs by assessing ADRs on study completion.
   Assessment of Laboratory parameters like Liver function tests (LFT), Renal function tests (RFT), Lipid profile, complete blood count (CBC), ESR, Hb%, Urine Examination and ECG on study completion

3. Study Design-

Randomized, multi-center, double blind, placebo controlled, prospective clinical study

4. The criteria for inclusion of subjects for this study shall be -

1. Males and females in the age group of 20-70 years
2. Subjects suffering from type 2 diabetes mellitus for more than one year, and stabilized on mono / polydrug oral hypoglycemic agent(s) for at least last 3 months.
3. Subjects having HbA1C value 6-10% (both inclusive) at screening.
4. Subjects having Fasting Plasma Glucose 126 -250 mg/dl (both inclusive) at screening.
5. Subjects having postprandial glucose not more than 350 mg/dl at screening
6. Subject's ECG not demonstrating any signs of uncontrolled arrhythmia / acute ischemia and X- ray chest not showing any active lesion of tuberculosis
7. A urine pregnancy test is required for all female subjects unless subject has had a hysterectomy, tubal ligation, or is > 2 years post menopause.
8. Subjects willing to follow the procedures as per the study protocol and voluntarily signing informed consent form.

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5. Subject Exclusion Criteria

1. Subjects on insulin therapy.
2. Subjects suffering from type-1 DM or types of Diabetes mellitus other than Type -2.
3. Subjects with known history of chronic hepatic or renal disease.
4. Subjects with known history of active malignancy.
5. Subjects with known history of significant cardiovascular event < 12 weeks prior to randomization.
6. Subjects with known history of major complications of Diabetes like Ketoacidosis.

   Nephropathy, Neuropathy, Retinopathy, and Diabetic wounds.
7. Subjects with known history of chronic, contagious infectious disease, such as active tuberculosis, Hepatitis B or C, or HIV.
8. Subjects with known history of active metabolic or gastrointestinal diseases that may interfere with nutrient absorption, metabolism, or excretion, excluding diabetes.
9. History of Use of any other investigational drug within 1 month prior to randomization
10. Known history of hypersensitivity to ingredients used in study drug
11. Pregnant and Lactating females.
12. Any other conditions which in the opinion of investigator will place the subject at risk or will influence the conduct of study or interpretation of results

6. Investigational Product : The investigational Products manufactured by Welex Laboratories Pvt Ltd is already approved by the FDA and are available in the market.

7. After getting clearance from the Ethical Committee for this clinical study, the subjects attending the O.P.D. at "KLEUBMK" Belagavi, meeting inclusion criteria and giving voluntary written consent, will be recruited for the study at O.P.D. basis. 40 patients (subjects) will be selected on screening visit and a written informed consent will be taken from subjects for their participation in the study.

8. Treatment Plan:

Study treatment shall be administered only to the subjects included in the study following the procedures set out in this protocol (See the inclusion and exclusion Criteria section)

All screened subjects shall be entered into the screening log. Subjects who meet the inclusion/exclusion criteria shall be recruited in the study. Recruited subjects shall be allotted a unique subject number and the number shall be entered in the enrolment log. If a subject drops out of the study after allocation of the unique subject number, that number shall not be re-allocated to another subject.

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The time and date of recruitment shall also be recorded in the enrolment log. The time between recruitment and admission of the drug should be as short as possible.

9. Treatment period

The total duration of the study is 90 days. Subjects will be asked to take 2 capsules of Ayubes twice daily, orally in the morning and evening with lukewarm water for 90 days.

10. Rescue Medication

An accurate record of used rescue medications will be kept in the CRF.

11. Diet /Activity/Other

All the subjects will be advised to continue their regular diet and exercise regimen (which they are already following) during the entire study.

12. Follow Up

Safety information shall be collected at each study visit. Subjects with SAEs or AEs that are ongoing at the end of the study treatment shall be followed until the resolution of the event.

13. Procedures to be performed daily during study treatment

Subjects of Type-2 DM attending outpatient Department at **KLE Ayurveda Hospital & Medical Research Center, Belagavi,** will be screened for eligibility criteria. On screening visit, a written informed consent will be obtained from subjects for their participation in the study. Subject's history will be recorded and his/her general and physical examination will be done. Then subject will undergo Fasting blood sugar. If subject's fasting blood sugar is 126 to 250 mg/dl (both inclusive), then subject's blood will be sent to laboratory for estimation of postprandial blood sugar level and HbA1c%. If postprandial blood sugar level is not more than 350 mg/dl and HbA1c value 6 to 10 % (both inclusive), then subject will be advised to undergo X- ray chest (PA View) and ECG. If subject's ECG is not demonstrating any signs of uncontrolled arrhythmia / acute ischemia and X- ray chest not showing any active lesion of tuberculosis, then subject will be advised to undergo investigations i.e. CBC, ESR, Hb%, Urine Sugar (Fasting & PP), Serum Insulin, Liver function tests, Renal function tests, Lipid profile, Urine routine and microscopic examinations, Urine pregnancy test (only if the subject is female of child bearing potential) and HIV test.

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Diary card to record daily symptoms of diabetes will be provided to subjects. A wash out period of 7 days (screening visit to baseline visit) will be advised during which subjects will have to refrain from anti-diabetic medicines (Herbal, Ayurvedic, homeopathic, Unani, siddha, Nutraceuticals etc.) other than OHA(s) prescribed by Investigator.

On baseline visit, subject will be recruited in the study if he/she meets all the inclusion criteria. Subjects will then be randomized to one of the two study groups as per the computer generated randomization list. Subjects will undergo general and systemic examinations. At baseline visit and on every follow up visit (except last follow up visit), subjects will be provided with diary card to record daily symptoms of DM. On every follow up visit, filled diary card will be collected and symptoms will be assessed and graded on clinical symptom scoring scale.

On baseline visit and at every follow up visit (except last follow up visit), as per computer generated randomization list, subjects will be provided either 'Capsule Ayubes or matching placebo. Subject will be advised to consume given medication in a dose of 2 capsules twice daily orally with lukewarm water after meals for 90 days. Subject will be advised to continue his/her allopathic anti-diabetic medicines (OHAs) taken under the supervision of the investigator. Drug compliance will also be assessed by the investigator on every follow up visit. Subjects will be advised to continue the diet and exercise regimen (which they are already following) during the entire study.

Subjects will be called to KLE Ayurveda Hospital & Medical Research Center, Belagavi for follow up visits on every 15th days till 90 days after the baseline visit. On every follow up visit, subjects will undergo general and systemic examinations and assessment of clinical symptoms of Type 2 DM will be done. Subject's blood sugar (Fasting & PP) and Urine sugar (Fasting & PP) will be checked every month.

On baseline visit and after every month till completion of study, subject's dose of OHA(s) will either be reduced or increased or will be kept as it is depending upon his/her status of blood sugar level. Also subject's quality of life will be assessed using WHO questionnaire at baseline visit and thereafter at every month till completion of the study.

Subject's global evaluation for overall improvement and Investigator's global evaluation for overall improvement will be done on completion of the study. Tolerability of the trial drugs will be assessed by the investigator and by the subject at the end of the study. All the subjects will be closely monitored for any Adverse Events starting from baseline visit till the end of the study visit. On final follow up visit (i.e.

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Day 90). subjects laboratory investigations viz. CBC, ESR, Hb%, BSL (fasting & PP), Urine Sugar (Fasting & PP), Serum Insulin . HbA1c%. Liver function tests, Renal function tests. Lipid profile. Urine routine & microscopic, and ECG will be performed. After completion of 90 days of study treatment, all the subjects will be asked to stop trial medication and take advice of investigator for further treatment.

14. ASSESSMENT OF SAFETY

a. Specifications of Safety Variables

Safety shall be assessed by clinical review of all safety parameters, including the following:

a. Adverse event reporting

b. Vital signs including pulse rate, respiratory rate, body temperature and blood pressure.

Safety variables shall be listed individually for detailed clinical review, when needed.

The changes from baseline in vital signs shall be presented descriptively by treatment (formulation). Additional tables shall summarize adverse events by severity and relationship to study product as well as leading to SAEs and withdrawal of the subjects from the study.

15. ETHICAL CONSIDERATIONS & REGISTRATION OF STUDY:

The study will be conducted, recorded and reported strictly in accordance with GCP guidelines laid down for ASU drugs. During the conduct of the clinical study, rights, safety and wellbeing of the study participants will be given prime importance.

Good laboratory practices (GLP) will be followed for all the Laboratory investigations to be performed under the study drug will be prepared with compliance to Good Manufacturing practices (GMP) as applicable for Ayurvedic products in India.

16. Ethics Committee review and communications

The study protocol and related documents will be submitted to the Ethics committee of respective study center for review and the approval. Subjects will not be recruited to the study until the IEC approves the study. Any changes in this study plan or protocol will be implemented only after they are reviewed and approved by the IEC. IEC will keep its close watch on the study conduct for the entire study duration.

For any IEC related query or complaints, person from ethics committee, to be approached, is chairman/secretary of the respective Ethics committee.

17. Written Informed consent process

On screening visit, voluntary written informed consent, for their participation in the study, will be obtained from the subjects on ICF; printed in the language best understood by them. During Informed consent process, subjects will be explained the objectives of the study, design of the study and possible

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risks and benefits of participation in the study. They will be given enough time to ask the questions to fully understand the study. If the subject is illiterate, informed consent process will be in presence of an impartial witness, if the subject agrees to participate in the study, his/her thumb impression will be taken on the ICF and also the signature (with date) of impartial witness will be obtained on the same ICF. One copy of the ICF will be handed over to the subject. The informed consent process will be documented

18. Subject confidentiality statement

The identity of the study subjects will not be provided to any party except study related personnel, Sponsor or their representatives, ethics committee and representatives of Government regulatory bodies. The data generated and recorded from the study will be kept confidential and in a coded form. The recorded data, after analysis, may be published by sponsor or with the investigators consent in peer reviewed scientific journals without revealing the identity of any subject.

19. Subject Insurance Policy

The Sponsor undertakes to bear any compensation and cost for medical treatment of any possible study related injuries to the study subjects, caused specifically due to the use of investigational product. Investigator shall be completely indemnified by the Sponsor in this regard.

20. CTRI registration:

The study will be registered with Clinical Trial Registry of India after approval from at least one of the IEC. The status of other EC approval will be updated accordingly.

21. Appointment of Research Associate : The Investigator or Institute shall appoint and entrust the study work to the at least one Post Graduate Scholar or Ayurveda Graduate from KLEUBMK. TIMER will make payments to the Research Associate for the clinical study as per mutually agreed terms.

22. Payments: 'TIMER' shall pay to KLEUBMK as per the agreed Budget of the study. **Service Tax or TDS or any other taxes will be applicable as per the rules.** Payment schedule will be 10% as advance payment before IEC approval, 50 % after IEC approval before initiation of study, 30% after fifty percent recruitment of subjects, and balance 10% at the time of final report submission. **(Payment agreed is exclusive of Service Tax or TDS or any other taxes which will be added to the budget)**

23. Judistriction: In case of any dispute not settled by mutual discussions, Belagavi shall be the area of Judistriction.

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Shahapur-BELAGAVI-03

24. Conduct of Clinical Study: The clinical study under this protocol will be done as per the current ASU-GCP guidelines for conducting clinical studies. The clinical study will be carried out as per the protocol agreed upon.

25. Documentation & Communications: Investigator will periodically communicate the process of the clinical trial to the CRO. Investigator will cooperate during the monitoring visits by providing all the relevant details. Maintaining the source documents and records for the relevant period of time (5 Years) will be done at the Site.

26. Publications, IPR: Any intellectual knowledge generated through the study shall belong to the sponsor and the investigator and organization shall not have any rights on it. Nothing related to the clinical study or the product shall be revealed to the press or any other organization/persons without the consent of the sponsor. The rights to publish the data will lie with the sponsor, however no data or publication will be done without the prior information and approval of the Investigator. The Investigators involved in the study will be the Authors of the Publication whenever it is done.

This M.O.U. has been signed by the parties at Belagavi on this ---12 day of Apr--2017.

For
KLEU's Shri B M K Ayurveda Mahavidyalaya
Belagavi. Karnataka

(Dr. B.S.Prasad)
Principal

PRINCIPAL
K.L.E. University's
Shri B. M. Kankanwadi
Ayurved Mahavidyalaya
Shahapur-BELAGAVI-03

For
Target Institute of Medical Education & Research
Mumbai

(Dr. Swapali Mahadik)
Project Head

Witness - 1) Tushar Bhagwat

2) Dr. Vedantam Giridhar

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Ref:

Memorandum of Understanding

Between

Dr. Prabhakar Kore Basic Science Research Centre,Belagavi

and

P. C. Jabin Science College,Vidynagar, Hubballi.

This MoU is executed on Date 14.03.2017 between "Dr. Prabhakar Kore Basic Science Research Center", a premier centre of Excellence, which expression shall mean and include unless repugnant to context hereof, it's successor-in-interest. administrators and assigns.

"Dr. Prabhakar Kore Basic Science Research Centre" is one of the research centres with a built up area of 10,000 Sq. ft. Hosting five labs that engage in basic research with state-of-the-art facilities for staff and research scholars. The research centre is focused on the key areas of Molecular Biology, Medical Microbiology. Pharmaceutical Analysis, Natural Product Research and Cell Culture. The centre is located at IIIrd floor, V. K. Institute of Dental Sciences Campus, KLE University, Nehru Nagar, Belagavi, - 590 010, Karnataka, India.

AND

P. C. Jabin Science College, Vidyanagar, Hubballi which expression shall mean and include unless repugnant to context hereof, it's successors-interest. administrators and assigns.

The KLE'S **P. C. Jabin Science College, Vidyanagar, Hubballi** was established in the year 1957, for imparting basic science education and nurturing the wonders of science. On its march, the college is accredited for 3rdcycle and awarded 'A' grade, with CGPA of 3.37 by NAAC. Recognizing the quality science education rendered by college, the UGC has awarded '*Autonomous*' status in the year 2007 and extended the same for second time in the year 2012. Based on the excellent performances in the academics, research and

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concern for community, the UGC has recognised College with Potential for Excellence in the year 2007 and extended the status for the phase- III in the year, 2014.

Whereas,

The parties have discussed and deliberated on various items of mutual interest and benefits and have deemed expedient to execute this memorandum of understanding so as to mutually co-operate in the field of curricula,research, training programs, and joint publications etc.

1. **Agreement on Sharing of Facilitates**

1.1 Both the organizations have agreed to share their respective R & D facilities in order to promote academic and research interaction.

1.2 There will be provision for mutual sharing of experts from **"Dr. Prabhakar Kore Basic Science Research Centre"**and resource persons from **"P. C. Jabin Science College, Vidyanagar, Hubballi".**

2. **Agreement on Joint R & D Projects**

2.1 Research projects in the identified areas will be jointly undertaken by**"Dr. Prabhakar Kore Basic Science Research Centre"**and **"P. C. Jabin Science College, Hubballi".** Both the organizations will submit collaborative research projects to various National and International funding agencies. Both the organizations would ensure the successful completion of the funded research projects.

2.2 For all the matters concerned a coordination committee overseeing the issues consisting of Six members (Three Members from **"Dr. Prabhakar Kore Basic Science Research Centre"**andthree members from **"P. C. Jabin Science College, Hubballi"**) for identifying the issues in joint R & D projects to be carried out under this MoU. The ethical approval of the projects undertaken would be granted by Ethics sub committees of **"Dr. Prabhakar Kore Basic Science Research Centre"** and **"P. C. Jabin Science College, Hubballi"**as registered under law.

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3. **Agreement on Technology transfer:**

3.1 Both **"Dr. Prabhakar Kore Basic Science Research Centre"** and **"P. C. Jabin Science College, Hubballi"** agree mutually to share the technology transfer benefits whenever feasible.

4. **Agreement on Joint Seminar/conference/Workshops/Hands on training programmes.**

4.1 Both **"Dr. Prabhakar Kore Basic Science Research Centre"** and "college" agree to hold / conduct events (joint Conference/Workshop/Hands on training programmes) whenever feasible in **"Dr. Prabhakar Kore Basic Science Research Centre" or "P. C. Jabin Science College, Hubballi"**.

5. **Agreement on Industrial visits:**

5.1. Both **"Dr. Prabhakar Kore Basic Science Research Centre"** and **"P. C. Jabin Science College, Hubballi"** agree to organize industrial visits whenever feasible, for the students, staffs and delegates and also during the Conference /Workshop/Hands on training programmes.

6. **Agreement on Industrial training:**

6.1 Both **"Dr. Prabhakar Kore Basic Science Research Centre"** and **"P. C. Jabin Science College, Hubballi"** agree to train the students and staff by organizing industrial training programmes whenever feasible related to technology, Analytical development, validation and documentation etc.

7. **Agreement on Placements:**

7.1 Both **"Dr. Prabhakar Kore Basic Science Research Centre"** and **"P. C. Jabin Science College, Hubballi"** agree to Provide summer internships to students is another area. This helps in motivating the students, understanding industry environment and practices, job profiles, projects they can undertake besides facilitating them to earn some money to be spent usefully in the next academic year / semester.

8. **Agreement on Duration, Amendment and Termination of MoU**

8.1 This MoU shall be valid for a period of five years from the date of its signing. During the period of the validity, the MoU can be amended any time by mutual consent of both the parties in writing. The MoU can also be terminated by either party giving the order a written notice of its desire to terminate the MoU by giving

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three months notice in advance. In the event of such termination both the parties shall cooperate in good spirit for the completion of the ongoing researchers.

8.2 In witness whereof of the two parties have signed this memorandum of understanding by the hand of, on behalf of **"Dr. Prabhakar Kore Basic Science Research Centre"** and by the hand on behalf of **"P. C. Jabin Science College, Hubballi"**on the date,month and year referred to above.

Dr. Prabhakar Kore Basic Science Research Centre KLE University Belagavi

Signed by and on behalf of
"Dr. Prabhakar Kore Basic Science Research Centre"

Signed by and on behalf of
"P. C. Jabin Science College, Hubballi"

Witness:

1. Dr. Sanjay Mishra

3. Dr. B. S. Agadi

2. Dr. Suneel Dodamani

4. (Mr. Rajeev R Potadar)

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SCHEDULE "A"

PROTOCOL

TITLE:

"A randomized, multi center, open label, two-treatment, two-period, two-sequence, multiple dose, crossover, pivotal steady state bioequivalence study of Everolimus 10 mg tablet, Manufactured by Teva Pharmaceuticals - Pliva Croatia Ltd., Prilaz baruna Filipovica 25, 10000 Zagreb Croatia vs. Afinitor®(Everolimus) 10 mg tablet of Novartis Pharmaceuticals Corporation, USA in advanced renal cell carcinoma (RCC) patients under fasting conditions."

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addition to the Review Period in the event Sponsor so requests to enable Sponsor to secure patent or other proprietary protection ("Delay Period"). The Principal Investigator shall keep the proposed publication confidential until the Review Period concludes and, if elected by Sponsor, the Delay Period has expired. The Principal Investigator understands that, with respect to any proposed publication or presentation, good faith consideration will be given to Sponsor's comments with due regard for Sponsor's commercial and proprietary interests and at Sponsor's request, any Confidential Information will be deleted from such article or presentation. Notwithstanding the foregoing, unless otherwise permitted in writing by Sponsor / Veeda, the Principal Investigator shall not be permitted to publish Confidential Information. For the purposes of this provision, Confidential Information shall not include the results of the Study. Institution shall have no right to publish or present pursuant to this Agreement.

6.2 Multi-Center Studies. It is agreed and understood by Principal Investigator that Study is a multi-center study and an independent, joint publication is anticipated to be authored by investigators in the multi-center study, including Principal Investigator. Therefore, Principal Investigator agrees not to publish or present the results or any information derived from the study without prior approval from the sponsor.

7. TERM & TERMINATION

7.1 Termination by Sponsor/Veeda. Veeda or Sponsor may terminate this Agreement (i) immediately if the Study is terminated by regulatory authorities or in the interest of public health; or (ii) without cause at any time during the Term of this agreement on thirty (30) days prior written notice to Institution and Principal Investigator.

7.2 Effect of Termination. Termination or expiration of this Agreement shall not affect any rights or obligations which have accrued prior thereto. In the event of termination of this Agreement, Principal Investigator and Institution shall complete the Study for then-enrolled Subjects where required by accepted medical practice.

8. INDEMNIFICATION

8.1 Sponsor Indemnification. Sponsor shall indemnify Principal Investigator and Institution, (including Principal Investigator's and Institution's affiliates, contractors, agents, fellows, employees and servants) (collectively "Investigator Indemnitees") for any damages and liabilities, including reasonable attorney's fees incurred by Investigator Indemnitees as a result of any claim or lawsuit against them arising directly out of the performance of the Study drug pursuant to the Protocol ("Claims"); provided however Sponsor will not be responsible for and assumes no liability for any loss, claims, and/or demands to the extent arising from any of the following: the negligence or willful misconduct of an Investigator Indemnitees or any Investigator Indemnitees failure to adhere to (i) the terms of the Protocol and/or this Agreement including any amendments thereto; or (ii) applicable federal, provincial, or local laws; or (iii) the written instructions relative to the use of the Study Product.

8.2 Institution Indemnification. Institution shall indemnify, defend and hold harmless Sponsor and Veeda (including Sponsor's and Veeda's affiliates, contractors, agents, fellows, employees and servants) (collectively "Sponsor Indemnitees") from any and all losses, injuries, harm, costs or expenses, including without limitation, reasonable attorney's fees, incurred by Sponsor Indemnitees that arise from the negligence or willful misconduct by Investigator Indemnitees (as defined above in clause 8.1). Principal Investigator and Institution shall carry professional

Indemnity Insurance and such other insurance required to indemnify under this clause, for the duration of this Agreement and for a reasonable period (which is not less than 1 year) after termination or expiration thereof. Principal Investigator and Institution shall provide the copy of insurance as and when required by Veeda or Sponsor.

8.3 Obligation to Notify. The foregoing agreement to indemnify is conditioned upon the obligation of the Indemnitee to:

(i) advise indemnifying party of any claim or lawsuit, in writing, within fifteen (15) days after Indemnitee has received notice of said claim or lawsuit, or within such other time frame so that indemnifying party's ability and rights to defend or settle such claim or lawsuit, as determined in Sponsor's sole discretion, are not prejudiced;

(ii) Assist indemnifying party and its representatives in the investigation and defense of any lawsuit and/or claim for which indemnification is provided; and

(iii) Not compromise or otherwise settle any such claim or lawsuit on behalf of indemnifying party without indemnifying party prior written consent.

8.4 Serious Adverse Event Reimbursement. Not withstanding any other terms contained in this Agreement, Sponsor will reimburse the Institution for any reasonable, necessary and properly documented medical expenses directly related to a Subject's Serious Adverse Event (as the term is defined in the Protocol, also referred to as an "SAE") that is because of the administration of the Study drug in accordance with the Protocol. Sponsor shall not be responsible for the reimbursement of SAE costs that are the result of a) the negligence, misconduct, lack of adherence to applicable law or breach of this Agreement by any agent/vendor or employee of the Principal Investigator or Institution

9. DEBARMENT

9.1 Debarment and Exclusion. Institution and Principal Investigator certify that they are not debarred or restricted from conducting clinical research and will not use in any capacity the services of any person debarred or restricted from conducting clinical research under applicable law with respect to services to be performed under this Agreement. Institution and Principal Investigator also certify that they are not excluded from any governmental health care program. Institution and Principal Investigator further certify that they are not subject to a government mandated corporate integrity agreement and has not violated any applicable anti-kickback or false claims laws or regulations. During the term of this Agreement and for three years after its termination, Principal Investigator and Institution will notify Veeda promptly in writing to the extent possible within two (2) business days if either of these certifications needs to be amended in light of new information or if Institution and/or Principal Investigator becomes aware of any material issues related to the medical licensure of any associated researchers. Institution and Principal Investigator will cooperate with Veeda and/or Sponsor regarding any responsive action necessary.

10. NOTICE

10.1 Notices. Except as otherwise provided herein, all notices, consents, or approvals required under this Agreement will be in writing delivered personally or delivered by facsimile, electronic mail, first class mail, or by a commercial overnight courier that guarantees next day delivery when

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possible (in the case of notice by facsimile or electronic mail, a confirmation shall thereafter be transmitted to the addressee by first class mail or by a commercial overnight courier that guarantees next day delivery), addressed as follows:

If to Veeda:
Veeda Clinical Research Pvt. Ltd.
Address: Veeda Clinical Research Private Ltd. **Veeda House** "Vedant Complex" 4th Floor, Next to YMCA Club, Above Shivalik Hyundai Showroom, S. G. Highway, Vejalpur – 380051, Ahmedabad, Gujarat-INDIA
Attention: Dr. E. Venu Madhav
Phone: +91 79 30013000
Fax: +91 79 30013010

If to Principle Investigator:

Name	: Dr Maheshkumar V kalloli
Address	: KLES Dr. Prabhakar Kore Hospital & MRC, Nehru nagar, Belagavi 59010, Karnataka
Phone	: 09945014996
Fax	**: 0831-2493099**

If to Institution:

Name	: Dr. M. V. Jali
Designation	: MD & CE
Address	: KLES Dr. Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi 59010, Karnataka
Phone	: 0831 2470400
Fax	: 0831 2493099

11. Miscellaneous

11.1 Binding Obligations. Principal Investigator and Institution represent and certify that the terms of this Agreement are valid and binding obligations are not inconsistent with any other contractual and/or legal obligations they may have, or with the policies of company with which it is associated.

11.2 Publicity. To the extent permitted by law or regulation, no party shall disclose the existence or terms of this Agreement nor use the name of any other party, nor the names of other party's employees, in any publicity, advertising or announcement without the consenting party's prior written approval.

11.3 Independent Contractor. Principal Investigator's and Institution's relationship to Veeda and Sponsor under this Agreement is that of an independent contractor, Principal Investigator and Institution have no authority to bind or act on behalf of Veeda or Sponsor.

11.4 Assignment. Principal Investigator and Institution may not assign this Agreement to any other party, nor may it subcontract any of its services hereunder, without Veeda's and Sponsor's prior written consent. Any attempted assignment without Veeda's and Sponsor's prior written consent shall be null and void and shall, for the avoidance of doubt, constitute a material breach of this Agreement.

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11.5 Sub-investigators. Principal Investigator and Institution hereby agree that as to any individuals identified on the applicable FDA Form 1572 or Investigator information and Agreement Form as sub-investigators for the Study, Principal Investigator and Institution shall ensure such individuals' compliance with the terms and conditions hereof.

11.6 Entire Agreement. This Agreement contains the entire understanding of the parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. This Agreement may be modified only by written agreement signed by the parties.

11.7 Governing Law. This agreement shall be governed by and interpreted in accordance with the Indian laws. Any disputes arising in connection with this Agreement shall be resolved through arbitration. The arbitrator shall be mutually decided among the parties. The arbitration shall be conducted under the Arbitration and Conciliation Act of 1996. The place of arbitration shall be Ahmedabad. Each party shall bear its own costs of the arbitration unless the arbitrator otherwise directs.

11.8 Survival. Notwithstanding termination of this Agreement for any reason, rights and obligations which by the terms of this Agreement survive termination thereof, shall remain in full force and effect including but not limited to Section 4 (Confidential Information), Section 5 (Intellectual Property) and Section 6 (Publication).

11.9 Severability. If any of the provisions or a portion of any provision, of this Agreement is held unenforceable or invalid by a court of competent jurisdiction, the validity and enforceability of the other portions of any such provision and/or the remaining provisions shall not be affected thereby.

11.10Conflict with Protocol. In the event of a conflict between the terms and conditions of this Agreement and those of the Protocol, the Protocol shall control in matters of science and the Agreement shall control in all other matters.

11.11Headings: Any headings, titles and captions used in this Agreement are for convenience and reference only. They do not purport to, and shall not be deemed to, limit or extend the scope or intent of the sections to which they pertain.

11.12 Veeda will assist the site to facilitate the execution of the study protocol with the procurement of the infusion pump and train the study staff on its functional operation for accurate dispensing of the study drug .

11.13 PI/Institute will be responsible for facilitating the availability of site level Phlebotomist dedicated for this study throughout the study duration.

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IN WITNESS WHEREOF, the parties have executed this Agreement as of the date written above.

For, Veeda Clinical Research Pvt. Ltd.

Name: Dr. E. Venu Madhav
Title: COO

Date: 23 Jun 2016

For, Principle Investigator

Name: Dr. Mahesh Kumar Kalloli
Title: Principle Investigator

Date: 25 JUN 2016

For, Institute

Name: Dr. M. V. Jali
Title: MD & CE

Date: 30/6/2016

Witness:

Name: Dr Deepak Tumari
Contact Details: 9964403640

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Registrar
KLE Academy of Higher Education
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SCHEDULE "B"

STUDY BUDGET

All defined terms shall have the same meaning attributed to them in the Agreement unless otherwise defined herein.

Institution/Principal Investigator will be paid based upon the number of Subjects properly enrolled and the visits completed by the Subjects as legibly, completely and accurately recorded in the CRFs.

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a) **Trial Budget:**

15-VIN-284	Screening	Period I						Period II						EOS	Total
Dr. Lokesh K N	**Visit 01**	**Day 0 & Day 01**	**Day 06**	**Day 11**	**Day 12**	**Day 13**	**Day 14**	**Day 15**	**Day 20**	**Day 25**	**Day 26**	**Day 27**	**Day 28**	**Day 29**	
Investigator Grant	5000	5000	4000	4000	4000	4000	7000	4000	4000	4000	4000	4000	7000	6000	66,000
Study Coordinator Grant	1000	500	500	500	500	500	2000	500	500	500	500	500	2000	1000	11,000
Investigations															
ECG	500													500	1,000
X-Ray	500														500
Local Lab: Bio Chemistry & Hematology								2500							2,500
Patient Housing		2000		2000	2000	2000	2000	2000		2000	2000	2000	2000	2000	22,000
Nursing Charges & Phlebotomy Charges	500	500	500	500	700	700	3000	500	500	500	700	700	3000	500	12,800
Admin Charge	200	200	200	200	200	200	200	200	200	200	200	200	200	200	2,800
Institutional Overhead (20 %)	1200	1100	900	900	900	900	1800	900	900	900	900	900	1800	1400	15,400
Patient Compensation	1000	2000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	2000	1000	16,000
Total Grant															**1,50,000**

Above budget is including all applicable taxes.

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KLE Academy of Higher Education and Research, BELAGAVI

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INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

सत्यमेव जयते

Certificate No.	:	IN-KA11899844806922O
Certificate Issued Date	:	19-Sep-2016 02:49 PM
Account Reference	:	NONACC (FI)/ kacrsfl08/ JAYANAGAR4/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKACRSFL08738079176422620
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	:	K L E SOCIETYS DR PRABHAKAR KORE HOSPITAL
Stamp Duty Paid By	:	QUINTILES RESEARCH INDIA PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

AUTHORISED SIGNATORY
The Bharathi Co-op Credit Society Ltd
Jayanagar, Bangalore

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.

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KLE Academy of Higher Education
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CLINICAL TRIAL AGREEMENT

Made between **Dr. Vardaraj Gokak**, having a place of business at KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi - 590010, Karnataka, India (the "Investigator"), **KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre**, having a place of business at Nehru Nagar, Belagavi - 590010, Karnataka, India (the "Institution"), **GDD Experts India Pvt. Ltd.** having a place of business at Ground Floor, Gulmohar Apartment, Opposite Hislop College, Nagpur- 440001, Maharashtra, India (the "Research Company"), **F. Hoffmann-La Roche Ltd**, having a place of business at Grenzacherstrasse 124, 4070 Basel, Switzerland ("Sponsor") and **Quintiles Research (India) Private Limited**, having its office at B-101-106, Shapath IV, S G Road, Ahmedabad- 380 051, India ("Quintiles").

PROTOCOL NUMBER:	GA29102
PROTOCOL TITLE:	Phase III, randomized, double-blind, placebo controlled, multicenter study to evaluate the efficacy (maintenance of remission) and safety of Etrolizumab compared with placebo in patients with moderate to severe active Ulcerative Colitis who are naive to TNF Inhibitors
PROTOCOL DATE:	28 August 2015
SPONSOR:	F. Hoffmann-La Roche Ltd
PRINCIPAL INVESTIGATOR:	Dr. Vardaraj Gokak
KEY ENROLLMENT DATE: (date by which site is to enroll at least one (1) subject)	100 Calendar Days after Site Initiation Visit

WHEREAS, the Investigator and Institution [or "and Research Company"], if any, (hereafter, jointly, the "Site") are willing to conduct a clinical trial (the "Study"), in accordance with the above-referenced protocol and any subsequent amendments thereto (the "Protocol") and Sponsor and Quintiles request the Site to undertake such Study;

WHEREAS, Quintiles has been duly authorized by the Sponsor to carry out certain obligations of the Sponsor in the conduct of the Study, consistent with the terms of this Agreement;

NOW THEREFORE, the following is agreed:

1. Quintiles and Sponsor hereby appoint the Site to conduct the Study, and the Site agrees to ensure that the Site and the Site's employees, agents, and staff will conduct the Study in accordance with the Protocol (as may be amended from time to time by Sponsor), the terms of this agreement, including the Terms and Conditions attached as Attachment A, the Payment Schedule and Budget attached as Attachment B, and any other attachments hereto, which all are incorporated by reference herein (the "Agreement"), good clinical practices, and all applicable laws and regulations. The Site hereby confirms that it has enough time and resources to perform the Study according to the highest quality standards. The Site understands and agrees that if Site has not enrolled at least one (1) subject by the Key Enrollment Date then Sponsor may terminate this Agreement in accordance with Section 5 of Attachment A.

   Enrollment of Patients
   The Effective Date of this Agreement is as listed in Section 3. 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 contract is reached.

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In addition, Sponsor has a right to limit or increase unilaterally and at any time the number of subjects participating in the Study.

1. Payments shall be made in accordance with the provisions set forth in Attachment B, with the last payment being made after the Site completes all its obligations hereunder, and Quintiles has received all completed case report forms ("CRFs") and, if Quintiles requests, all other Confidential Information as defined in Attachment A, Section 2 (Confidential and Proprietary Information). The Site will act as an independent contractor, and shall not be considered the employee or agent 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 Site. The Site acknowledges and agrees that Investigator's judgment with respect to Investigator's advice to and care of each subject is not affected by the compensation Site receives hereunder.

   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.

   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 (the "Payee"):

PAYEE NAME:	GDD EXPERTS INDIA PVT. LTD.
PAYEE ADDRESS:	Ground Floor, Gulmohar Apartment, Opposite Hislop College, Nagpur- 440001, Maharashtra, India
PAN OF PAYEE	AADCG0363Q

   It should be noted that all the payments made to the Payee are subject to Tax Deducted at Source (TDS) in accordance with India tax laws, as amended from time to time. Quintiles will deduct the tax at the time of making payments unless a valid Certificate (Form 15 AA – for no TDS) from tax authority is made available.

   Site will have thirty (30) days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

   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 will be 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. **Investigator acknowledges that if Investigator is not the Payee, neither Quintiles nor Sponsor will pay Investigator, even if the Payee fails to reimburse Investigator.**

3. This Agreement will become effective on the date of approval of the Study by Drugs Controller General India or on 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 the provision in Attachment A. Quintiles shall attach a copy of the letter from the Drugs Controller General India approving the Study to this Agreement as Attachment C, and the parties agree that such letter shall be incorporated by reference herein. If such approval letter has not been received as of the date the parties sign this Agreement, Quintiles shall keep the original signed Agreements until receipt of such

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approval letter, and upon receipt of such letter, Quintiles shall attach a copy of the letter to each original Agreement as Attachment C and forward an original Agreement to each other party, while retaining one original Agreement its files. If such approval letter already has been received prior to the signatures of the parties, Quintiles shall immediately attach a copy of the letter hereto as Attachment C, and upon signature of all parties, each party shall receive an original of the Agreement, which shall include such letter as Attachment C. In the event of a conflict between the Protocol and this Agreement, the terms of this Agreement will govern.

4. The date of execution of this Agreement is as listed in Section 3 above. Consequently, the Site will not be permitted to screen patients, randomize patients, receive Investigational Product or receive any start up payment until the validity date of this contract is reached.

5. Prior to and during the course of the Study, Quintiles or Study Sponsor may request to collect personal data which may be subject to data privacy laws or regulations (collectively "Data Privacy Legislation") relating to the Study from the Site, including from its investigators, sub-investigators, other Site staff or personnel involved in the conduct of the Study. The Investigator hereby consents to the processing of Investigator's personal data collected by Quintiles or Sponsor, and Investigator and Institution agree to obtain any consents, as may be necessary in accordance with applicable Data Privacy Legislation, for the processing of any personal data collected by Quintiles or the Sponsor from its investigators, sub-investigators, staff and personnel involved in the conduct of the Study. Such consent shall authorize the transfer of personal data, to countries other than the Site's own country, including without limitation the United States, even though data protection may not exist or be as developed in those countries as in the Site's own country, for the following purposes: a) the conduct and interpretation of the Study; b) review by governmental or regulatory agencies, Sponsor, Quintiles, and their agents, and affiliates and collaborators; c) satisfying legal or regulatory requirements; d) publication on www.clinicaltrials.gov and websites and databases that serve a comparable purpose; and e) storage in databases for use in selecting sites in future clinical trials. In the event any Site personnel participating in the Study are not willing to provide such consent, Site acknowledges that such personnel will not be able to participate in the Study.

6. Institution and Principal Investigator agree that the compensation they receive from this Agreement 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. Site agrees that it will not bill any patient, insurer, or governmental agency for any items, visits, services or expenses provided or paid for by Quintiles or Sponsor.

   Institution and Principal Investigator and GDD Experts India Pvt. Ltd. represent and warrant that neither they nor any individual or entity acting on their behalf, nor any payee under this Agreement, will, directly or indirectly, offer or pay, or authorize an offer or payment of, any money or anything of value to any Public Official (defined below) or public entity, with the knowledge or intent that the payment, promise or gift, in whole or in part, will be made in order to influence an official act or decision that will assist Quintiles, Sponsor or the Site in securing an improper advantage or in obtaining or retaining business or in directing business to any person or entity.

   In addition to other rights or remedies under this Agreement or at law, Sponsor and/or Quintiles may terminate this Agreement if Site and GDD Experts India Pvt. Ltd. breaches any of the representations or warranties contained in this Section or if Quintiles or Sponsor learns that improper payments are being or have been made to Public Officials by Site or any individual or entity acting or its behalf.

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For the purposes of this Agreement, "Public Official" means any officer or employee of a government, a public international organization or any department or agency thereof, or any person acting in an official capacity, including, for a public agency or enterprise; and any political party or party official, or any candidate for public office.

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

By: Subashri Shivkumar

Name: Subashri Shivkumar

Title: Head Clinical Development Services

Date: 29/Sept/2016

ACKNOWLEDGED AND AGREED BY SPONSOR (Quintiles executing on Sponsor's behalf):

By: Subashri Shivkumar

Name: Subashri Shivkumar

Title: Head Clinical Development Services

Date: 29/Sept/2016

ACKNOWLEDGED AND AGREED BY THE PRINCIPAL INVESTIGATOR:

By: [signature]

Name: Dr. Vardaraj Gokak

Title: Principal Investigator

Date: 28/9/16

ACKNOWLEDGED AND AGREED BY KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre :

By: [signature]
Medical Director & Chief Executive
KLES Dr. Prabhakar Kore Hospital &
Medical Research Centre, BELAGAVI.

Name: Dr. M. V. Jali

Title: Medical Director

Date: 21/10/2016

ACKNOWLEDGED AND AGREED BY GDD EXPERTS INDIA PVT. LTD.:

By: [signature]

Name: Vinod Gyanchandani

Title: Head- Clinical Operations

Date: 30/sep/2016.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

ATTACHMENT A
TERMS AND CONDITIONS

Capitalized terms not defined herein shall have the meanings assigned to them in the attached Agreement.

1) Conduct of the Study. The parties to the Agreement agree that the Study will be performed in strict accordance with the Protocol, all applicable laws, regulations and guidelines, and good clinical practices ("GCPs"), and Indian Medical Council (Professional Conduct, Etiquette and Ethics)(Amendment) Regulations, 2009 – Part-I ("MCI Regulations"). The Investigator shall review all case report forms ("CRFs") to ensure their accuracy and completeness, shall review and understand the information in the Investigator's brochure, shall ensure that all informed consent requirements are met (including any needed authorizations for the use, storage and transfer of personal data), shall ensure that all required reviews and approvals (or favorable opinions) by applicable regulatory authorities and Institutional Review Boards ("IRBs") or Independent Ethics Committees ("IECs") are obtained and shall provide a copy of such approval to Quintiles prior to enrollment of any subjects. A sample informed consent form has been provided by the Sponsor for use in the Study; any modifications to this form must be approved by Quintiles or Sponsor prior to its use, such approval not to be unreasonably withheld. The Site agrees to ensure that all clinical data are accurate, complete, and legible. The Site shall promptly and fully produce all data, records and information relating to the Study to Quintiles and Sponsor and their representatives during normal business hours, and shall assist them in promptly resolving any questions and in performing audits or reviews of original subject records, reports, or data sources. The Site agrees to cooperate with the representatives of Quintiles and Sponsor who visit the Site, 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 warrants that it has the legal authority to share the clinical data and Study-related records and information with Quintiles and Sponsor. The Site shall use the product being tested (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 all Investigational Product and any comparator products in a locked, secured area at all times. Upon completion or termination of the Study, the Site shall return all unused Investigational Product, comparator products, equipment, and materials and all Confidential Information (as defined below).

2) Confidential and Proprietary Information. All information (including, but not limited to, documents, descriptions, data, CRFs, photographs, videos and instructions), and materials (including, but not limited to, the Investigational Product and comparator products), provided to the Site by Quintiles, Sponsor, or their agents, (whether verbal, written or electronic), and all data, reports and information, relating to the Study or its progress (hereinafter, the "Confidential Information") shall be the property of Sponsor. The Site shall keep the Confidential Information strictly confidential and shall disclose it only to its employees involved in conducting the Study, who are subject to confidentiality obligations that are consistent with this Agreement, on a need-to-know basis. These confidentiality obligations shall continue until ten (10) years after completion of the Study, but shall not apply to Confidential Information to the extent that it: a) is or becomes publicly available through no fault of the Site; b) is disclosed to the Site by a third party not subject to any obligation of confidence; c) must be disclosed to IRBs, IECs, or applicable regulatory authorities; d) must be included in any subject's informed consent form; e) is published in accordance with Article 3 herein; or, f) is required to be disclosed by applicable law, provided that the Site shall give Sponsor and Quintiles prompt, advance written notice to permit Quintiles, Sponsor or their agents to object to or otherwise limit such disclosure. The existing inventions and technologies of Sponsor, Quintiles, or the Site are their separate property and are not affected by this Agreement. Sponsor shall have exclusive ownership of any inventions or discoveries arising in whole or in part from Confidential Information or arising from the conduct of the Study. The Site will promptly notify Sponsor in writing if it or Investigator conceives or makes any such inventions or discoveries and, at Sponsor's expense, execute any documents and give any testimony necessary for Sponsor to obtain patents in any country or to otherwise protect Sponsor's interests in such inventions or

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discoveries. The Site agrees to comply with any applicable data privacy or data protection legislation of the country in which the data originated.

3) **Publication.** Site understands that this Study is being conducted at multiple research sites. Site is free to publish or present the Study results obtained at the Site, but only after the first publication or presentation that involves the multi-center data or eighteen (18) months after the completion of the multi-center Study, whichever is first. At least sixty (60) days prior to submitting or presenting a manuscript or other materials relating to the Study to a publisher, reviewer, or other outside persons, the Site shall provide to Sponsor a copy of all such manuscripts and materials, and allow Sponsor sixty (60) days to review and comment on them. If the Sponsor requests, the Site shall remove any Confidential Information (other than Study results) prior to submitting or presenting the materials. In addition, at Sponsor's request, the Site shall delay publication for an additional ninety (90) days to allow Sponsor the opportunity to file for patent protection. No party hereto shall use any other party's name in connection with any advertising, publication or promotion without prior written permission.

4) **Inspection and Debarment.** When given reasonable notice, the Site agrees to allow authorized Quintiles, Sponsor and regulatory authority personnel direct access to the Site's records relating to the Study, including subject medical records, for monitoring, auditing, and inspection purposes. If any source data are kept on computer files only, the site shall make print-outs of all patients' data relevant to the Study for the purpose of source data verification, signed, dated and retained as source documents. 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 permit Quintiles and Sponsor to attend any such inspections. The Site will make reasonable efforts to separate, and not disclose, all confidential materials that are not required to be disclosed during such inspections. Site and Investigator each represents and warrants that there are no pending for-cause regulatory audits, investigations or proceedings involving Site, Investigator, or any of their employees or agents performing Study activities which relate to compliance with laws regarding the conduct of any clinical research. The Investigator and the Institution shall be jointly responsible for maintaining essential Study documents in the manner specified by current good clinical practice ("GCP") guidelines and applicable laws for fifteen (15) years after the completion of the Study or such longer period as specified by current GCP guidelines and applicable laws. In addition, Site shall take measures to prevent accidental or premature destruction of these documents. If the Investigator leaves an institution, then responsibility for maintaining Study records shall be determined in accordance with applicable regulations. During the Study and for 15 years thereafter, if an investigator or sub-investigator leaves an institution or otherwise changes addresses, he or she shall promptly notify Sponsor and Quintiles of his or her new address. The Site represents and warrants that neither it, nor any of its employees, agents or other persons performing the Study under its direction, has been debarred, disqualified or banned from conducting clinical trials or is 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.

6) **Termination.** Sponsor may suspend enrollment or terminate this Agreement effective immediately upon written notice. The Site may terminate this Agreement upon written notice if circumstances beyond the Site's reasonable control prevent the Site from completing the Study, or if the Site reasonably determines that it is unsafe to continue the Study. Upon receipt of notice of termination, the Site shall immediately cease any subject recruitment, follow the specified termination procedures, ensure that any required subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs, and Quintiles shall make a final payment for visits or milestones properly performed pursuant to this Agreement in the amounts specified in the Attachment B; provided, however, that ten percent (10%) of this final payment will be withheld until final acceptance by Sponsor of all subject CRF pages and all data clarifications issued and satisfaction of all other applicable conditions set forth in the Agreement. Neither Quintiles nor Sponsor shall be responsible to the Site for any lost profits, lost opportunities, or other consequential damages.

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6) Claims and Disclaimers. The Site shall promptly notify Quintiles and Sponsor in writing of any claim of illness, injury or death or damage actually or allegedly arising from the conduct of the Study. Sponsor agrees to indemnify and hold harmless the Site and Investigator from any third party claims of illness, injury or damage directly arising out of the conduct of the Study in accordance with the Protocol, except to the extent any such illness, injury or damage is caused by the Site or Investigator's negligence, misconduct, failure to follow the Protocol or breach of applicable law or regulation. Sponsor shall have the right to control the defense of any such claims and the Site shall cooperate fully with Sponsor in handling such claims. Quintiles expressly disclaims any liability in connection with the Investigational Product, including any liability for any product claim arising out of a condition caused by or allegedly caused by the administration of such product except to the extent that such liability is caused by the negligence, willful misconduct or breach of this Agreement by Quintiles. Neither Quintiles nor Sponsor will be responsible for, and the Site agrees, to the extent allowed by law, to indemnify and hold them harmless from, any third party claims of illness, injury or damage resulting from the Site's negligence, failure to adhere to the Protocol, failure to obtain informed consent, unauthorized warranties, breach of this Agreement, breach of applicable law or regulation or willful misconduct.

7) Financial Disclosure. In order to allow Sponsor to comply with its U.S. regulatory requirements, the Site agrees that, for each listed or identified investigator or sub investigator who is directly involved in the treatment or evaluation of research subjects, it shall promptly return to Quintiles a financial 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. Quintiles may withhold payments if it does not receive a completed form from each such investigator and sub investigator. The 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 its completion. The 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. if the Site is outside of the U.S., even though data protection may not exist or be as developed in those countries as in the Site's own country.

8) Shipping of Dangerous Goods and Infectious Materials. The shipment of dangerous goods and infectious materials (including infectious subject specimens) is subject to local, national, and international laws and regulations. The Site is responsible for ensuring that each individual who packages or handles any dangerous goods or infectious materials for shipping from the Site complies with all applicable laws and regulations.

9) Adverse Event Reporting. Investigator agrees to report any serious adverse events (SAEs) as required by law, regulation and the Protocol. Within 24 hours (or such other time as specified in the Protocol) of first knowledge of any SAE or any event that could affect the safety of the Study participants, Investigator will notify Quintiles and the Sponsor via the electronic data capture system (eDC). In the case of the eDC being offline, the responsible Site staff will fax the paper SAE form to Quintiles Lifecycle Safety using the toll free fax number (+353 1 809950) and enter the SAE into the eDC system as soon as it is back online.

10) Additional Contractual Provisions. This Agreement, including these Terms and Conditions, constitutes the sole and complete agreement between the parties and replaces all other written and oral agreements relating to the Study. No amendments or modifications to this Agreement shall be valid unless in writing and signed by all the parties. 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. 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 Sponsor. Sponsor may, and/or Quintiles may upon Sponsor's request, assign this Agreement to a third party, (and Quintiles may upon Sponsor's request assign its rights and obligations under this Agreement to Sponsor), and Sponsor and/or Quintiles (as the case may be) shall not be responsible for any obligations or

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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. 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, including without limitation Sections 2, 3, 4, 6 , 7 and 10 of this Attachment A.

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ATTACHMENT B
BUDGET AND PAYMENT SCHEDULE

A. PAYMENT TERMS

Quintiles will reimburse the Payee every month, on a completed visit per subject basis in accordance with the attached budget. Ninety percent (90%) of each payment due, including any Screening Failure (see Article C below), will be made based upon prior enrollment data confirmed by subject Case Report Forms ("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 to Quintiles, as well as confirmation that all electronic patient diaries have been returned and upon satisfaction of all other applicable conditions set forth in the Agreement. Site shall have thirty (30) days from the receipt of the final payment to dispute any discrepancies relating to payments made pursuant to this section. Site understands that at some point following such period, Quintiles will close its books relating to the Study and any disputes received after such period may be forwarded to Sponsor for resolution.

Site represents that the services it provides under this Agreement are taxable services under the laws governing service tax in India, and that it is required to charge service tax for the services rendered to Quintiles at the prevailing rate. Site represents that it is entitled to require such payment of the service tax under the laws of India. Site undertakes to provide Quintiles with an invoice, to be sent to Quintiles at the address mentioned in Section E of this attachment, in respect of such taxable services and such invoice shall be in accordance with the terms of the Service Tax Rules of 1994 as may be amended from time to time or any successor legislation.
It should be noted that all the payments made to the Payee are subject to Tax Deducted at Source (TDS) in accordance with India tax laws, as amended from time to time. Quintiles will deduct the tax at the time of making payments unless a valid Certificate (Form 15 AA – for no TDS) from tax authority is made available

Major, disqualifying Protocol violations are not payable under this Agreement

B. SCREENING FAILURE PAYMENTS:

Quintiles will pay the Site up to 5 screening failure patients, at a rate of Twenty Thousand Two Hundred and Forty Rupees (INR 20,240) per Screen Failure. If the site reaches the cap of 5 screen failure, it should be discussed with relevant CPM before more patients can be screened.

C. DISCONTINUED OR EARLY TERMINATION PAYMENTS:

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

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D. ORIGINAL 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

Please note that invoices will not be processed unless they reference the Sponsor name, Protocol number and Investigator and will be included with the regular payments. After receipt and verification, reimbursement for invoices will be included with the next regularly scheduled payment for subject activity.

- **Institution Review Boards ("IRBs") or Independent Ethics Committees ("IECs") Payments**

IRB/IEC costs will be reimbursed on a pass-through basis and are not included in the attached Budget. Any subsequent re-submissions or renewals, upon approval by Quintiles and Sponsor, will be reimbursed upon receipt of appropriate documentation.

- **Study Start-Up Fee**

A one time, non-refundable payment of **Sixty Thousand Rupees (INR 60,000)** to cover Study Start-Up activities [which includes institutional overhead], will be made upon completion and receipt by Quintiles of all original contractual and regulatory documentation and receipt of original invoice.

- **Record Storage Fee/Archiving Fee**

A record storage payment of **One Lakh, Twenty Thousand Rupees (INR 1, 20,000)**, [which includes institutional overhead], will be made upon receipt of original supporting invoices from a third party vendor and are not included in the attached Budget. In accordance with Sponsor's Protocol requirements, Institution shall maintain all site study records in a safe and secure location to allow easy and timely retrieval, when needed.

- **Patient Travel Expenses**

Patient travel expenses will be reimbursed upon receipt of original supporting invoices from third party vendors at a flat rate of **Five Hundred Rupees (INR 500) or up to (INR 1000)** per visit per patient per round trip) and are not included in the attached Budget. Invoices must contain the following information in order for a payment to be issued- Subject number or initials, amount paid, visit number in which patient travel is being requested.

- **PRESCREENING ACTIVITIES:**

To recognize Site's efforts in the Study prescreening procedures, Quintiles will compensate Site **Six Thousand Eight Hundred and Thirty Rupees (INR 6,830)** for each subject screened and randomized who was entered in the prescreening log at least 1 month before screening (the "Prescreening Payment"). To be eligible for the Prescreening Payment, Site must document that prescreening occurred at least 1 month prior to screening by submitting the prescreening log to Quintiles once per week. Site agrees that it will submit to Quintiles the prescreening log, completed screening documents, randomization CRF pages, and any additional information requested by Quintiles to appropriately document the subject prescreening, screening, and randomization activities. To receive the Prescreening Payment, Site shall issue an invoice to Quintiles containing the Patient Randomization Number of the qualifying subject.

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- **PREGNANCY TEST, ALCOHOL AND GAUZE:**

Quintiles will provide the Site with pregnancy tests, alcohol pad and gauze during the course of the Study, in reasonable and needed amounts. Site will provide such materials to patients (study subjects) to take home for the purposes of Study protocol procedures.

- **ADVERSE EVENT REPORTING:**

Investigator will report any serious adverse events (SAEs) as required by law, regulation and the Protocol. Within 24 hours (or such other time as specified in the Protocol) of first knowledge of any SAE or any event that could affect the safety of the Study participants, Investigator will notify Quintiles and the Sponsor via the electronic data capture system (eDC). In the case of the eDC being offline, the responsible Site staff will fax the paper SAE form to Quintiles Lifecycle Safety using the toll free fax number (+353 1 809950) and enter the SAE into the eDC system as soon as it is back online.

F. INFRASTRUCTURE / EQUIPMENT:

1. <u>eDiaries and Tablet Return</u>:

<u>Section 1</u>: The final payment will be made after Sponsor has received copies of all completed Case Report Forms ("CRFs") for each of the Subjects participating in the Study with all queries resolved as well as confirmation that all electronic patient diaries have been returned. Site shall have thirty (30) days from the receipt of the final payment to dispute any discrepancies relating to payments made pursuant to this section 1. Site understands that at some point following such period, QUINTILES will close its books relating to the Study and any disputes received after such period may be forwarded to Sponsor for resolution.

<u>Section 2</u>: Subject to the conditions set forth below, Sponsor or QUINTILES will provide HTC-HD2 T8585 Handheld Computer (eDiary) and Acer Iconia W510P (eQuestionnaires), which is required for use in the Study and that Site does not otherwise own or have access to (the "Equipment") to Site for use in the Study.

(i) <u>Equipment Use; Maintenance</u>. Site agrees to house the Equipment on site and to use the Equipment solely in connection with the Study during the term of the Agreement. Site agrees to maintain the Equipment in good working condition, reasonable wear and tear excepted. In the event that the Equipment malfunctions or ceases to operate during the conduct of the Study through no fault of Site, Sponsor or QUINTILES will arrange for appropriate maintenance or replacement of the Equipment, including, at Sponsor's option, reimbursing Site for reasonable maintenance or replacement expenses.

(ii) Return or Purchase of Equipment. Upon completion or any earlier termination of the Study at Site, Site shall, at its option, either: (A) return the Equipment to Sponsor/Sponsor at Sponsor's/Sponsor's expense; or (B) reimburse Sponsor/Sponsor for the residual fair market value of the Equipment as of the date of termination. Sponsor/Sponsor or QUINTILES may, at its option, either withhold the final payment to Site until the Equipment is returned, or until Site reimburses Sponsor/Sponsor for the residual fair market value of the Equipment as of the date of completion or termination of the Study. IN THE EVENT OF TRANSFER OR ASSIGNMENT UNDER THIS PARAGRAPH, THE EQUIPMENT SHALL BE TRANSFERRED AND ASSIGNED "AS IS," AND SPONSOR/SPONSOR MAKES NO WARRANTY OR REPRESENTATION, EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO FITNESS, MERCHANTABILITY, QUALITY, DESIGN, CONDITION, SUITABILITY OR PERFORMANCE OF THE EQUIPMENT.

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2. **Bioclinica Devices:**

Subject to the conditions set forth below, Sponsor or Quintiles will provide Lenovo Thinkpad E450 Laptop- Includes Power Supply and Ethernet Cable- , Dazzle Video Creator Platinum HD- Video Input Adapter and Transcend 8GB USB Memory Stick, which is required for use in the Study and that Site does not otherwise own or have access to (the "**Bioclinica Devices**") to Site for use in the Study.

(i) Bioclinica Devices Use: Maintenance. Site agrees to house the Bioclinica Devices on site and to use the Bioclinica Devices solely in connection with the Study during the term of the Agreement. Site agrees to maintain the Bioclinica Devices in good working condition, reasonable wear and tear excepted. In the event that the Bioclinica Devices malfunctions or ceases to operate during the conduct of the Study through no fault of Site, Sponsor or Quintiles will arrange for appropriate maintenance or replacement of the Bioclinica Devices, including, at Sponsor's option, reimbursing Site for reasonable maintenance or replacement expenses.

(i) Return or Purchase of Bioclinica Devices. Upon completion or any earlier termination of the Study at Site, Site shall, return the Bioclinica Devices to Sponsor/Quintiles at Sponsor's/Quintiles' expense. Sponsor or Quintiles may withhold the final payment to Site until the Bioclinica Devices is returned.

G. BUDGET DETAILS:

The Budget is as follows:

It is agreed that the Site will receive INR **Two Lakh Eighty Two Thousand One Hundred and Seven only (INR 282,107)** per completed patient for the Study according to the schedule indicated below. This per patient amount is intended to cover the following study- related costs incurred by the Site:

- costs related to the patients visits (day care cost, stay)
- costs for study related communications
- salaries of study staff and Investigator
- Institute service charges and overheads

Budget Table:

Visit No.	Per Patient Amount Including 20% Overhead (INR)
Screening Visit	26,717
Visit 0	15,762
Visit 4	14,824
Visit 8	10,985
Visit 10	21,910
Visit 12	16,980
Visit 16	10,985
Visit 20	16,433
Visit 24	11,741
Visit 32	16,790
Visit 44	17,189
Visit 56	16,223
Visit 62	29,827

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Phone call Visit 28, 36, 40, 48, 52, 60**		34,327
12- Week Safety Follow Up-	26,717	7,467
	15,762	13,950
TOTAL Amount Per Completed Patient Including 20% Overhead (INR)		**282,107**

Unscheduled Visit*	10,897
Early Withdrawal from Treatment*	17,857
12- Week Safety Follow Up - Unscheduled Visit*	10,897

***Unscheduled Visit Fee and Early Withdrawal from Treatment Fee will be paid upon receipt of completed eCRFs, not included in the total cost per subject.**

****If Phone call does not occur, clinic visit to be paid upon receipt of detailed invoice for weeks 28, 36, 40, 48, 52 and 60.**

Additional Invoice Details

INVOICED ITEMS:	Unit Cost (including OH) (INR)
Serum pregnancy test	300
Urine pregnancy test	200
Chest X-ray, includes interpretation and report	500
TB screen (QuantiFeron - TB Gold Test)	1,084
TB screen (Skin Test)	514
Colonoscopy, with biopsy	6,500
Sigmoidoscopy, with biopsy (Colonic biopsies (formalin, RNA later))	6,100
Etrolizumab / etrolizumab placebo	622
Clinic Visits for weeks 28, 36, 40, 48, 52, 60 if Phone Visit did not occur	5,823
PML Neurologic Examination	2,000
PK sampling (serum)	200
Central Labs (Hematology, Chemistry, Hepatitis B DNA)	191
Stool sample collection	300
Colonic biopsy (CMV)	6,500
Urinalysis	200
Central Labs (Anti-therapeutic antibody, CRP) includes Collection, Preparation and Processing	402
MCS	440
Partial MCS	284
Colonic biopsy (histopathological confirmation of UC)	6,500
Biopsy; Staining and preparation of the slides including shipping and handling	600
Neurologist - Per Hour	1,000
Brain MRI with contrast, includes interpretation and report	11,000
Brain MRI without contrast, includes interpretation and report	6,000
Lumbar puncture	2,600
Cerebrospinal fluid (CSF) analysis for JCV by PCR; includes lab handling for shipment to central lab	1,687
Reconsenting Fee	932
Investigator prescreening activities (per randomized patient from prescreening log)	6,830

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Note:

- This Budget includes all study costs related to the Protocol (including but not limited to laboratory costs, patient travel expenses and site overheads), except for any other payments contained within this Attachment.
- All questions regarding study payments or the Financial arrangements should be directed to Quintiles at the address noted above during normal business hours (IST).

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ATTACHMENT C

APPROVAL LETTER

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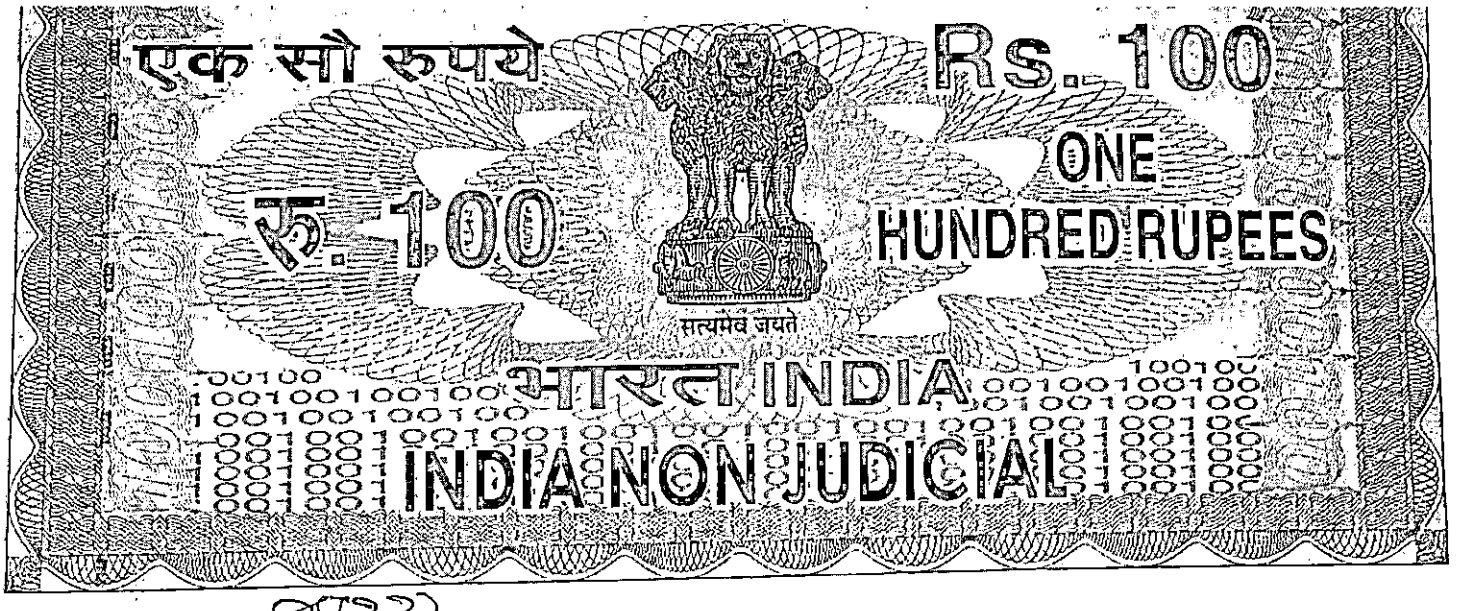

ગુજરાત ગુજરાત GUJARAT

BB 174606

નંબર:.....રો.....

તારીખ:.....માહે.....સને ૨૦૧૭

નામ: 12 JAN 2017

સરનામું:

શૈલેષકુમાર વાસુદેવભાઇ ત્રિવેદી

લા. નં.:- એફ. બી.- ૬૩/૧૯૮૬

અમદાવાદ-સીટી સીવીલ કોર્ટના રાણંદી

લેનાર ની સહીX:

Cliantha Research Limited
Opp. Pushparaj Towers,
Nr. Judges Bunglows,
Bodakdev, Ahmedabad-380054.
Ph. : +91-79-26853088-92
Fax : +91-79-26853093

CLINICAL TRIAL AGREEMENT

PROTOCOL MYL-1402O-3001

This Clinical Trial Agreement (the **"Agreement"**) is effective on the date fully executed by the parties (the **"Effective Date"**) and entered into by and between

CLIANTHA RESEARCH LIMITED, a company incorporated under the Companies Act, 1956 having its Registered Office at Opp. Pushparaj Towers, Nr. Judges Bunglows, Bodakdev, Ahmedabad – 380 054, India (hereinafter referred to as **"CRO"** which expression, unless repugnant to the context or meaning thereof shall mean and include its affiliates, employees, assignees, subsidiaries, nominees, agents and successors-in-interest)

AND

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findings that could adversely affect the Subject's safety, could have an impact on the conduct the Study, or could alter the ECs / IRB's approval to continue the Study.

CRO will be responsible to notify on time the health authorities in India.

15. MISCELLANEOUS

A. Use of Names; Publicity. Except as otherwise required by applicable law, regulation or co order, no Party to this Agreement will use the name or other identifying marks of any other Pa or its affiliates or its staff/employees, agents in any advertisement or sales promotional material in any publication, press release, or other public statement without prior written approval of t other Party; provided however that Sponsor may identify the Institution as a participating clini site and the Principal Investigator as an investigator in a Study. The Institution and the Princi Investigator shall have the right to acknowledge the Sponsor's support of the research perform under this Agreement in scientific publications and other scientific communications (any su publications or communications shall be made in accordance with Section 7 herein). Each of Parties hereto shall not disclose to any third party the terms of this Agreement even existence this Agreement without the prior written consent of the other Party, except to advisors, investc and others on a need-to-know basis under circumstances and ensure the confidentiality there or to the extent required by law, regulation or court order.

B. Independent Contractors. The Parties acknowledge that the relationship between the Spons CRO, Institution and Principal Investigator created by this Agreement is that of independ contractors and shall not to be considered as partner, agent, employee, or representative of Cl or the Sponsor. That neither the Principal Investigator nor Institution or CRO may create assume any obligation on behalf of the Sponsor.

C. Limitation of Liability. In no event shall the Parties be liable to each other for any spec incidental, or consequential damages arising out of or relating to this Agreement, or the subj matter hereof, however caused and whether such claim is based in contract, tort (includ negligence), or otherwise, even if an authorized representative of the Sponsor is advised of possibility of such damages.

D. Notices. Any notices required or permitted to be given hereunder shall be in writing, shall addressed to the Party to whom such notice is intended as follows, or such other address and, number as such Party may substitute by written notice hereunder, and shall be effective receipt.

Any notice to Sponsor shall be addressed as follows:

Address : MYLAN LABORATORIES LIMITED INDIA,
Clinical Research Centre, Saradhi Chambers, Plot No. 4-A, Beside
Poulomi Hospital, Rukminipuri, Dr. A. S. Rao Nagar,
Hyderabad 500062
Attn : Dr. Sanjeev Hengde

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Dr. Mahesh Kalloli, the Principal Investigator presently employed at KLE's Dr. Prabhakar Kore Hospital & MRC, Belagavi-590010, Karnataka, India(hereinafter referred to as the **"Principal Investigator"** which expression, unless repugnant to the subject or context therein, shall mean and include his legal heirs, administrators, executors and assigns)

AND

KLE's Dr. Prabhakar Kore Hospital & MRC, Belagavi-590010, Karnataka, India hereinafter referred to as the **"Institution"** which expression, unless repugnant to the subject or context therein, shall mean and include its authorized representative(s), administrators, executors, assigns & successors-in-interest).

Dr. Ravi C, CMS Clinical Research Pvt.Ltd., (hereinafter referred to as the "SMO" which expression, unless repugnant to the subject or context therein, shall mean and include its authorized representative(s), administrators, executors, assigns & successors-in-interest).

CRO, Principal Investigator and Institute is referred to herein individually as a "Party" and collectively as "Parties".

Whereas, **Mylan GmbH** (hereinafter referred to as the **"Sponsor"**) through its Agent CRO desires the Institution to study (add study drug in comparison with reference and/or placebo) and the Institution is willing to perform a clinical study of the Study Drug (defined herein below); and

WHEREAS, the Study (defined below) is of mutual interest and benefit to the Sponsor, CRO, Institution and Principal Investigator and will further the investigational and research objectives of the Institution and Principal Investigator;

WHEREAS, the Principal Investigator and the Institution have the **qualified personnel and the facilities** equipped according to Good Clinical Practices (GCP) to undertake the Study with the responsibility for the proper conduct of the Study (defined herein below);

NOW, THEREFORE, in consideration of the promises and mutual covenants herein contained, the Parties agree as follows:

1. THE STUDY AND THE PROTOCOL

A. The MYL-1402O-3001(the **"Study Drug"**) shall be conducted, under the direction of the Principal Investigator, in the treatment of patients (**"Subjects"**) in accordance with this Agreement and the protocol identified as Protocol ID No MYL-1402O-3001 and entitled " **Multicenter, Double- Blind, Randomised, Parallel-Group Study to Assess the Efficacy and Safety of MYL-1402O Compared With Avastin ®, in the First –line Treatment of Patients with Stage IV Non Squamous Non –Small Cell Lung Cancer"** a copy of which is attached hereto as Exhibit A (the **"Protocol"**), including any subsequent duly authorized amendments, and which is hereby incorporated by reference (the **"Study"**). The Study will be monitored by the CRO as per the Protocol.

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D. Claims. The indemnifying Party, at its own expense, shall have the exclusive right to ... claims, control investigation and litigation, and select counsel, including the right to compro... or settle any claims, actions, suits, demands, or judgments, provided that it shall not compromi... or settle any such action with an admission of liability or wrongdoing by the indemnified Party without such Party's written consent.

E. Representation. In the event a claim or action is or may be asserted, the non-indemnifying Party shall have the right to select and obtain representation by separate legal counsel. If the non-indemnifying Party exercises such right, all costs and expenses incurred by the non-indemnifying Party for such separate counsel shall be fully borne by the non-indemnifying Party; provided, that without the Indemnifying Party's prior written consent, the non-indemnifying Party shall make no admission to, or any settlement or agreement with, any person or party who is in any manner related to the liabilities for which indemnification may be sought by an non-indemnifying Party Indemnitee.

F. Subject Injury. Subject shall be entitled to financial compensation as well as reimbursement of reasonable and necessary medical expenses from the CRO in case of Subject injury or death during clinical trial in accordance with Rule 122DAB of Drugs and Cosmetics Rules, 1945 as may be amended from time to time.

12. INSURANCE

A. Parties represent and warrant that they possess and shall maintain, for the duration of the Agreement and thereafter, at its own expenses, insurance coverage for their respective services in the performance of the Study. Each Party shall provide the other Party with proof of insurance upon request.

B. Institution Insurance. Institution and Principal Investigator shall maintain during the term of this Agreement, general liability insurance and professional liability insurance coverage sufficient to meet its indemnification obligations on appropriate conditions and will provide to Sponsor and CRO thirty (30) days prior written notice of cancellation of its coverage.

This Clause 12 shall survive termination of this Agreement.

13. TERM AND TERMINATION

A. Term. This Agreement shall begin on the Effective Date and shall remain in full force and effect until the completion of the Study and the submission of the Final Report pursuant to Clause 4(F) (*iv*), above, unless earlier terminated in accordance with this Agreement.

B. Termination.

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Study prior to termination. Within ninety (90) days [illegible] termination, the Institution and the Principal Investigator shall provide to the Sponsor any data collected in connection with the Study, including, without limitation, Study reports and the Final Report described in Clause 4(F), above, and, except as otherwise provided herein, shall return to the Sponsor any and all materials and Confidential Information provided by the Sponsor for the conduct of the Study, at the Sponsor's expense, provided, however, that the Institution may retain one (1) copy of the Confidential Information for record keeping purposes and shall make no further use of, all Sponsor Confidential Information, and any other records, data, materials and information that are the property of Sponsor. The CRO shall remain liable for payment for any CRFs submitted prior to the effective date of termination, or within ninety (90) days thereafter, in compliance with the terms of this Agreement. Notwithstanding any termination or expiration of the Study or this Agreement, Institution shall remain responsible for compliance with all obligations under Applicable Laws and other requirements as per this Agreement with regards to disposition of the Study Materials.

viii. Survival. Termination of this Agreement by either Party shall not affect the rights and obligations of the Parties accrued prior to termination. All provisions in this Agreement which, by their nature, extend beyond termination of the Agreement, together with the provisions of Clauses 4(F), 5, 6, 7, 9, 10, 11, and 12 shall survive any termination of this Agreement for any reason.

14. Drug Safety and Reporting. The recording of adverse events (AEs) is an important aspect of the Study documentation. It is the Principal Investigator's responsibility to document all AEs according to the detailed guidelines of the Protocol. The Principal Investigator agrees to answer any questions of Sponsor and/or CRO's Medical Monitor concerning any AEs. According to the Protocol, the Principal Investigator will assess at each visit whether any adverse event (AE) including abnormal laboratory values has occurred. The details of all AEs, whether reported by the Subject or observed by the Principal Investigator / Study personnel during the entire Study, will be recorded onto the appropriate source document. Each adverse event must be recorded in the AE section of the case report form (CRF), regardless of the causal relationship.

The Principal Investigator must immediately report all serious adverse events (as defined in Protocol), which occur during the course of the Study and up to the date of the Subject's last visit, to the addressee given below. The SAE Report form will be used for documentation and reporting.
Initial and follow up SAE reports are to be faxed / Mail the Medical Affairs Department of CRO for onward transmission to SPONSOR

If the event is unexpected and fatal or life threatening and is considered by the Principal Investigator possibly related to the Study medication, the Drug Safety Department of CRO shall be informed immediately by telephone and followed immediately by fax/ Mail.

CRO undertakes to notify the Principal Investigator and SPONSOR of all serious unexpected adverse events, which occur during the course of the Study in any other location and are reported in an expedited manner to health authorities. The Principal Investigator will inform the local

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INSTITUTE

By: 18/1/2017

(Signature & Date)

Dr. M.V.Jali

BY EXECUTING THIS DOCUMENT IN THE SPACE PROVIDED BELOW, THE PRINCIPAL INVESTIGATOR HEREBY ACKNOWLEDGES AND AGREES TO COMPLY WITH THE TERMS OF THIS AGREEMENT AND THE APPLICABLE PROTOCOL, AS AMENDED FROM TIME TO TIME

PRINCIPAL INVESTIGATOR

By: 16/01/2017

(Signature & Date)

Dr. Mahesh Kalloli

CLIANTHA RESEARCH LIMITED

By: 12 JAN 17

(Signature & Date)

Dr. Dharmesh Domadia, Associate Vice President- Global Clinical Operations

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Confidential

H. Severability. In the event that any provision of this Agreement is determined to be illegal, invalid or unenforceable by a court of competent jurisdiction, the remainder of this Agreement shall remain in full force and effect without said provision. The Parties shall negotiate in good faith a substitute clause for any provision declared illegal, invalid or unenforceable, which shall most nearly approximate the original intent of the Parties in entering this Agreement.

I. Execution. The Institution's IRB/IEC shall be the authorized representative of the Institution to approve the Protocol and any amendments thereto. This Agreement may be executed in one or more counterparts, all of which together shall constitute one and the same agreement. This Agreement may be executed by facsimile or other electronic signature.

J. Changes to the Protocol. If at a future date changes in the Protocol appear desirable, such changes may be made through prior written agreement between Sponsor and Institution. If such changes affect the cost of the Study, Institution will submit to Sponsor a written estimate for approval. If in the course of performing this Agreement, however, generally accepted standards of clinical research and medical practice relating to the safety of Subjects require a deviation from the Protocol, such standards will be followed. In such case, the Party aware of the need for a deviation will immediately inform the other of the facts causing such deviation as soon as the facts are known to the Party.

K. Covenant Not to Hire. Sponsor shall not, and shall not permit any of its affiliates to, employ or offer to employ any Key Personnel (as defined in this Section) until one year following termination or expiration of this Agreement, unless Institution, or Institution's affiliate, as the case may be, gives its written consent thereto. "Key Personnel" shall mean those individuals employed by Institution, who perform research related services for Institution or any of its affiliates, including, but not limited to, persons serving as research coordinators and grant account managers.

IN WITNESS WHEREOF, the undersigned have entered into this Agreement as of the date first set forth above.

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The further details for the payments should be provided as

1. **Cheque in the favor of: CMS CLINICAL RESEARCH PVT. LTD.**
2. **PAN Number: AAFCC8457M**
3. **Name of Bank: HDFC Bank**
4. **Branch: Hyderabad**
5. **Account No: 50200007478582**
6. **Branch Code: 000368**
7. **IFS CODE : HDFC0000368**

E. Reimbursement. Upon completion of the Study or earlier termination of this Agreement as provided herein, the Institution shall reimburse the CRO for any amounts that were paid by the CRO to the Institution which exceed the amounts to which the Principal Investigator was entitled for completed Subject visits under the Budget and Payment Schedule of this Agreement.

F. Payments for Screen Failure: CRO shall pay only per Subject charges for screen failure. The maximum ratio for screen failure Subjects shall be 3:1 i.e. maximum one screen failure per three randomized Subjects.

G. Payment for Study Coordinator: PI will make sure payment to study coordinator / involved study team to ensure that the Quality and deliverables of the Project are not affected at any phase of the study.

H. All payments payable by CRO are subject to deduction of taxes at source ('TDS') as per applicable law unless relevant exemption certificate is produced by the Site. Service tax will be paid, if applicable, on generation of valid invoice showing the amount of service tax to be charged before any payment is made under this Agreement

4. OBLIGATIONS OF THE INSTITUTION AND THE PRINCIPAL INVESTIGATOR

A. IEC/IRB Approval. The Principal Investigator shall be responsible, with the cooperation of the Institution and CRO/Sponsor, for obtaining approval from the IEC / IRB of the Protocol and the Subject's Informed Consent Form. The Principal Investigator shall provide the CRO or Sponsor's designee with written confirmation of the IEC / IRB's approval prior to the treatment of Subjects. If the IEC/IRB withdraws approval of the Study, at any time, the Principal Investigator shall be immediately notified by the Sponsor or CRO, providing a written explanation of the circumstances leading to such withdrawal of approval, and the Principal Investigator shall cease the treatment of all Subjects under the Study.

B. Performance of the Study. The Principal Investigator shall conduct the Study solely at the Institution. Principal Investigator will personally conduct or supervise the investigation of the Study. Principal Investigator will ensure that all persons assisting in the performance of the Study are informed of their obligations with regard to the Study. Principal Investigator agrees to report promptly, in writing, any non-compliance of the Protocol. The Principal Investigator shall exercise due care in the conduct of the Study, and represent and warrant that it will be conducted

EXHIBIT B: BUDGET:

Principal Investigator : Dr. Mahesh Kalloli

Site Address : KLE's Dr. Prabhakar Kore Hospital & MRC, Belagavi-590010, Karnataka, India

PAYMENT SCHEDULE

Payment Schedule for the total study Grant for first X patients is as follows:

Overall Per Patient Budget

Amount in Indian rupees per patient	Reimbursement
313200/-	Includes the following ● PI and site team payment including Co- Investigator (s), Site coordinator(s), Nurse(s), Dietician as applicable ● Patient hospital charges like room charges and meal charges ● Institutional overhead ● Stationary and Miscellaneous
11,000/-	Patient compensation INR 500 per visit x 22 visits
324200/-	**Total Amount**

Budget Bifurcation

Patient Visits	*Hospital/ Day Care Charges	PI charges	PI Grant (INR) Visitwise
Screening	0	10000	10000
Randomization	0	2000	2000
Period 1			
Cycle 1	3500	8000	11500
Cycle 2	3500	10000	13500
Cycle 3	3500	8000	11500
Cycle 4	3500	10000	13500
Cycle 5	3500	8000	11500
Cycle 6	3500	10000	13500
Period 2			
Cycle 701	2500	6000	8500
Cycle 702	2500	6000	8500
Cycle 703	2500	6000	8500
Cycle 704	2500	7000	9500
Cycle 705	2500	6000	8500
Cycle 706	2500	6000	8500

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i. Either Party may terminate this Agreement immediately upon written notice to the other if:

b. the authorization and approval to perform the Study in India is withdrawn by the DCGI and/or other applicable regulatory authority in India;

c. animal, human and/or toxicological test results, in the opinion of either Sponsor or Institution, support termination of the Study; or

d. the circumstances require termination of Study in order to protect the safety, rights, or welfare of Subjects enrolled in the Study. In the alternative, either Party may immediately dis-enroll any Subject to protect that Subject's safety, rights or welfare without terminating this Agreement, but shall promptly give the other Party written notice of the dis-enrollment.

ii. This Agreement may be terminated by either party, upon thirty (30) days prior written notice, if either of the following conditions occurs:

a. if either Party fails to comply with the terms of this Agreement within thirty (30) days of receipt of written notice, with opportunity to cure, from the other Party; or

b. if the Principal Investigator is unwilling or unable (for whatever reason) to act as Principal Investigator and no mutually acceptable replacement has been found in accordance with Clause 4C of this Agreement..

iii. This Agreement may be terminated by either Party for any reason other than those listed in Clause 12(B) upon thirty (30) days prior written notice.

iv. Upon the effective date of termination, there shall be an accounting conducted by Institution, subject to verification by Sponsor. Within thirty (30) days after receipt of adequate documentation therefrom, CRO will make payment to Institution for.

a. all services properly rendered and monies properly expended by the Institution until the date of termination not yet paid for; and

b. Reasonable non-cancelable obligations (as evidenced in writing) properly incurred for the Study by Institution prior to the effective date of termination.

v. Immediately upon receipt of a notice of termination, the Principal Investigator shall stop enrolling Subjects into the Study and shall cease conducting procedures on Subjects already enrolled in the Study as directed by CRO, to the extent medically permissible.

vi. Immediate Termination by the CRO/Sponsor. The CRO/Sponsor may terminate this Agreement, in whole or in part, effective immediately, upon written notice to the Principal Investigator; a) if the Sponsor, in its sole discretion, deems that the safety of the Subjects will be compromised by a delay in termination; or b) for any violation of the Study Schedule set forth in Clause 2) prior to the shipment of the Study Drug to the Institution.

vii. <u>Effect of Termination</u>. In the event this Agreement is expired or terminated prior to completion of the Study, for any reason, the Principal Investigator shall a) notify the IRB/IEC that the Study has been terminated; b) cease enrolling Subjects in the Study; c) cease treating Subjects under the Protocol as directed by the CRO to the extent medically permissible and appropriate, and d) terminate, as soon as practicable, but in no event more than thirty (30) days after the effective date of termination, all other Study activities; provided, however, upon the CRO's request, the Institution and the Principal Investigator shall continue to collect data and prepare and complete CRFs for Subjects treated in the

A. **Budget and Payment Schedule:** In consideration of the services performed, CRO shall reimburse the Institution all undisputed direct and indirect costs reasonably incurred by the Institution in accordance with the Budget and Payment Schedule, attached hereto as Exhibit B and incorporated herein by reference (the **"Budget and Payment Schedule"**). Payment shall be made by cheque. Payment shall be made within thirty (30) days after CRO has received invoice from the Principal Investigator. In addition, CRO shall reimburse directly the IEC / IRB for all costs associated with the Study. Notwithstanding the Payment Schedule mentioned in Exhibit B, the payment made by CRO shall be deemed to be as full and final payment payable by CRO as consideration for the services provided by Site including Principal Investigator, Institution and SMO.

B. **Payment of Costs Outside Budget and Payment Schedule.** Payment for any costs not specifically described in the Budget and Payment Schedule must be approved in advance in writing by the CRO's Project Manager.

C. **Payment Terms.** CRO shall have no obligation to make payments for any subject who is not qualified to participate in the Protocol based on the inclusion and exclusion criteria described in the Protocol. Queries pertaining to a subject's eligibility shall be addressed to and resolved by the CRO and sponsor's clinical and/or medical monitor identified in the Protocol prior to entry of any such subject into the study.

The foregoing notwithstanding:

Upon submission of such documentation as may be requested, to the extent not already paid by CRO, CRO will pay the actual cost of completed visits in accordance with the Budget and Payment Schedule for the Subjects who are dropped from the Study or withdraw from the Study; provided, however, such costs were incurred at a time when, in the good faith judgment of CRO, none of the Institution, its employees or agents, or the Principal Investigator knew or could have reasonably determined that such Subject was not or would not be an Eligible and Evaluable Subject. **"Eligible and Evaluable Subjects"** are defined as Subjects who have satisfied all the Protocol requirements, including compliance with dosing regimen and visit schedule, and are eligible to be included in the statistical analysis for the Study; and Institution and Principal Investigator agree that all payments made under this Section are made solely for the performance of activities relating to the Study and for no other purpose.

D. **Payment Recipient and Mailing Address.** All cheques shall be made payable to the entity / person mentioned in the Clause 3A.

The mailing address for checks shall be:

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respect to its debarment or a Notice of Intent to Disqualify, the CRO shall have the right to terminate this Agreement immediately without further cost or liability. The Principal Investigator represents and warrants on his own behalf that he has not used, in any capacity, the services of any individual, corporation, partnership, or association which has been debarred, and neither shall use, in any capacity, the services of any individual, corporation, partnership, or association which has been debarred. In the event that the Principal Investigator becomes aware of the debarment or threatened debarment of any individual, corporation, partnership, or association providing services to the Principal Investigator which directly or indirectly relate to Principal Investigator's activities under this Agreement, the Principal Investigator shall notify the CRO immediately and the CRO shall have the right to terminate this Agreement immediately without further cost or liability.

B. Of the CRO. The CRO represents and warrants that (i) it has the legal authority and right to enter into this Agreement, (ii) it has no obligation to any other party that is in conflict with the CRO's obligations under this Agreement, and (iii) this Agreement has been duly executed and delivered by it and constitutes a valid, binding obligation enforceable against it in accordance with its terms.

CRO represents and warrants to Institution and Principal Investigator the following: (i) any Study Drug or device administered or used in carrying out the Protocol has been approved by the DCGI or FDA or by the other regulatory agencies if applicable for investigational use; and (ii) CRO has at all times complied with and will continue to comply with all DCGI or FDA and comparable foreign rules, regulations, requirements, and guidelines regarding administration, manufacture, and production of drugs and devices under regulatory control of the DCGI or FDA and/or comparable foreign agencies in connection with any drug or device administered or used pursuant to the Protocol. In particular, CRO shall comply with all DCGI or FDA reporting rules that require it to inform Institution and/or Principal Investigator of any serious and unexpected adverse experience associated with the Study Drug or device.

C. No Other Representations or Warranties. Except for the limited representations and warranties given in this Clause 8, none of the Sponsor, the CRO, the Institution, or the Principal Investigator makes or receives any representations or warranties, express or implied, statutory or otherwise, and each expressly disclaims any implied warranties of merchantability, fitness for a particular purpose, or non-infringement.

D. Of the Institution: Institution will ensure that the Principal Investigator remits to the Sponsor all clinical data, including without limitation, case record forms, medical reports and the information generated during the performance of the Study. Institution will notify the CRO and Sponsor immediately if the Principal Investigator ceases to be employed by or associated with the Institution.

10. GOVERNING LAW

This Agreement shall be governed by and construed in accordance to the Laws of India. Disputes, if any, shall be arbitrated upon under the Arbitration and Conciliation Act, 1996 in English language and the venue shall be Hyderabad, India. It is expressly agreed that the arbitral award

without limitation all source documents and data, and correspondence involving the IEC/IRB and applicable regulatory agencies); (iii) inspect and copy, at Sponsor's expense, any or all written and electronic data and work product relating to the Study; and (iv) collect financial billing and economic outcomes (including expense reports) provided that collection of such information is clearly described in the Informed Consent Form and appropriately authorized by the Subject and the IEC/IRB. The Principal Investigator and the Institution shall cooperate with the Sponsor and use reasonable efforts to promptly provide all of the information requested by the Sponsor.

The Institution and the Principal Investigator shall also cooperate with the Sponsor and with any regulatory agencies in the event of announced or unannounced monitoring, audit or inspection by such regulatory agencies. The Institution and the Principal Investigator shall notify the Sponsor by telephone of the intended or possible inspection within **twenty four (24) hours** of becoming aware of it; in addition, notice of the intended or possible inspection shall be sent to Sponsor within **forty eight (48) hours** of the telephonic notification. If a written response is required, the Institution and Principal Investigator shall permit representatives of the Sponsor to review and comment on such response prior to its being sent to the regulatory agencies. The Institution and Principal Investigator shall provide Sponsor with a copy of any report received in connection with, or as a result of such inspection within **three (3) days** of its receipt.

F. Supplies.

a. The CRO or Sponsor's designee shall supply to the Principal Investigator, at no charge, sufficient quantity of the Study Drug to conduct the Study, as well as the materials, equipment and information which the Protocol specifies. The Principal Investigator acknowledges that the Study Drug is experimental in nature, and therefore shall use prudence and reasonable care in the use, handling, storage, transportation, disposition and containment of the Study Drug and any of its derivatives. Within **thirty (30) days** following the completion or termination of the Study, all unused Study Drugs, devices and other materials that were furnished to the Institution by or on behalf of Sponsor shall, at Sponsor's expense, be returned to Sponsor, or if Sponsor so directs destroyed in accordance with instructions provided by the Sponsor. The Sponsor shall solely own all rights, title and interest in the Study Drug, including any materials derived therefrom and all intellectual property rights therein. The transfer of physical possession of the Study Drug here under, and/or the possession or use of the Study Drug by the Principal Investigator, shall neither constitute nor be construed as a sale, lease, or offer to sell or lease the Study Drug or other transfer of title in or to the Study Drug. Further, the Principal Investigator shall use the Study Drug solely for the conduct of the Study and in accordance with the Protocol unless they obtain the prior written authorization of the Sponsor.

b. Any instruments, materials or other equipment supplied/provided by the CRO to the Principal Investigator shall be used solely for the purpose of conducting the Study and as per the Protocol/ Study requirements/ Study manuals under the Agreement. Also, any damage caused to the equipment supplied/provided by the CRO under the said Agreement or any repairing cost incurred in order to maintain the said equipment or repair the damage done while conducting the Study shall be borne solely by the Principal Investigator and no liability of the same shall be placed upon the CRO.

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without limitation all source documents and data, and correspondence involving the IEC/IRB and applicable regulatory agencies); (iii) inspect and copy, at Sponsor's expense, any or all written and electronic data and work product relating to the Study; and (iv) collect financial billing and economic outcomes (including expense reports) provided that collection of such information is clearly described in the Informed Consent Form and appropriately authorized by the Subject and the IEC/IRB. The Principal Investigator and the Institution shall cooperate with the Sponsor and use reasonable efforts to promptly provide all of the information requested by the Sponsor.

The Institution and the Principal Investigator shall also cooperate with the Sponsor and with any regulatory agencies in the event of announced or unannounced monitoring, audit or inspection by such regulatory agencies. The Institution and the Principal Investigator shall notify the Sponsor by telephone of the intended or possible inspection within **twenty four (24) hours** of becoming aware of it; in addition, notice of the intended or possible inspection shall be sent to Sponsor within **forty eight (48) hours** of the telephonic notification. If a written response is required, the Institution and Principal Investigator shall permit representatives of the Sponsor to review and comment on such response prior to its being sent to the regulatory agencies. The Institution and Principal Investigator shall provide Sponsor with a copy of any report received in connection with, or as a result of such inspection within **three (3) days** of its receipt.

F. Supplies.

a. The CRO or Sponsor's designee shall supply to the Principal Investigator, at no charge, sufficient quantity of the Study Drug to conduct the Study, as well as the materials, equipment and information which the Protocol specifies. The Principal Investigator acknowledges that the Study Drug is experimental in nature, and therefore shall use prudence and reasonable care in the use, handling, storage, transportation, disposition and containment of the Study Drug and any of its derivatives. Within **thirty (30) days** following the completion or termination of the Study, all unused Study Drugs, devices and other materials that were furnished to the Institution by or on behalf of Sponsor shall, at Sponsor's expense, be returned to Sponsor, or if Sponsor so directs destroyed in accordance with instructions provided by the Sponsor. The Sponsor shall solely own all rights, title and interest in the Study Drug, including any materials derived therefrom and all intellectual property rights therein. The transfer of physical possession of the Study Drug here under, and/or the possession or use of the Study Drug by the Principal Investigator, shall neither constitute nor be construed as a sale, lease, or offer to sell or lease the Study Drug or other transfer of title in or to the Study Drug. Further, the Principal Investigator shall use the Study Drug solely for the conduct of the Study and in accordance with the Protocol unless they obtain the prior written authorization of the Sponsor.

b. Any instruments, materials or other equipment supplied/provided by the CRO to the Principal Investigator shall be used solely for the purpose of conducting the Study and as per the Protocol/ Study requirements/ Study manuals under the Agreement. Also, any damage caused to the equipment supplied/provided by the CRO under the said Agreement or any repairing cost incurred in order to maintain the said equipment or repair the damage done while conducting the Study shall be borne solely by the Principal Investigator and no liability of the same shall be placed upon the CRO.

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Disclosing Party: The term "Disclosing Party" shall mean the Party disclosing Confidential Information to other Party.

Receiving Party: The term "Receiving Party" shall mean the Party receiving Confidential Information from the other Party.

All Confidential information shared hereunder for purpose of completion of Study and who are legally bound by confidentiality and non-use obligations, no less restrictive than those contained in this Agreement and any other confidentiality agreement executed. In addition, Institution, Principal Investigator and Site shall not use any Confidential Information for any purpose other than the conduct of the Study and shall ensure that the co-investigator who has access to Confidential Information is informed of its confidential nature and agrees to comply with the obligations of confidentiality and non-use, as set out in this Agreement and any other confidentiality agreement executed.

In addition to any other rights and obligations contained herein or elsewhere in the Agreement, Sponsor, or CRO on Sponsor's behalf, shall be entitled to seek an injunction from a court of competent jurisdiction for the purpose of stopping or preventing any existing or anticipated breach of the terms Confidentiality and of this Agreement.

B. Notwithstanding anything to the contrary in this Agreement, nothing herein shall (i) prevent the Institution from disclosing to the DCGI or any other appropriate regulatory agency Confidential Information (including Study results) that indicates that the administration or use of the Study Drug or device is associated with a serious risk of harm to the Subjects, provided that Institution furnishes at least fourteen (14) days advance written notice to the Sponsor and Sponsor fails during such time to either make the disclosure requested by Institution or to adequately demonstrate to the Institution that it has complied with all applicable disclosure requirements, or (ii) prevent Institution and/or Principal Investigator from informing the Subjects or potential Subjects of any adverse experiences or risks associated with the Study Drug or device.

C. Non-Disclosure and Non-Use. Except as otherwise expressly provided herein, for the term of this Agreement, and for a period of ten (10) years thereafter, the Parties shall not disclose to any third party Confidential Information and shall not use for any purpose other than as expressly provided for herein any such Confidential Information, without the express written consent of the Disclosing Party. Without limiting the foregoing, the Parties shall disclose Confidential Information only to those employees of the respective Party who require such Confidential Information for the purposes of this Agreement and who are bound by an obligation of confidentiality and non-use no less stringent than set forth herein. Upon disclosing Confidential Information to any employee, the employing Party shall advise them of the confidential nature of the information, and shall require them to take all necessary and reasonable precautions to prevent the unauthorized disclosure thereof. In the event that the Parties are required to disclose Confidential Information pursuant to an order or requirement of a court, administrative agency, or other governmental body, the Parties, as the case may be, may disclose the Confidential Information provided that the Receiving Party provides the Disclosing Party with reasonable advance notice thereof to enable the Disclosing Party to seek an appropriate protective order or

to prevent the disclosure. In such a situation, the Receiving Party shall provide reasonable assistance to the other Party to obtain a protective order or to prevent disclosure.

D. Medical Confidentiality. Notwithstanding any of the foregoing, Sponsor and CRO shall maintain the confidentiality of all medical records, case history, test reports, fitness data and charts to which it may have access in accordance with all applicable federal, state and local confidentiality laws and regulations and its corresponding regulations issued under DCGI or other applicable regulations. Sponsor shall not use, disclose, maintain, store, or transmit any individually identifiable Subject information except as permitted by such laws.

E. The PI and Institution hereby acknowledge and agree that in accordance with the applicable laws and codes, and in particular with any transparency obligations contained therein, certain value transfers between pharmaceutical companies and healthcare professionals and/or healthcare or academic institutions or hospitals, are subject to mandatory publication. The Parties acknowledge that, in accordance with said obligations the Sponsor is responsible for the publication of the relevant information in the appropriate format and within the applicable timeframe. Such information shall at least include the amount, purpose and recipient of the value transfers. The PI and Institution hereby explicitly agrees with such publication by Sponsor, provided the publication is in accordance and strictly limited to the requirements of the said laws and codes, and does not go beyond the requirements of the applicable privacy laws.

6. Protection. Without limiting the foregoing, the Parties shall maintain reasonable procedures to prevent accidental or other loss of any Confidential Information of the Disclosing Party, and shall use at least the same procedures and degree of care which each uses to protect its own confidential information, but in no case less than reasonable care. In the event of loss, disclosure or use of any Confidential Information in violation of this Agreement, the Receiving Party shall immediately notify the Disclosing Party. The Parties shall prevent the disclosure of medical records and private or personal information, whether confidential or not, to the extent required by applicable laws or regulations.

7. PUBLICATION

Subject to governing law, the Sponsor shall have the sole right to review, use, publish, and disclose any data, information, or results developed or arising out of the Study as the Sponsor, in its discretion, deems appropriate, including, without limitation, in submissions to the FDA and other governmental agencies. If Principal Investigator wants to publish information arising from his/her participation in the Study, the prior written approval from Sponsor is required.

8. OWNERSHIP OF MATERIALS, DATA, INVENTIONS, AND DISCOVERIES

A. Materials and Data. The Sponsor shall solely own all right, title and interest in and to the Study Drug and any and all information, data or other materials delivered to the Institution or the Principal Investigator by or on behalf of the Sponsor as well as any derivatives, progeny, or improvements developed therefrom, and all intellectual property rights therein. Further, all data and work product arising out of or relating to the Study, including, without limitation, the Study Records, CRFs, reports, and specimens, and all intellectual property rights therein, shall be the

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be free to dispose of its interest in accordance with its technology transfer policies. If Sponsor and Institution fail to reach agreement on the terms for an exclusive license of a particular Institution Invention within four (4) months after Sponsor provides notice that it wishes to exercise its option, then for a period of one (1) year thereafter, the Institution shall not offer to license the Institution Invention to any third party on materially better terms than those last offered to the Sponsor without first offering such terms to Sponsor, in which case Sponsor shall have a period of thirty (30) days to accept the offer.

C. **No Other Rights.** Except as expressly set forth herein, none of the Sponsor, the Principal Investigator, or the Institution transfers to any other Party hereto, by operation of this Agreement or otherwise, rights to any patent, copyright, trademark or other intellectual property right of any kind.

9. REPRESENTATIONS, WARRANTIES AND COVENANTS

A. **Of the Principal Investigator.** The Principal Investigator represents and warrants that (i) he has the legal authority and right to enter into this Agreement; (ii) he has no obligation to any third party that is in conflict with, or has the potential to conflict with, its obligations under this Agreement; (iii) he has and will maintain throughout the conduct of the Study, all training, information, licenses, approvals and certifications necessary for safely, adequately, and lawfully performing the Study; (iv) he will not enter into any agreement with any third party to directly or indirectly fund or support the Study without the express written consent of the CRO (excluding laboratory investigations, radiological investigations or any other requirement to fulfill Protocol criteria), and (v) this Agreement has been duly executed and delivered by it and constitutes a valid, binding obligation enforceable against it in accordance with its terms.

The Principal Investigator represents and warrants that no clinical study or trial in which he was involved was terminated for any reason prior to completion that was due, in whole or in part, to the Principal Investigator's non-compliance with the applicable protocol and/or safety requirements of the study or any applicable local, state or federal law. The Principal Investigator further represents and warrants that he has not received any written notice from the DCGI/FDA or NIH of any violation of any applicable law relating to clinical studies that has not been disclosed to the CRO and attached to this Agreement as an Exhibit hereto. For the purposes of the prior sentence, "written notice" shall include, but not be limited to, DCGI or FDA lists of Inspectional Observations (FDA Form 483), Notices of Adverse Findings, regulatory letters, warning letters, notices of intent to initiate clinical investigator disqualification proceedings under national regulations or under 21 C.F.R. 312.70 or 21 C.F.R. 812.119 or any similar regulation ("**Notice of Intent to Disqualify**"). The Principal Investigator further represents and warrants that he has never been disqualified from receiving investigational drugs or medical devices by the DCGI or FDA or NIH or any other federal governmental body. In the event that any of the foregoing events in this paragraph occur during the course of this Study, the Principal Investigator shall provide the CRO with a full written explanation of the circumstances of such an incident within ten (10) days of the occurrence of such an incident. If the Institution or the Principal Investigator becomes debarred as per the national or local regulations, this Agreement will

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INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

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Certificate No.	:	IN-KA11902609174689O
Certificate Issued Date	:	19-Sep-2016 02:51 PM
Account Reference	:	NONACC (FI)/ kacrsfl08/ JAYANAGAR4/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKACRSFL08738139812158600
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	:	K L E SOCIETYS DR PRABHAKAR KORE HOSPITAL
Stamp Duty Paid By	:	QUINTILES RESEARCH INDIA PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

AUTHORISED SIGNATORY
The Bharathi Co-op Credit
Society Ltd
Jayanagar, Bangalore

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.

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CLINICAL TRIAL AGREEMENT

Made between **Dr. Vardaraj Gokak**, having a place of business at KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi - 590010, Karnataka, India (the "Investigator"), **KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre**, having a place of business at Nehru Nagar, Belagavi - 590010, Karnataka, India (the "Institution"), **GDD Experts India Pvt. Ltd.** having a place of businessat Ground Floor, Gulmohar Apartment, Opposite Hislop College, Nagpur- 440001, Maharashtra, India (the "Research Company"), F. Hoffmann-La Roche Ltd, having a place of business at Grenzacherstrasse 124, 4070 Basel, Switzerland ("Sponsor") and **Quintiles Research (India) Private Limited**, having its office at B-101-106, Shapath IV, S G Road, Ahmedabad- 380 051, India ("Quintiles").

PROTOCOL NUMBER:	GA28951
PROTOCOL TITLE:	An Open-label extension and safety monitoring study of moderate to severe Ulcerative Colitis patients previously enrolled in Etrolizumab Phase II/III studies
PROTOCOL DATE:	22 October 2015
SPONSOR:	F. Hoffmann-La Roche Ltd
PRINCIPAL INVESTIGATOR:	**Dr. Vardaraj Gokak**
KEY ENROLLMENT DATE: (date by which site is to enroll at least one (1) subject)	100 Calendar Days after Site Initiation Visit

WHEREAS, the Investigator and Institution [or "and Research Company"], if any, (hereafter, jointly, the "Site") are willing to conduct a clinical trial (the "Study"), in accordance with the above-referenced protocol and any subsequent amendments thereto (the "Protocol") and Sponsor and Quintiles request the Site to undertake such Study;

WHEREAS, Quintiles has been duly authorized by the Sponsor to carry out certain obligations of the Sponsor in the conduct of the Study, consistent with the terms of this Agreement;

NOW THEREFORE, the following is agreed:

1. Quintiles and Sponsor hereby appoint the Site to conduct the Study, and the Site agrees to ensure that the Site and the Site's employees, agents, and staff will conduct the Study in accordance with the Protocol (as may be amended from time to time by Sponsor), the terms of this agreement, including the Terms and Conditions attached as Attachment A, the Payment Schedule and Budget attached as Attachment B, and any other attachments hereto, which all are incorporated by reference herein (the "Agreement"), good clinical practices, and all applicable laws and regulations. The Site hereby confirms that it has enough time and resources to perform the Study according to the highest quality standards. The Site understands and agrees that if Site has not enrolled at least one (1) subject by the Key Enrollment Date then Sponsor may terminate this Agreement in accordance with Section 5 of Attachment A.

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Enrollment of Patients
The Effective Date of this Agreement is as listed in Section 3. 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 contract is reached.

In addition, Sponsor has a right to limit or increase unilaterally and at any time the number of subjects participating in the Study.

2. Payments shall be made in accordance with the provisions set forth in Attachment B, with the last payment being made after the Site completes all its obligations hereunder, and Quintiles has received all completed case report forms ("CRFs") and, if Quintiles requests, all other Confidential Information as defined in Attachment A, Section 2 (Confidential and Proprietary Information). The Site will act as an independent contractor, and shall not be considered the employee or agent 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 Site. The Site acknowledges and agrees that Investigator's judgment with respect to Investigator's advice to and care of each subject is not affected by the compensation Site receives hereunder. 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 (the "Payee"):

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.

PAYEE NAME:	GDD EXPERTS INDIA PVT. LTD.
PAYEE ADDRESS:	Ground Floor, Gulmohar Apartment, Opposite Hislop College, Nagpur- 440001, Maharashtra, India
PAN OF PAYEE	AADCG0363Q

It should be noted that all the payments made to the Payee are subject to Tax Deducted at Source (TDS) in accordance with India tax laws, as amended from time to time. Quintiles will deduct the tax at the time of making payments unless a valid Certificate (Form 15 AA – for no TDS) from tax authority is made available.

Site will have thirty (30) days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

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 will be 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. **Investigator acknowledges that if Investigator is not the Payee, neither Quintiles nor Sponsor will pay Investigator, even if the Payee fails to reimburse Investigator.**

3. This Agreement will become effective on the date of approval of the Study by Drugs Controller General India or on 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 the provision in Attachment A. Quintiles shall attach a copy of the letter

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from the Drugs Controller General India approving the Study to this Agreement as Attachment C, and the parties agree that such letter shall be incorporated by reference herein. If such approval letter 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 letter, and upon receipt of such letter, Quintiles shall attach a copy of the letter to each original Agreement as Attachment C and forward an original Agreement to each other party, while retaining one original Agreement its files. If such approval letter already has been received prior to the signatures of the parties, Quintiles shall immediately attach a copy of the letter hereto as Attachment C, and upon signature of all parties, each party shall receive an original of the Agreement, which shall include such letter as Attachment C. In the event of a conflict between the Protocol and this Agreement, the terms of this Agreement will govern.

4. The date of execution of this Agreement is as listed in Section 3 above. Consequently, the Site will not be permitted to screen patients, randomize patients, receive Investigational Product or receive any start up payment until the validity date of this contract is reached.

5. Prior to and during the course of the Study, Quintiles or Study Sponsor may request to collect personal data which may be subject to data privacy laws or regulations (collectively "Data Privacy Legislation") relating to the Study from the Site, including from its investigators, sub-investigators, other Site staff or personnel involved in the conduct of the Study. The Investigator hereby consents to the processing of Investigator's personal data collected by Quintiles or Sponsor, and Investigator and Institution agree to obtain any consents, as may be necessary in accordance with applicable Data Privacy Legislation, for the processing of any personal data collected by Quintiles or the Sponsor from its investigators, sub-investigators, staff and personnel involved in the conduct of the Study. Such consent shall authorize the transfer of personal data, to countries other than the Site's own country, including without limitation the United States, even though data protection may not exist or be as developed in those countries as in the Site's own country, for the following purposes: a) the conduct and interpretation of the Study; b) review by governmental or regulatory agencies, Sponsor, Quintiles, and their agents, and affiliates and collaborators; c) satisfying legal or regulatory requirements; d) publication on www.clinicaltrials.gov and websites and databases that serve a comparable purpose; and e) storage in databases for use in selecting sites in future clinical trials. In the event any Site personnel participating in the Study are not willing to provide such consent, Site acknowledges that such personnel will not be able to participate in the Study.

6. Institution and Principal Investigator agree that the compensation they receive from this Agreement 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. Site agrees that it will not bill any patient, insurer, or governmental agency for any items, visits, services or expenses provided or paid for by Quintiles or Sponsor.

   Institution and Principal Investigator and GDD Experts India Pvt. Ltd. represent and warrant that neither they nor any individual or entity acting on their behalf, nor any payee under this Agreement, will, directly or indirectly, offer or pay, or authorize an offer or payment of, any money or anything of value to any Public Official (defined below) or public entity, with the knowledge or intent that the payment, promise or gift, in whole or in part, will be made in order to influence an official act or decision that will assist Quintiles, Sponsor or the Site in securing an improper advantage or in obtaining or retaining business or in directing business to any person or entity.

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In addition to other rights or remedies under this Agreement or at law, Sponsor and/or Quintiles may terminate this Agreement if Site and GDD Experts India Pvt. Ltd. breaches any of the representations or warranties contained in this Section or if Quintiles or Sponsor learns that improper payments are being or have been made to Public Officials by Site or any individual or entity acting or its behalf.

For the purposes of this Agreement, "Public Official" means any officer or employee of a government, a public international organization or any department or agency thereof, or any person acting in an official capacity, including, for a public agency or enterprise; and any political party or party official, or any candidate for public office.

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

By: Subashri Shivkumar

Name: Subashri Shivkumar

Title: Head Clinical Development Services

Date: 29/Sept/2016

ACKNOWLEDGED AND AGREED BY SPONSOR (Quintiles executing on Sponsor's behalf):

By: Subashri Shivkumar

Name: Subashri Shivkumar

Title: Head Clinical Development Services

Date: 29/Sept/2016

ACKNOWLEDGED AND AGREED BY THE PRINCIPAL INVESTIGATOR:

By: _____

Name: Dr. Vardaraj Gokak

Title: Principal Investigator

Date: 18/9/16

ACKNOWLEDGED AND AGREED BY KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre:

By: _____

Name: Dr. M. V. Jali

Title: Medical Director

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

Date: 21/9/2016

ACKNOWLEDGED AND AGREED BY GDD EXPERTS INDIA PVT. LTD.:

By: _____

Name: Vinod Gyanchandani

Title: Head- Clinical Operations

Date: 30/SEP/2016

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ATTACHMENT A
TERMS AND CONDITIONS

Capitalized terms not defined herein shall have the meanings assigned to them in the attached Agreement.

1) Conduct of the Study. The parties to the Agreement agree that the Study will be performed in strict accordance with the Protocol, all applicable laws, regulations and guidelines, and good clinical practices ("GCPs"), and Indian Medical Council (Professional Conduct, Etiquette and Ethics)(Amendment) Regulations, 2009 – Part-I ("MCI Regulations"). The Investigator shall review all case report forms ("CRFs") to ensure their accuracy and completeness, shall review and understand the information in the investigator's brochure, shall ensure that all informed consent requirements are met (including any needed authorizations for the use, storage and transfer of personal data), shall ensure that all required reviews and approvals (or favorable opinions) by applicable regulatory authorities and Institutional Review Boards ("IRBs") or Independent Ethics Committees ("IECs") are obtained and shall provide a copy of such approval to Quintiles prior to enrollment of any subjects. A sample informed consent form has been provided by the Sponsor for use in the Study; any modifications to this form must be approved by Quintiles or Sponsor prior to its use, such approval not to be unreasonably withheld. The Site agrees to ensure that all clinical data are accurate, complete, and legible. The Site shall promptly and fully produce all data, records and information relating to the Study to Quintiles and Sponsor and their representatives during normal business hours, and shall assist them in promptly resolving any questions and in performing audits or reviews of original subject records, reports, or data sources. The Site agrees to cooperate with the representatives of Quintiles and Sponsor who visit the Site, 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 warrants that it has the legal authority to share the clinical data and Study-related records and information with Quintiles and Sponsor. The Site shall use the product being tested (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 all Investigational Product and any comparator products in a locked, secured area at all times. Upon completion or termination of the Study, the Site shall return all unused Investigational Product, comparator products, equipment, and materials and all Confidential Information (as defined below).

2) Confidential and Proprietary Information. All information (including, but not limited to, documents, descriptions, data, CRFs, photographs, videos and instructions), and materials (including, but not limited to, the Investigational Product and comparator products), provided to the Site by Quintiles, Sponsor, or their agents, (whether verbal, written or electronic), and all data, reports and information, relating to the Study or its progress (hereinafter, the "Confidential Information") shall be the property of Sponsor. The Site shall keep the Confidential Information strictly confidential and shall disclose it only to its employees involved in conducting the Study, who are subject to confidentiality obligations that are consistent with this Agreement, on a need-to-know basis. These confidentiality obligations shall continue until ten (10) years after completion of the Study, but shall not apply to Confidential Information to the extent that it: a) is or becomes publicly available through no fault of the Site; b) is disclosed to the Site by a third party not subject to any obligation of confidence; c) must be disclosed to IRBs, IECs, or applicable regulatory authorities; d) must be included in any subject's informed consent form; e) is published in accordance with Article 3 herein; or, f) is required to be disclosed by applicable law, provided that the Site shall give Sponsor and Quintiles prompt, advance written notice to permit Quintiles, Sponsor or their agents to object to or otherwise limit such disclosure. The existing inventions and technologies of Sponsor, Quintiles, or the Site are their separate property and are not affected by this Agreement. Sponsor shall have exclusive ownership of any inventions or discoveries arising in whole or in part from Confidential Information or arising from the conduct of the Study. The Site will promptly notify Sponsor in writing if it or Investigator conceives or makes any such inventions or discoveries and,

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at Sponsor's expense, execute any documents and give any testimony necessary for Sponsor to obtain patents in any country or to otherwise protect Sponsor's interests in such inventions or discoveries. The Site agrees to comply with any applicable data privacy or data protection legislation of the country in which the data originated.

3) Publication. Site understands that this Study is being conducted at multiple research sites. Site is free to publish or present the Study results obtained at the Site, but only after the first publication or presentation that involves the multi-center data or eighteen (18) months after the completion of the multi-center Study, whichever is first. At least sixty (60) days prior to submitting or presenting a manuscript or other materials relating to the Study to a publisher, reviewer, or other outside persons, the Site shall provide to Sponsor a copy of all such manuscripts and materials, and allow Sponsor sixty (60) days to review and comment on them. If the Sponsor requests, the Site shall remove any Confidential Information (other than Study results) prior to submitting or presenting the materials. In addition, at Sponsor's request, the Site shall delay publication for an additional ninety (90) days to allow Sponsor the opportunity to file for patent protection. No party hereto shall use any other party's name in connection with any advertising, publication or promotion without prior written permission.

4) Inspection and Debarment. When given reasonable notice, the Site agrees to allow authorized Quintiles, Sponsor and regulatory authority personnel direct access to the Site's records relating to the Study, including subject medical records, for monitoring, auditing, and inspection purposes. If any source data are kept on computer files only, the site shall make print-outs of all patients' data relevant to the Study for the purpose of source data verification, signed, dated and retained as source documents. 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 permit Quintiles and Sponsor to attend any such inspections. The Site will make reasonable efforts to separate, and not disclose, all confidential materials that are not required to be disclosed during such inspections. Site and Investigator each represents and warrants that there are no pending for-cause regulatory audits, investigations or proceedings involving Site, Investigator, or any of their employees or agents performing Study activities which relate to compliance with laws regarding the conduct of any clinical research. The Investigator and the Institution shall be jointly responsible for maintaining essential Study documents in the manner specified by current good clinical practice ("GCP") guidelines and applicable laws for fifteen (15) years after the completion of the Study or such longer period as specified by current GCP guidelines and applicable laws. In addition, Site shall take measures to prevent accidental or premature destruction of these documents. If the Investigator leaves an institution, then responsibility for maintaining Study records shall be determined in accordance with applicable regulations. During the Study and for 15 years thereafter, if an investigator or sub-investigator leaves an institution or otherwise changes addresses, he or she shall promptly notify Sponsor and Quintiles of his or her new address. The Site represents and warrants that neither it, nor any of its employees, agents or other persons performing the Study under its direction, has been debarred, disqualified or banned from conducting clinical trials or is 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.

5) Termination. Sponsor may suspend enrollment or terminate this Agreement effective immediately upon written notice. The Site may terminate this Agreement upon written notice if circumstances beyond the Site's reasonable control prevent the Site from completing the Study, or if the Site reasonably determines that it is unsafe to continue the Study. Upon receipt of notice of termination, the Site shall immediately cease any subject recruitment, follow the specified termination procedures, ensure that any required subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs, and Quintiles shall make a final payment for visits or milestones properly performed pursuant to this Agreement in the amounts specified in the

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Attachment B; provided, however, that ten percent (10%) of this final payment will be withheld until final acceptance by Sponsor of all subject CRF pages and all data clarifications issued and satisfaction of all other applicable conditions set forth in the Agreement. Neither Quintiles nor Sponsor shall be responsible to the Site for any lost profits, lost opportunities, or other consequential damages.

6) Claims and Disclaimers. The Site shall promptly notify Quintiles and Sponsor in writing of any claim of illness, injury or death or damage actually or allegedly arising from the conduct of the Study. Sponsor agrees to indemnify and hold harmless the Site and Investigator from any third party claims of illness, injury or damage directly arising out of the conduct of the Study in accordance with the Protocol, except to the extent any such illness, injury or damage is caused by the Site or Investigator's negligence, misconduct, failure to follow the Protocol or breach of applicable law or regulation. Sponsor shall have the right to control the defense of any such claims and the Site shall cooperate fully with Sponsor in handling such claims. Quintiles expressly disclaims any liability in connection with the Investigational Product, including any liability for any product claim arising out of a condition caused by or allegedly caused by the administration of such product except to the extent that such liability is caused by the negligence, willful misconduct or breach of this Agreement by Quintiles. Neither Quintiles nor Sponsor will be responsible for, and the Site agrees, to the extent allowed by law, to indemnify and hold them harmless from, any third party claims of illness, injury or damage resulting from the Site's negligence, failure to adhere to the Protocol, failure to obtain informed consent, unauthorized warranties, breach of this Agreement, breach of applicable law or regulation or willful misconduct.

7) Financial Disclosure. In order to allow Sponsor to comply with its U.S. regulatory requirements, the Site agrees that, for each listed or identified investigator or sub investigator who is directly involved in the treatment or evaluation of research subjects, it shall promptly return to Quintiles a financial 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. Quintiles may withhold payments if it does not receive a completed form from each such investigator and sub investigator. The 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 its completion. The 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. if the Site is outside of the U.S., even though data protection may not exist or be as developed in those countries as in the Site's own country.

8) Shipping of Dangerous Goods and Infectious Materials. The shipment of dangerous goods and infectious materials (including infectious subject specimens) is subject to local, national, and international laws and regulations. The Site is responsible for ensuring that each individual who packages or handles any dangerous goods or infectious materials for shipping from the Site complies with all applicable laws and regulations.

9) Adverse Event Reporting. Investigator agrees to report any serious adverse events (SAEs) as required by law, regulation and the Protocol. Within 24 hours (or such other time as specified in the Protocol) of first knowledge of any SAE or any event that could affect the safety of the Study participants, Investigator will notify
Investigator will notify Quintiles and the Sponsor via the electronic data capture system (eDC). In the case of the eDC being offline, the responsible Site staff will fax the paper SAE form to Quintiles Lifecycle Safety using the toll free fax number (+353 1 809950) and enter the SAE into the eDC system as soon as it is back online.

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10) Additional Contractual Provisions. This Agreement, including these Terms and Conditions, constitutes the sole and complete agreement between the parties and replaces all other written and oral agreements relating to the Study. No amendments or modifications to this Agreement shall be valid unless in writing and signed by all the parties. 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. 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 Sponsor. Sponsor may, and/or Quintiles may upon Sponsor's request, assign this Agreement to a third party, (and Quintiles may upon Sponsor's request assign its rights and obligations under this Agreement to Sponsor), and Sponsor and/or Quintiles (as the case may be) 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. 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, including without limitation Sections 2, 3, 4, 6 , 7 and 10 of this Attachment A.

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ATTACHMENT B

BUDGET AND PAYMENT SCHEDULE

A. PAYMENT TERMS

Quintiles will reimburse the Payee every month, on a completed visit per subject basis in accordance with the attached budget. Ninety percent (90%) of each payment due, including any Screening Failure (see Article C below), will be made based upon prior enrollment data confirmed by subject Case Report Forms ("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 to Quintiles, as well as confirmation that all electronic patient diaries have been returned and upon satisfaction of all other applicable conditions set forth in the Agreement. Site shall have thirty (30) days from the receipt of the final payment to dispute any discrepancies relating to payments made pursuant to this section. Site understands that at some point following such period, Quintiles will close its books relating to the Study and any disputes received after such period may be forwarded to Sponsor for resolution.

Site represents that the services it provides under this Agreement are taxable services under the laws governing service tax in India, and that it is required to charge service tax for the services rendered to Quintiles at the prevailing rate. Site represents that it is entitled to require such payment of the service tax under the laws of India. Site undertakes to provide Quintiles with an invoice, to be sent to Quintiles at the address mentioned in Section E of this attachment, in respect of such taxable services and such invoice shall be in accordance with the terms of the Service Tax Rules of 1994 as may be amended from time to time or any successor legislation.

It should be noted that all the payments made to the Payee are subject to Tax Deducted at Source (TDS) in accordance with India tax laws, as amended from time to time. Quintiles will deduct the tax at the time of making payments unless a valid Certificate (Form 15 AA – for no TDS) from tax authority is made available.

Major, disqualifying Protocol violations are not payable under this Agreement

B. DISCONTINUED OR EARLY TERMINATION PAYMENTS:

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

C. ORIGINAL 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.

Please note that invoices will not be processed unless they reference the Sponsor name, Protocol number and Investigator and will be included with the regular payments. After receipt and

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verification, reimbursement for invoices will be included with the next regularly scheduled payment for subject activity.

- **Institution Review Boards ("IRBs") or Independent Ethics Committees ("IECs") Payments**

IRB/IEC costs will be reimbursed on a pass-through basis and are not included in the attached Budget. Any subsequent re-submissions or renewals, upon approval by Quintiles and Sponsor, will be reimbursed upon receipt of appropriate documentation.

- **Study Start-Up Fee**

A one time, non-refundable payment of **Sixty Thousand Rupees (INR 60,000)** to cover Study Start-Up activities [which includes Institutional overhead], will be made upon completion and receipt by Quintiles of all original contractual and regulatory documentation and receipt of original invoice.

- **Record Storage Fee/Archiving Fee**

A record storage payment of **One Lakh, Twenty Thousand Rupees (INR 1, 20,000),** [which includes institutional overhead], will be made upon receipt of original supporting invoices from a third party vendor and are not included in the attached Budget. In accordance with Sponsor's Protocol requirements, Institution shall maintain all site study records in a safe and secure location to allow easy and timely retrieval, when needed.

- **Patient Travel Expenses**

Patient travel expenses will be reimbursed upon receipt of original supporting invoices from third party vendors at a flat rate of **Five Hundred Rupees (INR 500) or up to (INR 1000)** per visit per patient per round trip) and are not included in the attached Budget. Invoices must contain the following information in order for a payment to be issued- Subject number or initials, amount paid, visit number in which patient travel is being requested.

- **PREGNANCY TEST, ALCOHOL AND GAUZE:**

Quintiles will provide the Site with pregnancy tests, alcohol pad and gauze during the course of the Study, in reasonable and needed amounts. Site will provide such materials to patients (study subjects) to take home for the purposes of Study protocol procedures.

- **ADVERSE EVENT REPORTING:**

Investigator will report any serious adverse events (SAEs) as required by law, regulation and the Protocol. Within 24 hours (or such other time as specified in the Protocol) of first knowledge of any SAE or any event that could affect the safety of the Study participants, Investigator will notify Quintiles and the Sponsor via the electronic data capture system (eDC). In the case of the eDC being offline, the responsible Site staff will fax the paper SAE form to Quintiles Lifecycle Safety using the toll free fax number (+353 1 809950) and enter the SAE into the eDC system as soon as it is back online.

F. INFRASTRUCTURE / EQUIPMENT:

1. **<u>e-Diaries and Tablet Return</u>:**

<u>Section 1</u>: The final payment will be made after Sponsor has received copies of all completed Case Report Forms ("CRFs") for each of the Subjects participating in the Study with all queries resolved as well as confirmation that all electronic patient diaries have been returned. Site shall have thirty (30) days from the receipt of the final payment to dispute any discrepancies relating to payments made pursuant to this section 1. Site understands that at some point following such period, QUINTILES will close its books relating to the

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Study and any disputes received after such period may be forwarded to Sponsor for resolution.

Section 2: Subject to the conditions set forth below, Sponsor or QUINTILES will provide HTC-HD2 T8585 Handheld Computer (eDiary) and Acer Iconia W510P (eQuestionnaires), which is required for use in the Study and that Site does not otherwise own or have access to (the "Equipment") to Site for use in the Study.

(i) Equipment Use; Maintenance. Site agrees to house the Equipment on site and to use the Equipment solely in connection with the Study during the term of the Agreement. Site agrees to maintain the Equipment in good working condition, reasonable wear and tear excepted. In the event that the Equipment malfunctions or ceases to operate during the conduct of the Study through no fault of Site, Sponsor or QUINTILES will arrange for appropriate maintenance or replacement of the Equipment, including, at Sponsor's option, reimbursing Site for reasonable maintenance or replacement expenses.

(ii) Return or Purchase of Equipment. Upon completion or any earlier termination of the Study at Site, Site shall, at its option, either: (A) return the Equipment to Sponsor/Sponsor at Sponsor's/Sponsor's expense; or (B) reimburse Sponsor/Sponsor for the residual fair market value of the Equipment as of the date of termination. Sponsor/Sponsor or QUINTILES may, at its option, either withhold the final payment to Site until the Equipment is returned, or until Site reimburses Sponsor/Sponsor for the residual fair market value of the Equipment as of the date of completion or termination of the Study. IN THE EVENT OF TRANSFER OR ASSIGNMENT UNDER THIS PARAGRAPH, THE EQUIPMENT SHALL BE TRANSFERRED AND ASSIGNED "AS IS," AND SPONSOR/SPONSOR MAKES NO WARRANTY OR REPRESENTATION, EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO FITNESS, MERCHANTABILITY, QUALITY, DESIGN, CONDITION, SUITABILITY OR PERFORMANCE OF THE EQUIPMENT.

1. Bioclinica Devices:

Subject to the conditions set forth below, Sponsor or QUINTILES will provide Lenovo Thinkpad E450 Laptop Includes Power Supply and Ethernet Cable- , Dazzle Video Creator Platinum HD- Video Input Adapter and Transcend 8GB USB Memory Stick which is required for use in the Study and that Site does not otherwise own or have access to (the "Bioclinica Devices") to Site for use in the Study.

(i) Bioclinica Devices Use; Maintenance. Site agrees to house the Bioclinica Devices on site and to use the Bioclinica Devices solely in connection with the Study during the term of the Agreement. Site agrees to maintain the Bioclinica Devices in good working condition, reasonable wear and tear excepted. In the event that the Bioclinica Devices malfunctions or ceases to operate during the conduct of the Study through no fault of Site, Sponsor or QUINTILES will arrange for appropriate maintenance or replacement of the Bioclinica Devices, including, at Sponsor's option, reimbursing Site for reasonable maintenance or replacement expenses.

(ii) Return or Purchase of Bioclinica Devices. Upon completion or any earlier termination of the Study at Site, Site shall, return the Bioclinica Devices to Sponsor/Quintiles at Sponsor's/Quintiles' expense. Sponsor or QUINTILES may withhold the final payment to Site until the Bioclinica Devices is returned.

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G. BUDGET DETAILS:

The Budget is as follows:

It is agreed that the Site will receive INR Five Lakh Ninety Eight Thousand One Hundred and Eighty Four only (INR 598,184) per completed patient for the Study according to the schedule indicated below. This per patient amount is intended to cover the following study- related costs incurred by the Site:

- costs related to the patients visits (day care cost, stay)
- costs for study related communications
- salaries of study staff and Investigator
- Institute service charges and overheads

Budget Table:

Visit No.		Per Patient Amount Including 20% Overhead (INR)
In-Clinic Etrolizumab Administration Every 4 Weeks	Visit 0	11,485
	Visit 4	13,138
	Visit 8	9,920
	Visit 12	16,817
At-Home Etrolizumab Administration Every 4 Weeks	Clinic Visit at Every 12-Week Interval	363,048
	Clinic Visit at Every 48 Week Interval	123,831
	Clinic Visit at Week 108	16,988
12- Week Safety Follow Up	Week 6	5,348
	Week 12/ Early Termination	16,294
92-week Extended PML Monitoring Period	24, 48, 68, and 92 Weeks after Patient Discontinuation from Study OR Symptom-Driven Unscheduled Telephone call OR Early Termination	21,314
TOTAL Amount Per Completed Patient Including 20% Overhead (INR)		598,184

Unscheduled Visit*	10,897
Early withdrawal from Treatment Visit*	17,857
12- Week Safety Follow Up - Unscheduled Visit*	10,897

*Unscheduled Visit Fee and Early Withdrawal from Treatment Fee will be paid upon receipt of completed eCRFs, not included in the total cost per subject.

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Additional Invoiced Items:

INVOICED ITEMS:	Unit Cost (including OH) (INR)
Serum pregnancy test	300
Urine pregnancy test	200
Informed consent for patients enrolling only in Part 2 (SM)	1,133
Etrolizumab administration, per occurrence	622
In clinic Etrolizumab administration on 4th and 8th week of every 12 weeks	4,474
ECG	300
Concomitant medications	302
Adverse events	688
Limited/Symptom driven physical examination, including GI (includes Vital signs (BP, pulse rate))	2,926
Flexible sigmoidoscopy, with colonic biopsies	6,100
PML neurologic examination	2,000
Colonoscopy, with colonic biopsies	6,500
Biopsy; Staining and preparation of the slides including shipping and handling	600
Central Labs (JCV antibody, storage for JCV, Anti-therapeutic antibody) Includes Collection, Preparation and Processing	402
Partial Mayo Clinic Score (pMCS)	284
Mayo Clinic Score (MCS)	440
Central Labs (Hematology, Chemistry (including LFTs), Hepatitis B DNA, CRP)	191
PK sampling (serum)	200
Neurologist - Per Hour	1,000
Brain MRI with contrast, includes interpretation and report	11,000
Brain MRI without contrast, includes interpretation and report	6,000
Lumbar puncture	2,600
Cerebrospinal fluid (CSF) analysis for JCV by PCR; includes lab handling for shipment to central lab	500
Reconsenting Fee	932

Note:

- This Budget includes all study costs related to the Protocol (including but not limited to laboratory costs, patient travel expenses and site overheads), except for any other payments contained within this Attachment.
- All questions regarding study payments or the financial arrangements should be directed to Quintiles at the address noted above during normal business hours (IST).

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ATTACHMENT C

APPROVAL LETTER

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CLINICAL STUDY AGREEMENT

PROTOCOL: CS2514-2017-0004

SITE: //356-005//

// DR. JAYAPRAKASH APPAJIGOL //

ENTASIS THERAPEUTICS, INC.//30-APR-2019//

VERSION: //VERSION #1//

COUNTRY : INDIA

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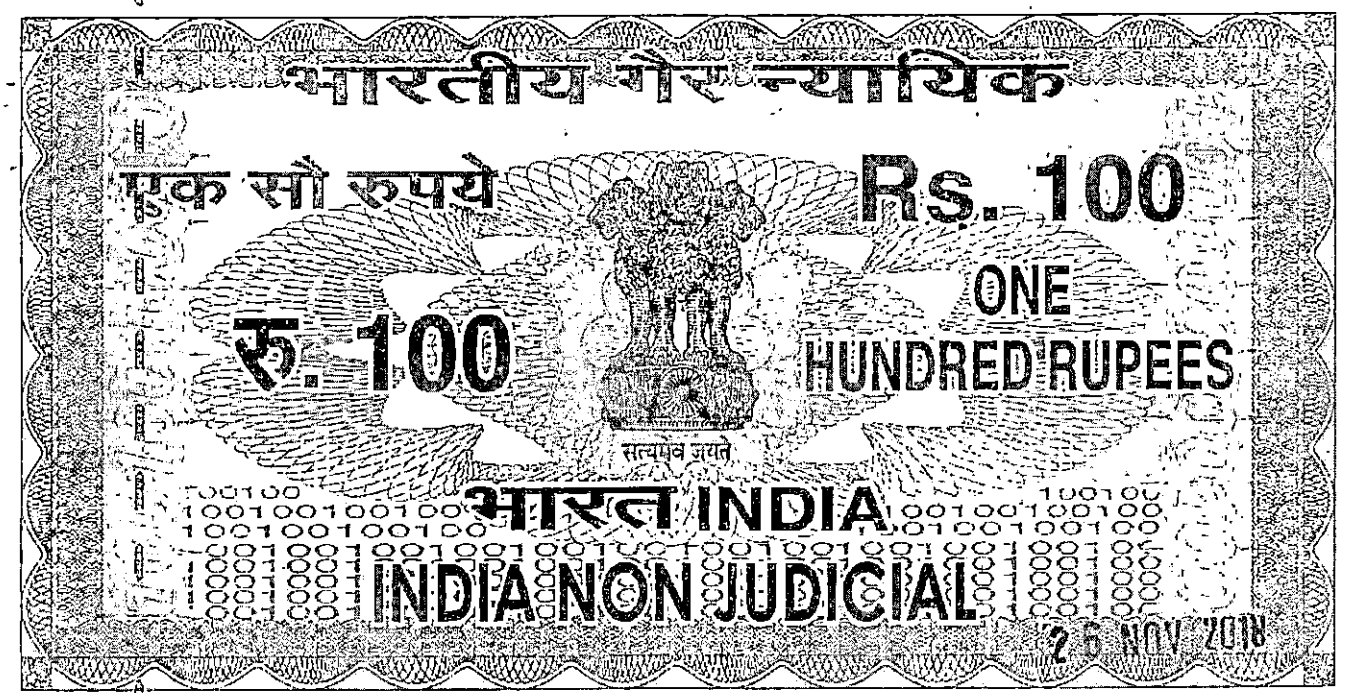

प्रतिज्ञापत्र, प्रतिज्ञापत्र व्यतिरिक्त	AGREEMENT
दस्ताचा प्रकार/अनुच्छेद	
दस्त नोंदणी करणार आहेत का?	
नोंदणी करणार असल्यास मुख्य निबंधक कार्यालयाचे नांव	
मिळकतीचे वर्णन	
मोबदला रक्कम	
मुद्रांक विकत घेणाऱ्याचे नांव	
दस्तऐवज करून देणाऱ्याचे नांव व पत्ता	
मुद्रांक शुल्क रक्कम	26 NOV 2018
मुद्रांक बिक्री नोंदवही अनु. क्रमांक/दिनांक	J4404
मुद्रांक विकत घेणाऱ्याची सही	

ठाणे
19 NOV 2018

CLINICAL STUDY AGREEMENT

This clinical study agreement ("Agreement"), effective as of 30-APR-2019 (the "**Effective Date**"), is entered into by and among **Entasis Therapeutics, Inc.**, a United States Delaware corporation with an office at 35 Gatehouse Drive, Suite E0, Waltham, MA 02451 USA ("**Sponsor**"), acting through its authorized representative **Medpace Clinical Research LLC** with an office at Medpace Clinical Research LLC with an office at Office No. 817, 8th Floor, Rupa Solitaire, Building No. A-1, Sector-1, Millenium Business Park, Next to DAKC, Mahape, Navi Mumbai 400710, India ("**CRO**") and, **K.L.E.S Dr. Prabhakar Kore Hospital and Medical Research Centre**, a clinical research site with its principal office and place of business at NH Service Rd, Nehru Nagar, Belgaum, Karnataka 590010, India, ("**Institution**") and **Dr. Jayaprakash Appajigol**, with an address at K.L.E.S Dr. Prabhakar Kore Hospital and Medical Research Centre, NH Service Rd, Nehru Nagar, Belgaum, Karnataka 590010, India ("**Investigator**") and GDD Experts India Pvt. Ltd, a clinical research site with its principal office and place of business at GDD Experts India Pvt. Ltd, Ground Floor, Gulmohar Complex, Opposite Hislop College, Civil Lines, Nagpur-440001, Maharashtra, India ("**SMO**"). Sponsor, Institution, Investigator and SMO are each sometimes referred to herein as a "**Party**" and collectively as the "**Parties**".

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WHEREAS, Sponsor is the sponsor of a multi-center clinical study of Sulbactam-ETX2514 (the "**Study Drug**"), under Protocol No. CS2514-2017-0004, titled "A Randomized, Active-Controlled Study to Evaluate the Efficacy and Safety of Intravenous Sulbactam-ETX2514 in the Treatment of Patients With Infections Caused by Acinetobacter baumannii-calcoaceticus Complex" (as it may be amended from time to time by the Sponsor, the "**Protocol**" and the performance of the Protocol at all sites shall be referred to herein as the "**Multi-Center Clinical Study**"); and

WHEREAS, Institution, Investigator and SMO possess expertise in the conduct and performance of clinical studies; and

WHEREAS, Sponsor has entered into a separate agreement with Medpace, Inc., together with its affiliate Medpace Clinical Research, LLC. CRO may, acting as an independent contractor on behalf of Sponsor, manage, monitor and coordinate the conduct of the Multi-Center Clinical Study on Sponsor's behalf; and

WHEREAS, Sponsor desires that Institution, Investigator and SMO participate in the conduct of the Multi-Center Clinical Study in accordance with the Protocol and the terms and conditions of this Agreement, and Institution and Investigator desire to participate in the conduct of the Multi-Center Clinical Study in accordance with the Protocol and the terms and conditions of this Agreement (such conduct at Institution shall be referred to herein as the "**Study**").

NOW THEREFORE, in consideration of the foregoing and the mutual covenants and promises set forth herein and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties agree as follows:

1 SCOPE OF WORK

1.1 Investigator, who is employed by or under contract with Institution, will be responsible for the conduct of the Study at Institution in strict compliance with the terms and conditions of this Agreement, any written instructions from Sponsor and/or its designee, all generally accepted standards of Good Clinical Practice, the Protocol, and with all applicable local laws and regulations governing the performance of clinical investigations. Institution represents and warrants that (a) it has consented to the conduct of the Study by Investigator at the Institution facilities located at the address set forth above; and (b) conduct of the Study at Institution does not conflict with any other obligation of Institution. Investigator and SMO will comply with the policies and procedures of Institution, including any applicable financial policies. Investigator and SMO will notify Sponsor and its designee promptly of any conflict between the terms of this Agreement and any such policy or procedure, and the parties will attempt to reach an appropriate accommodation. A copy of the Protocol has been provided to Institution and Investigator and is hereby incorporated by reference, together with any and all amendments thereto, into this Agreement.

1.2 Before the Study is initiated, Institution, Investigator and SMO will ensure that the Study is approved by the responsible ethics committee, which must be constituted in accordance with the requirements prescribed under the relevant statues and guidelines applicable in India (the "**EC**"). Institution Investigator and SMO will further ensure that the Study is subject to continuing oversight by the EC throughout the conduct of the Study. Changes or supplements to the Protocol may be made by Sponsor from time to time, upon written notice to Institution and Investigator. Institution, Investigator and SMO shall not alter or amend, and shall not permit any member of the Study Personnel to alter or amend, the Protocol in any way without the prior written consent of Sponsor. If required by applicable law, changes to the Protocol must be approved by the EC and the applicable Regulatory Authority.

1.3 Sponsor or its designee will provide the Study Drug to Institution at no cost to Institution, Investigator or SMO in amounts sufficient for the conduct of the Study as specified in the Protocol, as well as certain other Study medications, Equipment (as defined in Schedule B) and materials to be determined by Sponsor at its sole discretion (collectively, the "**Study Supplies**"). All Study Supplies are and will

remain the sole property of Sponsor. Institution, Investigator and SMO will maintain control of the Study Supplies in accordance with applicable law, and in the manner outlined in the Protocol, this Agreement and any additional documents or written instructions provided or otherwise made available by Sponsor or its designee related to the receipt, handling, maintenance, storage, use and/or distribution of the Study Supplies. Institution Investigator and SMO will use Study Supplies solely to conduct the Study in accordance with the Protocol and that the Study Supplies are not transferred to any third parties. Institution, Investigator and SMO will be responsible to Sponsor for the Study Supplies entrusted to them and will notify Sponsor or its designee immediately if any Study Supplies are lost, damaged or destroyed.

1.4 Institution, Investigator and SMO will report adverse events experienced by subjects enrolled in the Study ("**Study Subjects**") (a) to Sponsor within twenty-four (24) hours of learning of such an event; (b) in accordance with instructions in the Protocol; and (c) pursuant to applicable law.

1.5 Institution, Investigator and SMO will enroll Study Subjects in the Study in accordance with the Protocol. Sponsor may require Institution and Investigator to discontinue subject enrollment at Institution if the total enrollment needed for the Multi-Center Clinical Study is achieved.

1.6 Investigator and SMO will be responsible for obtaining informed consent from each of the Study Subjects prior to the commencement of any Study-related procedure in accordance applicable law. The informed consent documents must be in a form approved by Sponsor and the EC ("**Consent Documents**"). Investigator and SMO will ensure that a copy of the Consent Documents signed by the Study Subject is provided to the Study Subject.

1.7 In accordance with applicable law, Sponsor plans to engage Medpace Clinical Research India Pvt., Ltd., an Indian corporation with a business address at c/o SKP Group, B-376, 3rd Floor, Nirman Vihar, New Delhi, Delhi 110092, India and place of business at Office No. 817, 8th Floor, Rupa Solitaire and Building No. A-1, Sector-1, Millenium Business Park, Mahape, Navi Mumbai 400710, Maharashtra, and an affiliate of CRO, to serve as the legal representative of Sponsor and as the legal representative of Sponsor, assist Sponsor in connection with certain obligations as required under applicable law.

2 INVESTIGATOR

2.1 Investigator will be responsible for the conduct of the Study in accordance with the terms of this Agreement and the Protocol. If, for any reason, he/she is unable to continue to serve as Investigator, Institution shall provide prompt written notice to Sponsor. If Institution and Sponsor cannot agree on a successor Investigator within thirty (30) days of receipt of such notice by Sponsor, then, Sponsor will have the right to immediately terminate the Study upon written notice to Institution, subject to Sections 8.4, 8.5 and 8.6. Institution and Investigator warrant and represent that Investigator is fully qualified to conduct the Study and to serve in the capacity of Investigator. Any sub-investigator and research staff who perform any portion of the Study ("**Study Personnel**") shall be employees of or under contract with Institution or SMO and appropriately trained and qualified to assist in the conduct of the Study. Institution, Investigator and SMO shall be responsible for Study Personnel's compliance with the terms of this Agreement and shall be jointly and severally liable for the acts of Study Personnel. Institution and Investigator represent that neither Institution nor Investigator is a U.S. citizen or resident or U.S. corporation or U.S. partnership, and that all payments Institution receives under this Agreement will be for services rendered outside the United States.

2.2 Investigator will complete and return to Sponsor or its designee (i) United States Food and Drug Administration Form 1572 Statement of Investigator or equivalent; and (ii) the financial disclosure document provided by Sponsor or its designee, which document discloses the amounts payable to Investigator and any financial interests which Investigator and/or his/her family members may have in Sponsor and/or the Study Drug. Investigator will be responsible for having all sub-investigator(s) complete and provide Sponsor or its designee with such financial disclosure forms. Such forms

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disclosure forms will be kept updated by Investigator and any sub-investigators during the Study and the updates will be provided to Sponsor or its designee, for a period of one (1) year after Study completion.

3 COMPLIANCE WITH APPLICABLE LAWS.

Institution, Investigator and SMO will assume all those responsibilities assigned under all applicable laws, rules, regulations, guidelines and standards including, without limitation, Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002, Drugs and Cosmetics Act (1940) and Drugs and Cosmetics Rules (1945), governing clinical trials, all relevant International Conference on Harmonization Good Clinical Practice (**"ICH GCP"**) guidelines, Ethical Guidelines of the Indian Council of Medical Research, Indian GCP, standards and the World Medical Association Declaration of Helsinki "Ethical Principles for Medical Research Involving Human Subjects", and any other applicable laws and guidance relating to clinical trials of medicines, human rights, supply of medicines, collection and handling of human tissue and biological samples, and all applicable laws relating to the confidentiality, privacy and security of patient information.

4 CONFIDENTIAL INFORMATION

4.1 **"Confidential Information"** means all information that is (a) provided by or on behalf of Sponsor to Institution or Investigator, SMO or Study Personnel in connection with this Agreement or the Study, or (b) developed, obtained, or generated by Institution, Investigator, SMO or Study Personnel as a result of performing the Study under this Agreement (except for a Study subject's medical records). Confidential Information includes, but is not limited to, the Protocol, Study Data, results, reports from sites conducting the Multi-Center Clinical Study, all approvals and correspondence with or from the EC or other entities with oversight responsibilities for the Study, all Study correspondence, all Study Drug and other Study medication accountability forms and all CRFs; *provided, however,* that Institution and Investigator may use and/or publish Study Data solely in accordance with the Publications and Publicity Section of this Agreement. Confidential Information is the sole property of Sponsor.

4.2 Institution, Investigator and SMO shall not and shall ensure Study Personnel do not, use Confidential Information for any purposes other than to conduct the Study. Institution, Investigator and SMO will not disclose Confidential Information to any third parties other than Study Personnel and the responsible EC, who are under an agreement to be bound by the obligations of this Section 3 with respect to all Confidential Information. Institution, Investigator and SMO shall safeguard Confidential Information with the same standard of care that is used with Institution's confidential information, but in no event with less than reasonable care.

4.3 The obligations of non-disclosure and non-use under this Agreement will not apply to any portion of Confidential Information that Institution or Investigator or SMO can demonstrate by competent proof:

4.3.1 Is at the time of disclosure or later becomes publicly available through no fault or omission on the part of Institution or Investigator or SMO;

4.3.2 Is already known to Institution or Investigator or SMO at the time of disclosure and is free of any obligations of confidentiality;

4.3.3 Was obtained by Institution or Investigator or SMO from a third party which is not legally prohibited from disclosing such information; or

4.3.4 Is independently developed by Institution or Investigator or SMO without the aid, application or use of Confidential Information, as evidenced by contemporaneous written records.

4.4 If disclosure of Confidential Information beyond that expressly authorized in this Agreement is required by applicable law, that disclosure does not constitute a breach of this Agreement so long as Institution or Investigator or SMO, as applicable, (a) notifies Sponsor in writing sufficiently prior to making such disclosure in order to permit Sponsor adequate time to seek confidential treatment of such information, (b) discloses only that Confidential Information required to comply with the legal requirement, and (c) continues to maintain the confidentiality of such Confidential Information with respect to all other third parties; *provided that*, Institution and Investigator and SMO will not be required to notify Sponsor in writing prior to making such disclosure to the extent such prior notification is prohibited by applicable law.

4.5 Both prior to and during the conduct of the Study, Investigator, SMO and Study Personnel may provide Sponsor and its designee with their personal data (as defined under applicable law) (the "**Personal Data**"). Investigator consents to the processing (including use, disclosure or transfer) of his/her Personal Data by Sponsor and its designee, and Investigator and SMO consent for the same on behalf of their respective agents and affiliates and national and foreign governmental or regulatory agencies for the following purposes (the "**Purposes**") (a) the conduct of clinical trials; (b) review by governmental or regulatory agencies, Sponsor and its designees and its and their respective agents, and affiliates; (c) satisfying legal or regulatory requirements; and (d) storage in databases for use in selecting investigators and institutions for future clinical trials. Investigator also agrees to the transfer of his/her Personal Data abroad, including to countries not having an equivalent level of protection as the country where the Study is taking place. Institution, Investigator and SMO represent and warrant that all Study Personnel have consented in writing to the processing of their Personal Data for the Purposes, including the transfer to other countries not having an equivalent level of protection as the country where the Study is taking place, and will notify Sponsor or its designee immediately in writing if such consent is withdrawn.

5 RECORDKEEPING

5.1 Institution and Investigator will collect and submit to Sponsor or its designee all data generated in the conduct of the Study including completed case report forms in the form and/or electronic medium supplied or specified by Sponsor or its designee ("**CRFs**"), X-rays, MRIs or other types of medical images, ECGs, EEGs or other types of tracings or printouts, and data summaries and other data as may be required under the Protocol (collectively, the "**Study Data**"). Institution and Investigator will ensure accurate and timely collection, recording, and submission of Study Data. Sponsor is the exclusive owner of all Study Data. Institution and Investigator will maintain complete and accurate medical records with respect to Study Subjects. All Study Subjects' medical records will be the property of Institution.

5.2 "**Biological Samples**" means blood, fluid and/or tissue samples collected from Study Subjects as may be set forth in the Protocol, and tangible materials directly or indirectly derived from such samples. Institution and Investigator will collect, retain and/or use Biological Samples solely as set forth in the Protocol and in accordance with Applicable Law. Institution and/or Investigator will provide Sponsor with quantities of Biological Samples as required by the Protocol. Sponsor may use such Biological Samples as specified in the Protocol, and as permitted in the Consent Documents and under applicable law. For the avoidance of doubt, nothing in this Section 4 limits the Institution, Investigator or Study Personnel from collecting biological samples independent of the Protocol from Study Subjects ("**Separate Samples**") as required for such Study Subjects' care or Institution's research purposes; *provided, however*, that Institution, Investigator and Study Personnel shall not (a) annotate or link Separate Samples with any information related to Sponsor, the Protocol, or the administration of, response to, or adverse events associated with, the Study Drug ("**Study Drug Information**"), except to the extent such information is necessary for Study Subject care purposes; (b) conduct any research on or using the Study Drug or the Study Drug Information, other than for the Study, without the Sponsor's prior written consent; or (c) disclose any Study Drug Information to any third party other

than as expressly permitted in this Agreement. In no event will Sponsor be liable for any claims, losses or damages arising from or related to the collection or use of Separate Samples by Institution, Investigator or Study Personnel. Institution and Investigator individually and jointly represent that any Separate Samples shall be collected under and according to an informed consent form separate from the Consent Documents used in the Study.

5.3 Institution and Investigator shall maintain all records, data, documents or information related to the performance of the Study until the later of:

5.3.1 twenty-five (25) years following completion or early termination of the Study; and

5.3.2 the period required by Applicable Law and regulations.

5.4 At the end of such required retention period, Institution or Investigator shall not destroy any such records without first giving Sponsor sixty (60) days' prior written notice of its intent to do so and an opportunity to transfer the records to Sponsor or its designee, at Sponsor's reasonable expense. Institution will ensure that such records remain available to Sponsor and/or its designees at all times, regardless of whether the individual named as Investigator ceases to be affiliated with Institution.

5.5 Subject to the requirements of the Confidential Information section, following the end of the required retention period, Institution may retain in its possession an archival copy of Confidential Information that consists of any and all data, documents or information related to the performance of this Agreement solely to monitor its surviving obligations under this Agreement.

6 ACCESS TO RECORDS AND AUDITS

6.1 Institution will permit Sponsor and its designees to, at Institution's premises and at reasonable times, inspect progress of the Study, Study records and compliance with this Agreement. Sponsor will notify Institution prior to any inspection of the date and time of the inspection. Sponsor and its designees may review and/or request copies of data derived from the Study, and Institution or Investigator shall promptly provide such data. Study Subjects' medical records, including those maintained in electronic format, will be made available where appropriate for the purpose of source document verification and/or audit procedures. Institution and Investigator will be and will ensure that appropriate Study Personnel will be available during normal business hours and at mutually agreeable times to discuss or review Study Data and to resolve any questions relating to such data. Institution and/or Investigator will notify Sponsor and/or its designee by telephone and subsequently in written form, of any significant changes, including, but not limited to, changes in Study Personnel, Investigator, or physical location, that occur during the Study.

6.1.1. Within twenty-four (24) hours of receiving from the Drug Controller General of India or any other any governmental or regulatory body (a **"Regulatory Authority"**), a request to inspect Institution or Investigator in connection with the Study, Institution and/or Investigator shall provide written notification to Sponsor and any Sponsor designees of such inspection and shall also provide Sponsor and/or its designee with copies of any communications with a Regulatory Authority during and after such inspection. Sponsor and/or its designee(s) shall have the right to be present at any such inspections and shall have the opportunity to provide, review, and comment on any responses that may be required. Further, Institution and/or Investigator will provide Sponsor and/or its designee with copies of all materials, correspondence, statements, forms and records which Institution prepares, receives or obtains pursuant to this inspection.

7 COSTS AND PAYMENT SCHEDULE

In consideration of the proper performance of the Study by the Institution, Investigator, SMO and Study Personnel under the terms of this Agreement, Sponsor, either directly or through its designee, will pay the

payee designated in Schedule A ("**Payee**") the amounts specified in Schedule A appended hereto and incorporated herein by reference. The amounts specified in Schedule A represent Institution's, Investigator's and SMO's costs of conducting the Study. Institution, Investigator and SMO accept such payment to the Payee as full consideration for services rendered and Payee will be solely responsible for making any and all payments due to Institution, Investigator, SMO and Study Personnel for their conduct of the Study. Neither Sponsor nor CRO shall have any obligation or liability whatsoever to make payments under this Agreement to any party other than Payee. All costs outlined on Schedule A shall remain firm for the duration of the Study, unless otherwise agreed to in writing by the Institution, Investigator, SMO and Sponsor. It is understood and agreed that no reimbursement will be provided by Sponsor for subjects who are randomized into the Study in violation of the Protocol, or who do not conform to the Protocol's inclusion and exclusion criteria or for whom serious deviations from the Protocol are made. The budget contained in Schedule A is inclusive of all applicable taxes. Should any tax laws require withholding, the Party legally responsible shall be liable for withholdings. Notwithstanding the foregoing, Sponsor may issue a written amendment, signed only by Sponsor, for the purpose of increasing the Study costs as described in the Schedule A. SMO provides clinical trials related services to the Institution. SMO works in compliance with the all applicable laws, rules and regulations. SMO's responsibilities under this Agreement shall include receiving and allocating payments made by the Sponsor or CRO on behalf of the Sponsor, to Institution, Investigator and/or Study Personnel, in accordance with the terms and conditions stipulated under this Agreement. CRO / Sponsor shall not be held liable for any disputes, including but not limited to financial, which may raise during the Study conduct between the Institution, Investigator and/or the SMO.

8 TERM AND TERMINATION

8.1 This Agreement shall commence as of the Effective Date and, unless terminated earlier as provided for in this section, shall continue until the completion of the Study.

8.2 Either Sponsor, Institution, Investigator or SMO (the "**Non-Breaching Party**") may terminate this Agreement for a material breach of a provision of this Agreement by another Party (the "**Breaching Party**") if the Breaching Party fails to cure the breach within thirty (30) days after receipt of written notice from the Non-Breaching Party specifying in detail the nature of the breach.

8.3 Sponsor may terminate the Study at any time upon giving thirty (30) days' advance written notice to Institution and Investigator. Further, Sponsor may terminate the Study immediately upon written notice to Institution, Investigator and SMO for the following reasons:

8.3.1 if Sponsor and Investigator mutually agree such termination is necessary to protect the safety, health or welfare of Study Subjects;

8.3.2 if a suitable replacement for the Investigator is not found, as set forth under Section 2.1;

8.3.3 if the regulatory authorization to perform the Multi-Center Clinical Study is withdrawn; or

8.3.4 if the Investigator fails to screen, recruit or a sufficient number of subjects to participate in the Study.

8.4 Sponsor, or CRO on behalf of Sponsor, will be obligated to pay Payee solely for those items set forth in the Schedule A that have been incurred prior to the date of notice of termination. Institution and Investigator shall promptly refund to Sponsor or shall cause Payee to promptly refund all unearned advance payments made by Sponsor or its designee under the Schedule A.

8.5 Upon completion or early termination of the Study:

8.5.1 this Agreement will terminate;

8.5.2 Investigator will immediately stop enrolling subjects into the Study and cease administering Study Drug and other Study medications to Study Subjects and conducting Study procedures

on Study Subjects, to the extent consistent with the safety and welfare of the affected Study Subjects;

8.5.3 Sponsor, either directly or through its designee, will pay Payee for all reasonable costs accrued by Institution, Investigator and SMO in the performance of the Study as of the date of notice of termination, in accordance with Schedule A, including non-cancelable obligations incurred prior to the date of notice of termination;

8.5.4 in no event shall Sponsor be obligated to pay any invoices submitted after the time period for submitting final invoices set forth in Schedule A has expired;

8.5.5 Institution, Investigator and SMO will furnish to Sponsor, within thirty (30) days of the effective date of termination, all Study Data, including completed or partially completed CRFs and, if applicable, any Biological Samples;

8.5.6 In accordance with Sponsor's instructions, Institution, Investigator and SMO will return to Sponsor or, at Sponsor's option, destroy all documents, Confidential Information, and Study Supplies provided by Sponsor or its designees for the conduct of the Study, to Sponsor or its designee within thirty (30) days. If Sponsor requests that such documents, Confidential Information or supplies be destroyed, Institution, Investigator and SMO will destroy same and provide Sponsor with written certification of such destruction;

8.5.7 If applicable, Investigator and SMO will promptly submit final written reports to Sponsor as specified in the Protocol.

8.6 Upon completion of the Study, the terms of Sections 8.5.1, 8.5.2, 8.5.4 through 8.5.6 will apply as of the Study completion date.

8.7 The Sections titled Investigator, Confidential Information, Recordkeeping, Access to Records, Costs and Payment Schedule, Term and Termination, Intellectual Property, Publications and Publicity, Notices, Indemnification, Debarment, Anti-Bribery/Anti-Corruption, Independent Contractor and Miscellaneous shall each survive the termination or expiration of this Agreement.

9 INTELLECTUAL PROPERTY

Institution, Investigator and SMO jointly and severally acknowledge and agree that all inventions, discoveries, know-how, and improvements (including new uses and improvements of the Study Drug), whether or not protectable under patent, copyright or other intellectual property law, resulting from the performance of the Study, or the use of the Study Drug or the Confidential Information, made by Institution or Investigator or SMO, alone or jointly with others (collectively, with all associated intellectual property rights, the "**Inventions**") will be the sole and exclusive property of Sponsor. Institution, Investigator and SMO will and will ensure all Study Personnel will, promptly disclose to Sponsor in writing all Inventions and will assign and does assign to Sponsor all right, title and interest throughout the world to Inventions without any obligation of Sponsor to pay any royalties or other consideration to Institution or Investigator or SMO. Institution, Investigator and SMO will, and will cause Study Personnel to (a) cooperate fully in obtaining patent and other proprietary protection for any patentable or protectable Inventions all in the name of Sponsor and at Sponsor's cost and expense; and (b) execute and deliver all requested applications, assignments, and other documents and take such other measures as Sponsor or its designee reasonably requests, in order to perfect and enforce Sponsor's rights in the Inventions. Institution, Investigator and SMO represent and warrant that all Study Personnel have an obligation to assign and otherwise effectively vest in Institution and/or Investigator and/or SMO any and all rights that such Study Personnel might otherwise have in the results of their work without any obligation of Sponsor to pay any royalties or other consideration to such Study Personnel and as necessary to permit the Institution, Investigator and SMO to comply with their obligations under this Section 9.

10 PUBLICATIONS AND PUBLICITY

10.1 It is understood that the Study is part of the Multi-Center Clinical Study. After (a) publication of the Multi-Center Clinical Study results; (b) notification by Sponsor that the Multi-Center Clinical Study submission is no longer planned; or (c) the eighteen (18) month anniversary of the completion or early termination of the Multi-Center Clinical Study, whichever occurs first, Institution and Investigator may publish the Study Data in accordance with the provisions of Section 10.1.1 below:

10.1.1 Institution and Investigator shall provide Sponsor with an advance copy of any proposed publication or oral presentation at least sixty (60) days prior to the planned date of submission or presentation (the **"Review Period"**). During the Review Period Sponsor may request in writing and Institution and Investigator agree to, (a) the deletion of any Confidential Information other than Study Data, (b) any reasonable changes requested by Sponsor, and (c) a delay of such proposed submission for an additional period, not to exceed ninety (90) days after the Review Period, in order to protect the potential patentability of any Invention described therein. Sponsor, at its election, shall be entitled to receive in any such publication an acknowledgement of its sponsorship of the Study. Institution and Investigator shall ensure that the publications acknowledge Sponsor's sponsorship of the Study and that Institution and Investigator were paid by Sponsor for the conduct of the Study.

10.2 Except to the extent required by applicable law, no Party will use the name of another Party in any form of advertising, promotion or publicity or in any press release, without the prior written consent of that Party. Institution, Investigator and SMO expressly consent to Sponsor's listing of information about the Study on publicly accessible internet sites (for example, ClinicalTrials.gov, patient recruitment sites, etc.), including the name and contact information for Institution and/or Investigator and/or SMO.

10.3 SMO shall have no rights to publish or present to any third party any information related to the Study.

11 NOTICES

All notices required under this Agreement will be in writing and be deemed to have been given when delivered by hand; sent by certified mail; or delivered by internationally recognized bonded courier as follows, *provided that* all urgent matters, such as safety reports, will be promptly communicated as specified in the Protocol, and confirmed in writing:

IF TO SPONSOR:

Entasis Therapeutics
Attention: Emily Stone
35 Gatehouse Drive, Suite EO, Waltham, MA 02451
Clinical Operations Department
With a copy to: Chief Business Officer
(at Sponsor's address above)
and

Medpace Clinical Research, LLC
Attention General Counsel
5375 Medpace Way
Cincinnati, OH 45227
and

Medpace Clinical Research India Pvt. Ltd.

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Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

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Office No. 817, 8th floor
Rupa Solitaire
Building No. A-1, Sector-1
Millenium Business Park
Next to DAKC, Mahape
Navi Mumbai 400701

IF TO INSTITUTION:
K.L.E.S Dr. Prabhakar Kore Hospital and Medical Research Centre
NH Service Rd, Nehru Nagar,
Belgaum, Karnataka 590010, India

IF TO INVESTIGATOR:
Dr. Jayaprakash Appajigol
K.L.E.S Dr. Prabhakar Kore Hospital and Medical Research Centre
NH Service Rd, Nehru Nagar,
Belgaum, Karnataka 590010, India

IF TO SMO:
GDD Experts India Pvt. Ltd,
Ground Floor, Gulmohar Complex,
Opposite Hislop College,
Civil Lines, Nagpur-440001, Maharashtra, India

12 SIGNATURES

This Agreement may only be extended or otherwise amended by written agreement of the Parties. This Agreement, and any subsequent amendment(s), may be executed in counterparts and the counterparts, together, shall constitute a single agreement and shall become binding when any one or more counterparts hereof, individually or taken together, bears the signature of each of the Parties hereto.

13 INDEMNIFICATION

13.1 Sponsor Indemnification. Sponsor will indemnify SMO, Institution and Investigator against any third party claims, including reasonable attorney's fees for defending those claims (each, a "**Claim**") resulting from (a) the use of the Study Drug when administered in strict accordance with the Protocol and Sponsor's written instructions; (b) the negligence or willful misconduct on the part of Sponsor; or (c) Sponsor's breach of its obligations under this Agreement, except to the extent any such Claim falls within the Institution's indemnification under Section 13.2 and SMO's Indemnification under Section 13.3 below.

13.2 Institution Indemnification. Institution will indemnify Sponsor and its affiliates against any Claim resulting from (a) Institution's, Investigator's or Study Personnel's negligence or willful misconduct; or (b) Institution's or Investigator's breach of this Agreement or applicable law.

13.3 SMO Indemnification. SMO will indemnify Sponsor and its affiliates against any Claim resulting from (a) SMO's or its Study Personnel's negligence or willful misconduct; or (b) SMO's breach of this Agreement or applicable law.

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13.4 Indemnification Procedure. Each Party shall promptly notify the other Party in writing of any Claim or potential Claim for which such Party may seek indemnification, but in no event more than fifteen (15) days after the Party seeking indemnification has knowledge of the Claim or potential Claim. Failure to provide timely notice shall not negate the obligation of the other Party to indemnify except to the extent that the delay in notification resulted in additional damages or Claims to the Party seeking indemnification.

13.5 Sponsor Disclaimer. Institution, Investigator and SMO acknowledge that Sponsor will not be liable for and is not a party to warranties made by Institution, Investigator, SMO or any Study Personnel relating to the Study Drug other than any such warranties expressly provided in this Agreement.

13.6 Study Subject Injury. Without limiting Sponsor's rights under Section 13.2 and 13.4, Sponsor will reimburse a Study Subject in accordance with the terms of the Study Subject's signed Consent Documents and subject to such terms being in conformity with the applicable law, for reasonable and necessary out-of-pocket medical expenses incurred by such Study Subject for the diagnosis and treatment of injuries that are determined jointly by Investigator and Sponsor to be the direct result of (a) use of the Study Drug in accordance with the Protocol; or (b) a procedure that the Study Subject would not have undergone but for such Study Subject's participation in the Study; *provided*, that such injuries are not attributable to (i) Institution's, Investigator's, SMO's and any Study Personnel's negligence, willful misconduct or failure to adhere to the Protocol; or (ii) a pre-existing medical condition of the Study Subject or his/her underlying disease.

13.7 Sponsor Insurance. Sponsor has obtained, or will obtain prior to the start of the Study, the clinical trial insurance required by applicable law and will provide Institution or Investigator with evidence of such insurance upon written request by Institution or Investigator.

13.8 Institution Insurance. Institution will maintain medical malpractice insurance, professional liability (financial / E&O) insurance, general liability insurance and other appropriate insurance sufficient to cover Institution's, Investigator's and the Study Personnel's obligations under this Agreement. Institution will provide evidence of such insurance upon written request by Sponsor or its designee.

13.9 SMO Insurance. SMO will maintain medical malpractice insurance, professional liability (financial / E&O) insurance, general liability insurance and other appropriate insurance sufficient to cover SMO's and its Study Personnel's obligations under this Agreement. SMO will provide evidence of such insurance upon written request by Sponsor or its designee.

13.10 Limit of Liability of CRO. CRO expressly disclaims any and all liability whatsoever in connection with the Study Drug or the Protocol except to the extent that such liability arises from CRO's negligent act, omission or willful misconduct.

14 DEBARMENT

Institution, Investigator and SMO each represent that neither it/she/he, nor any Study Personnel (a) is or has been debarred by any Regulatory Authority or is restricted by applicable law from conducting clinical research; or (b) will use in any capacity the services of any person debarred by any Regulatory Authority or restricted from conducting clinical research under applicable law in connection with the conduct of the Study. During the Study and for a period of two (2) years following completion of early termination of the Study, Institution or Investigator or SMO shall immediately notify Sponsor in writing upon becoming aware of any such debarment, threat of debarment, or conviction or other matter that could result in any such debarment.

15 ANTI-BRIBERY/ANTI-CORRUPTION

In carrying out its responsibilities under this Agreement, no Party nor it nor any of its respective representatives will pay, offer or promise to pay, or authorize the payment of, any money, or give or promise to give, or authorize the giving of, any services or anything else of value, either directly or through a third party, to any

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official or employee of any governmental authority or instrumentality, or of a public international organization, or of any agency or subdivision thereof corruptly for the purpose of improperly (i) influencing any act or decision of that person in his official capacity, including a decision to fail to perform his functions with such governmental agency or instrumentality or such public international organization or such political party, (ii) inducing such person to use his/her influence with such governmental agency or instrumentality or such public international organization or such political party to affect or influence any act or decision thereof or (iii) securing any improper advantage.

16 ASSIGNMENT AND DELEGATION

This Agreement shall be binding upon and for the benefit of the Parties hereto, and their successors and permitted assigns. This Agreement, and all rights, duties and obligations hereunder, may not be assigned or delegated by Institution or Investigator or SMO without the prior express written consent of Sponsor. Any attempt made by Institution or Investigator or SMO to assign or delegate this Agreement in violation of this section shall be of no force or effect. If Sponsor provides its consent for Institution or Investigator or SMO to subcontract any of their obligations under this Agreement, Institution and/or Investigator and/ or SMO will (a) execute a written agreement with the permitted third party subcontractor which, at a minimum, provides for terms and conditions (including, but not limited to, ownership of Study Data and Inventions, obligations of confidentiality of information, etc.) that are consistent with the intent and terms of this Agreement; and (b) remain liable for the performance of such third party subcontractor. No assignment, delegation or transfer will relieve any Party of the performance of any accrued obligation that such Party may then have under this Agreement. Institution, Investigator and SMO acknowledge that Sponsor shall have the right to assign or delegate this Agreement or any portion thereof without the consent of Institution and/or Investigator and/ or SMO.

17 INDEPENDENT CONTRACTOR

The relationship of the Parties is that of independent contractors, and no employment or agency relationship shall be construed to exist between the Parties. Sponsor shall not be responsible for any employee benefits, pensions, workers' compensation, withholding or employment-related taxes relating to Institution, Investigator, SMO or any Study Personnel. No Party is authorized or empowered to act as agent for another Party for any purpose and will not, on behalf of another Party, enter into any contract, warranty or representation as to any matter.

18 FINANCIAL CHANGES

No financial adjustments shall be made because of modifications to the Protocol unless the Parties hereto amend this Agreement accordingly.

19 MISCELLANEOUS

19.1 General. This Agreement represents the entire understanding of the Parties and supersedes all prior negotiations, understandings or agreements (oral or written) among the Parties concerning the subject matter hereof. In the event of any inconsistency between this Agreement and the Protocol, the terms of the Protocol will control as to technical research and scientific matters and the terms of this Agreement shall govern for all other matters. If a provision of this Agreement is or becomes (i) illegal under any applicable law or regulation, (ii) invalid or (iii) otherwise unenforceable, such illegality, invalidity or unenforceability shall not affect the validity or enforceability of any other term or provision of this Agreement. Failure to insist upon compliance with any of the terms and conditions of this Agreement shall not constitute a general waiver or relinquishment of a Party's rights to the future enforcement of any such terms or conditions, but the same shall remain at all times in full force and

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effect, except with respect to an express written waiver relating to a particular matter for a particular period of time signed by an authorized representative of the waiving Party, as applicable.

19.2 Certain Disclosures; Transparency. Institution, Investigator and SMO acknowledge that Sponsor and its affiliates are required to abide by United States federal and state disclosure laws and certain transparency policies governing their activities, including providing reports to the government and to the public concerning financial or other relationships with healthcare providers. Institution, Investigator and SMO agree that Sponsor and its affiliates may, in their sole discretion, disclose information about the Agreement and about the Study, including relating to any transfers of value pursuant to this Agreement. Institution, Investigator and SMO agree to supply information reasonably requested by Sponsor for disclosure purposes.

19.3 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of India.

19.4 Dispute Resolution. The Parties will use their best efforts to settle all matters in dispute amicably. All disputes and differences of any kind related to this Agreement, which cannot be solved amicably by the Parties, shall be referred to arbitration as described in this Section 19.4. All disputes arising out of or in connection with this Agreement shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by one arbitrator appointed in accordance with such rules; provided, however, that during the period of arbitration on any dispute, the Parties shall continue to fulfil their obligations as set forth in this Agreement. The arbitration shall take place in Mumbai, India and shall be conducted in the English language. The award of the arbitrator shall be final and binding on all Parties. The Parties bind themselves to carry out the awards of the arbitrator.

19.5 Headings; Interpretation. This Agreement contains headings only for convenience and the headings do not constitute or form a part of this Agreement, and should not be used in the construction of this Agreement. The words "include," "includes" and "including" when used in this Agreement are deemed to be followed by the phrase "but not limited to."

[SIGNATURE PAGE FOLLOWS]

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IN WITNESS WHEREOF, this Agreement is executed as of the Effective Date by Investigator and by a duly authorized representative of each of Sponsor and Institution.

Sponsor by CRO pursuant to the [Letter of Authorization] dated [5-Feb-2019]	**Institution (K.L.E.S Dr. Prabhakar Kore Hospital and Medical Research Centre)**	**Investigator**
By (signature)	**By (signature)**	**By (signature)** 18/06/2019
Dr. Preeti Kabra **Name (print or type)**	Dr. M. V. JALI MD, FRCP (London) Medical Director & Chief Executive Chief Consultant - Diabetology KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi. **Name (print or type)**	Dr. Jayaprakash Appajigol **Name (print or type)**
Country Manager, India **Title**	**Title**	Principal Investigator **Title**

SMO
(GDD Experts India Pvt. Ltd)

12/Jun/19

By (signature) & date

Dr. Vinod Gyanchandani
Name (print or type)

Country Manager
Title

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Prof. Dr. V.A.KOTHIWALE
Registrar
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and Research, BELAGAVI

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Memorandum of Understanding (MOU)

Between:

Party-1:

World Alumni Network Pvt. Ltd. (WAN),
600 (FF2), Ring Road, Cross 15,
JP Nagar Phase 6,
Bangalore - 560078, India

and

Party-2:

KLE University's Institute of Physiotherapy,
Nehru Nagar, Belagavi-590 010
Karnataka, India

This MOU, dated 7th November 2016, establishes a mutual working relationship between the two parties (and their respective heirs, executors, administrators and assignees) as broadly outlined below:

Party-1's Role:

1. Party-1 is creating a state-of-the-art online platform as worldalumninetwork.com for all the alumni, students, staff, faculty and related individuals at global level to find, connect, communicate, collaborate and coordinate in an integrated and seamless online environment for academic, business, personal and other uses
2. Registration at this online platform by any individual is purely voluntary and it is between Party-1 and the individual members
3. Party-1 is making all the necessary investment on its own for developing the online platform with no financial obligation to Party-2
4. Party-1 will provide one Premium Membership as a respect to the head of the Party-2 at no cost to Party-2 (typically priced at tens of thousands of rupees for others)
5. Party-1 on its online platform will provide a link to Party-2's primary website

Party-2's Role:

1. To provide a clean and dependable information to members, and to ensure Party-2 can reach to the right members in its mass communication, the Party-2 will designate a person to overview the information provided by the members in the online platform
2. Since duplication of data online at multiple online places can make it difficult for finding the information, it is important for the Party-1 and Party-2 to work together closely and avoid any such duplication of data online at multiple places
3. Party-2 on its primary website will provide a link to Party-1's online platform

This MOU may be amended at any time with the mutual consent of both the parties.

Authorized signatures with seal:

Party-1

Mr. Roshan D.
Executive-University Relations
+91-9886391091

WORLD ALUMNI NETWORK P... LTD.

Party-2

Prof.(Dr). Sanjivkumar
Principal
0831- 2473906
+91-9448745648
kipt@india.com

Witnesses

Signature
Name Dr ANAND MEGGANNAVAR
Designation Asst. Prof.
Phone 9945282896

Signature
Name Dr. SNEHAL DHARMAYAT
Designation Asso. Prof
Phone 9448305413

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Prof. Dr. V.A. KOTHIWALE
Registrar
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and Research, BELAGAVI