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SUB-GRANT AGREEMENT (July 16, 2012)

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

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

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

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

The Sub-grant Agreement between the Parties comprises:

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

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

III. Responsibility

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

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

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

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

IV. Financial arrangements

1. Schedule of payments

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

2. Payment of the contribution

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

ACCOUNT DETAILS FOR USD PAYMENT

CORRESPONDENT BANK NAME AND ADDRESS:

BENEFICIARY BANK
NAME AND ADDRESS:

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

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

DEUTSCH BANK TRUST COMPANY AMERICAS NEWYORK

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

ACCOUNT NUMBER: **05043030000042**

3. Utilization of funds and accounting

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

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

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

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

V. Implementation

1. Period of implementation

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

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

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

2. Completion of Deliverables

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

VI. Reporting

1. Technical

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

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

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

2. Financial

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

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

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

VII. Audit

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

VIII. Change of SUB-AWARDEE Co-Principal Investigators

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

IX. Acknowledgement

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

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

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

X. Termination

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

XI. Global Access

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

XII. Publications

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

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

XIII. Intellectual Property Rights

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

XIV. Data Sharing

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

XV. Human Subjects

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

XVI. Terrorism

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

XVII. Liability

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

XVIII. Independent Contractor

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

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and shall be deemed to be, an independent contractor and not an agent or employee of the other Party. Neither Party shall have authority to make any statements, representations, nor commitments of any kind, or to take any action, which shall be binding on the other Party, except as may be explicitly provided for herein or authorized by the other Party in writing.

XIX. Assignment

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

XX. Settlement of disputes

Any dispute relating to the interpretation or application of this Agreement shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the Parties, or in the absence of agreement, with the rules of arbitration of the International Chamber of Commerce. The Parties shall accept the arbitral award as final.

XXI. Contact Information

Administrative Contacts

SUB-AWARDEE

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

sgoudar@jnmc.edu; +91 94481 26371

UBC

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

Scientific Contacts

SUB-AWARDEE

Dr Shivaprasad S Goudar,
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sgoudar@jnmc.edu; +91 94481 26371

UBC

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06

July 16, 2012

XXII. Entire Agreement

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

Accepted on behalf of the
The University of British Columbia:

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

Date: July 31/12

By: _____
Name:
Title:

Date: Aug 2/12

LEGAL APPROVED

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

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

Date: July 20, 2012

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

Date: 20/7/2012

Dr. V.A.Kothiwale
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ANNEX 1: ORIGINAL BMGF PRE-EMPT PROPOSAL (November, 2010)

I. Charitable Purpose

To test new community level strategies for the monitoring, prevention, and treatment of pre-eclampsia.

II. Executive Summary

Context The hypertensive disorders of pregnancy (HDP) complicate 5-10% of pregnancies and lead to serious maternal illness or death. The HDP include the conditions of pre-eclampsia, pre-existing hypertension and gestational hypertension. Pre-eclampsia is the most serious of these disorders and worldwide is the second leading cause of maternal death, and results in 63,000-72,000 maternal deaths each year. Over 99% of these deaths occur in low and middle income countries (LMICs). The WHO estimates that more than 500,000 fetuses and newborns die annually due to pre-eclampsia. The only way to cure pre-eclampsia is to deliver the placenta and infant. Pre-eclampsia-related maternal deaths result primarily from delays in diagnosis, triage, transport, and treatment.

Project goals The PRE-EMPT (PRE-eclampsia-Eclampsia Monitoring, Prevention and Treatment) initiative consists of five interrelated projects to be conducted over a four year period (Nov 2010 – Oct 2014). The primary foci are three community- and primary health center (PHC)-level intervention studies tailored to LMIC settings, and the secondary foci are 1) developing a multifaceted international research collaboration and 2) LMIC-oriented pre-eclampsia knowledge translation (KT) activities. Reducing the maternal and perinatal consequences of pre-eclampsia is the overarching theme of this proposal, and we aim to determine the impact of this program of research on those outcomes, rather than solely the powerful surrogate, the diagnosis of pre-eclampsia. Should pre- and early pregnancy calcium supplementation reduce the incidence of the diagnosis, as we envisage (Obj 1), it is unlikely that we will prevent all cases of pre-eclampsia. Therefore, we must improve community level case ascertainment and interventions by deriving new models of care using what we know today and will learn in the near future (Obj 2 & 3). By pooling resources to create a virtual database and biobank from trials and cohorts relating to the HDP from low, medium, and high income countries we will accelerate progress towards new knowledge in the near, medium and long term (Obj 4) – this will be a proof of principle exercise, and create the initial core data set and biobank, for a wider endeavor relating to complex pregnancies, as envisaged by the BMGF. While these activities are being undertaken, we will facilitate the development of new WHO HDP guidelines make to available what know today to the health systems and health care providers in all settings (Obj 5).

The *first* study will be a placebo-controlled randomized controlled trial (RCT) of pre-pregnancy and early pregnancy calcium supplementation in women with low calcium intake and at high risk for pre-eclampsia in their next pregnancy. The goal of this South African and Zimbabwean RCT is to determine whether or not pre- and early-pregnancy calcium supplementation prevents both the diagnosis and consequences of pre-eclampsia.

The *second* study will be to develop and validate the miniPIERS (Pre-eclampsia

Integrated Estimate of RiSk) and genPIERS models; as well as externally validate the fullPIERS model in seven LMIC centers. miniPIERS is solely symptom- and sign-based, and configured for use in resource-restrained settings. genPIERS will include, in addition to symptoms and signs, those few laboratory tests used in all participating LMIC centers. The miniPIERS and genPIERS models should aid in case identification, diagnosis, and risk stratification, thereby, accelerating triage and transport to centers where women will receive effective and evidence-based treatment. This effective care will avert the adverse maternal and perinatal consequences of pre-eclampsia.

The *third* study will prepare for a bold international multicenter cluster RCT, called CLIP (Community Level Interventions for Pre-eclampsia), that will test the impact of a community-level package of care to reduce adverse maternal and perinatal outcomes related to pre-eclampsia. The CLIP package will be tailored to different levels of care. For community health workers (CHWs), the package will include miniPIERS screening, diagnostic and triage tools, a loading dose of oral labetalol to treat severe hypertension, and a loading dose of $MgSO_4$ to prevent seizures of eclampsia in women with severe hypertension or to treat seizures in women with eclampsia. Women diagnosed with either pre-eclampsia or eclampsia will be transferred to the nearest PHC or hospital. The same package will be available at PHCs, to be administered by nurses, midwives, or medical officers (loading doses not repeated if already administered). Thereafter, women will be referred to hospitals that 1) meet a prescribed standard of care (e.g., antihypertensive and $MgSO_4$ use), and 2) have labor induction and Cesarean capability.

This third study will comprise two parts: 1) the CLIP Feasibility Study and 2) the CLIP Pilot RCT. The CLIP Feasibility Study will determine (a) current patterns of community and facility care of pre-eclampsia/eclampsia, (b) cost of the CLIP Pilot, and (c) feasibility to conduct the definitive CLIP cluster RCT in select (total: 4) South Asian and/or sub-Saharan African countries. The CLIP Pilot RCT will be a cluster RCT that will: 1) establish the required training programs, 2) estimate of the impact of the intervention on patient level maternal and perinatal outcomes, and 3) determine the sample requirements for the definitive CLIP trial. Ten clusters in Hyderabad and Matiari Districts, Sindh, , will participate in the CLIP Pilot Trial. The results, in combination with the results from the Feasibility Studies, will inform both the requirements for, and feasibility of the planned definitive CLIP Trial. Our *secondary foci* will be 1) establishing an international CoLaboratory and 2) facilitating KT. The CoLaboratory will bring together investigators to share 1) quality pregnancy cohort and other clinical data and 2) carefully collected biological samples for collaborative studies to facilitate new knowledge generation. Also, we will establish data and biomarker acquisition tools common to the entire PRE-EMPT project. The KT group will update the WHO HDP guidelines.

The *net result* will be a reduction in maternal and perinatal mortality and a lasting improvement in maternal and child health.

Interaction of objectives The goal of PRE-EMPT is to accelerate the transfer of current knowledge into both 1) new science (calcium supplementation RCT [Obj 1], PIERS [Obj 2], CLIP [Obj 3], and the CoLaboratory [Obj 4]) and 2) evidence-based care (CLIP and the WHO guidelines [Obj 5]) pertinent to women, communities, and caregivers in LMICs. Obj 1 - 3 will provide well characterized LMIC-derived data sets useful for the CoLaboratory with an integrated data and biosample collection strategy

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09

designed in Obj 4. This permits the inclusion of data especially relevant to the goals of PRE-EMPT into the integration of data by the CoLaboratory. Using strict requirements for data and sample quality, this integration will include cohorts from low, medium and high income countries, the LMIC data coming primarily from completed WHO trials and cohort studies, as well as well-defined studies from South Africa. Obj 2 informs both Obj 1 (e.g., PIERS maternal and perinatal outcomes) and Obj 3. In turn, items identified through the CoLaboratory will feed back into future iterations of the PIERS models, especially biomarkers amenable to low cost technology through mechanisms such as the BMGF Grand Challenges Program. All Objectives converge to update the knowledge translation tools and clinical recommendations provided in Obj 5.

Contributing to this initiative are content, methodological, and advocacy experts from low, middle and high income countries who participate in the Academic Steering Committee - an unprecedented coalition of expertise for pre-eclampsia research. The WHO team, which coordinates input from the UN, NGOs, and professional societies, will use the Academic Steering Committee as a source of, and sounding board for, their recommendations. This should result in best evidence-based advice, derived from PRE-EMPT and parallel activities, being offered to LMIC practitioners in the most timely fashion.

Organizational capacity/management plan (Figure 1) To accomplish these goals, we have formed a broadly skilled PRE-EMPT team, of which over a third are from LMICs. We will leverage existing collaborations with colleagues and the WHO, as well as develop new relationships. Each project's working group will include the PI (von Dadelszen, UBC) and project director (Sawchuck, UBC). The working group chairs will report monthly to the Management Committee (UBC and Dr JM Roberts, Pittsburgh), which will in turn report monthly to BMGF. UBC will be responsible for meeting the BMGF-UBC contract milestones and budget targets. The management committee will be advised by an Academic Steering Committee comprised of the management committee, working groups, and a rotating Technical Advisory Group of content and methodological experts.

III. Context

Pre-eclampsia has both maternal and fetal adverse effects. The *maternal syndrome* is more biologically complex than merely hypertension[1,2]. It is characterized by multiple organ dysfunctions which, when good blood pressure (BP) control removes the risk of stroke[3] and magnesium sulfate ($MgSO_4$) removes the risk of eclampsia[4-6], most often cause the associated deaths[7] (Fig 2). The *fetal syndrome* manifests as intrauterine growth restriction (IUGR), oligohydramnios, abnormal umbilical artery blood flow, and fetal acidemia – all of which contribute to elevated risk for perinatal morbidity and mortality.

There are *three main modifiable reasons why women and their fetuses/newborns die due to pre-eclampsia*: 1) lack of disease identification and delays in assessment and transportation to a higher level of care capable of providing effective and life-saving interventions; 2) delay and underutilization of interventions to arrest and/or treat disease progression; and 3) delayed delivery when indicated for maternal/fetal indications. Further, in some jurisdictions, access to effective interventions known to reduce maternal risks remains a serious challenge. Four key examples of such treatments for

10

pre-eclampsia that are poorly accessed in LMICs are (i) $MgSO_4$ for prevention and treatment of the grand mal seizures of eclampsia[4-6]; (ii) antihypertensive medication to lower maternal BP to reduce the risk of stroke[8]; (iii) antenatal corticosteroids to reduce neonatal risks (a recent meta-analysis shows beneficial effects up to 36 weeks' gestation, important if neonatal respiratory support is not available[9]); and (iv) facilitated delivery by induction or Cesarean section[2]. There is also evidence that, in settings of low calcium intake, calcium supplementation in the second half of pregnancy may reduce adverse outcomes of pre-eclampsia[10;11].

In this proposal, we present an evidence-based global pre-eclampsia initiative that includes: 1) a targeted community-based research program for women in LMIC whose objective is to provide women, their social networks and care givers a tool-kit that aims to (a) prevent the occurrence of pre-eclampsia; (b) identify women at increased risk for adverse outcomes, and (c) place women within a framework of care from community to referral center; 2) scientific advancement directed at recognition and innovative treatment; and 3) evidence-based KT strategies specifically designed for LMIC. The net result and objectives are to reduce maternal and perinatal mortality and sustainably improve maternal and child health.

IV. Project Framework

Project Framework Table

3. Treatment: The CLIP (Community Level Interventions for Pre-eclampsia) Feasibility Study & the CLIP Pilot cluster RCT. **Working group** *Chair:* Peter von Dadelszen *Vice Chair:* Beth Payne (coordinator) *Members:* see organizational chart (Figure 1)	**Hypothesis** *against which indicators will ultimately be assessed:* A community level evidence-based package of care (triage & treatment) can be introduced into care. *See below for individual indicators (Obj 3.1 – 3.4).*		*General assumptions for Objective 3:* 1. UBC-based clinical & data coordinating center. 2. Agreement from all participating sites. 3. IRB approvals in all sites in a timely manner. 4. Feasibility studies to determine probable recruitment rates.
Objective 3.1 **To conduct the CLIP Feasibility studies in selected South Asian &/or sub-Saharan African countries to determine (a) current patterns of care related to pre-eclampsia / eclampsia, and (b) facilitators & barriers to conduct of the definitive CLIP cluster RCT.**	1. Priority countries & communities for research selected (4 of 6)*. 2. Feasibility study including preparation, data accrual phase, & data management/analysis phases completed. 3. Barriers & facilitators for conduct of CLIP trial identified in all countries, including referral hospital evidence-based care. 4. Population-level data regarding incidence of pre-eclampsia & its complications developed. 5. Study of the availability of labetalol, $MgSO_4$, & other components of the package completed. 6. Study of referral hospitals ensuring >80% indicated use of	1. Feasibility study documents, small group tools, questionnaires, & teaching materials finalized & translated. 2. Data collated for each country. 3. Meeting abstracts & papers submitted to high impact meetings & for publication in high impact journal(s).	1. Infrastructure at community-, PHC-, & hospital-level settings can be developed to identify & track women pre-pregnancy & throughout gestation. 2. Research partners & key stakeholders are not limited by national guidelines. 3. Task shifting will be acceptable to key decision makers, stakeholders & communities.

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11

	antihypertensives & $MgSO_4$ completed. 7. Costs for Pilot CLIP RCT determined.		
Objective 3.2 **To complete CLIP Pilot Trial design & registration.**	1. Objective 3.1 studies completed in Hyderabad catchment, . 2. CHW, nursing, midwifery, & physician training completed. 3. Implementation tools and protocols developed. 4. Components of CLIP package of care developed.	1. Final trial design, sample size, outcomes, & budget will be finalized. 2. Patient level data will determine sample size calculation for definitive CLIP trial. 3. Protocols, including DCFs and tools for monitoring and evaluation, will be piloted. 4. Costs for definitive CLIP RCT determined.	1. Established CHW infrastructure will support pilot trial. 2. Infrastructure at community-, PHC-, & hospital-level settings to identify & track women throughout gestation. 3. Research partners & key stakeholders are not limited by guidelines of their countries of origin.
Objective 3.3 **To conduct the CLIP Pilot Trial.**	1. Pilot RCT to test the implementation of the community- & PHC-level focused CLIP package of care completed. 2. New science generated to fill knowledge gaps related to the CLIP package of care, & prevention of related adverse events. 3. Groundwork laid for definitive CLIP RCT & pediatric follow-up studies.	1. Training for trial completed. 2. Manuscript(s) summarizing results from the CLIP pilot trial accepted for publication in high impact journal(s). 3. Sufficient patient level data to refine design, power calculation, & assessable outcomes for definitive CLIP RCT.	1. In community use of i.m. $MgSO_4$ & p.o. labetalol are feasible. 2. Task shifting will be acceptable to key decision makers, stakeholders & communities. 3. Infrastructure to identify and track women throughout gestation. 4. Research partners & key stakeholders are not limited by national guidelines. 5. Adequate recruitment to RCT & follow-up rates.
Objective 3.4 **To complete dissemination, including design, costing & funding of the definitive CLIP RCT.**	1. Sufficient data to develop, cost, & fund the definitive CLIP RCT. 2. Design and site selection (South Asian &/or African countries) for the definitive CLIP cluster RCT completed*. 3. Increased knowledge of the role of CLIP package of care, and its elements, derived. 4. Results disseminated as abstracts and papers, & Objective 5 guidelines.	1. Meeting abstracts & papers summarizing results submitted to high impact meetings & for publication in high impact journal(s). 2. Protocols, including DCFs and tools for monitoring and evaluation, will be piloted & adapted for each setting. 3. Definitive CLIP RCT designed, costed, & funding applications completed. 4. Objective 5 guidelines.	1. Feasibility study & pilot trial data provide impetus for definitive CLIP RCT. 2. Integration of trial results into new WHO guidelines (see Objective 5). 3. Availability & utilization of antihypertensives & $MgSO_4$ increases (if indicated by RCT results). 4. New information on the specific effects of the CLIP package of care will guide descriptions of disease severity, resource planning, CHW training, clinical management, & LMIC-relevant guidelines.

OBJECTIVE 3: THE CLIP (COMMUNITY-LEVEL INTERVENTIONS FOR PRE-ECLAMPSIA) FEASIBILITY STUDY & THE CLIP PILOT CLUSTER RCT (SUB-GRANT PI: PETER VON DADELSZEN) (TABLE 5)

DESCRIPTION & ASSUMPTIONS

Here we present our current version of this complex endeavor (Table 5; see page 15), with the understanding that we will not be poised to start recruiting to the CLIP Pilot Trial until at least the beginning of year 2.

This objective consists of two parts: 1) the CLIP Feasibility Study and 2) the CLIP Pilot

12

RCT. The Pilot Feasibility Study will be conducted in and must be completed before initiation of the CLIP Pilot Trial (Table 5).

In general, previous research in this field has focused on institutional level interventions with $MgSO_4$ (eclampsia prevention and treatment[4-6]) and the treatment of severe pregnancy hypertension[8;42]. CLIP will focus on improving community case identification (using miniPIERS as a diagnostic and triage aid) and implementing rapid treatment using community- and PHC-level interventions to control severe hypertension and to prevent and treat the seizures of eclampsia. Trained and supported CHWs will institute these therapies prior to referral to an inpatient facility for definitive care (Table 6). By using a pragmatic approach of implementing a "package of care" we will address the main barriers to effective, and life-saving, care: delays in triage, transport, and treatment. If we limit ourselves to studying inpatient facility-level interventions with fully assessed treatment options, many women will die or be irreversibly affected by pre-eclampsia (e.g., either moribund or having suffered a stroke) prior to arriving at the inpatient facility.

The CLIP package of care (Table 6) In the intervention group clusters, CHWs will be trained to enquire about women's symptoms, weigh women, take women's BP (using sBP as it more closely reflects the risk for hypertensive stroke than does dBP[43;44]), and to check urine for proteinuria by either dipstick or boiling[45]; assuming, for illustrative purposes, that the components of the miniPIERS model remain stable. This will aid the diagnosis and risk assessment of women with pre-eclampsia. Once women enter more formalized care at PHC and hospital levels, that care can be guided by either genPIERS or fullPIERS, depending on the capacity of the health facility.

The preferred *oral antihypertensive* for the management of severe systolic hypertension is labetalol or, failing that, another beta-blocker. Our rationale is that oral labetalol has been well-tested in RCTs, and although less effective than some agents[42], is also less likely to cause hypotension[42], and can be administered orally[42]. Also, it does not bring with it the historical, but probably misplaced, concern that surrounds the contemporaneous use of nifedipine and $MgSO_4$[46].

There is RCT evidence that *$MgSO_4$* is the treatment of choice to prevent and manage the seizures of eclampsia when women are admitted to hospital in high, middle, or low income countries[4-6]. The best support is for the 'International Eclampsia Trial (IET)/Magpie' regimen. However, there is limited RCT[47-49], but substantial regional, experience (Hall & Theron, personal communications) of administering a loading dose of $MgSO_4$ to women with either 'severe' pre-eclampsia or eclampsia while they are still in their community prior to their transfer to hospital for definitive care. Professors Hall and Theron have over 10 years' experience in the Cape Flats with this regimen and there have been no episodes of maternal harm. Although the loading dose of $MgSO_4$ characteristically includes both intravenous (i.v.; 4g) and intramuscular (i.m.; 10g) administration, we have elected to use only the i.m. route. The use of i.v. medications by CHW is problematic and the i.m. medication, although not immediately effective, should reach steady state, therapeutic concentration by 1-2h[50].

Based on the success of this approach in the IET and Magpie, we will develop 'pre-eclampsia boxes' for use by CHWs and in PHCs. These boxes will include PIERS scoring tools, and single doses of oral antihypertensive and i.m. $MgSO_4$.

13

At present, we anticipate that the definitive CLIP *primary outcome* will be a combined maternal and perinatal outcome (either maternal death or severe morbidity and/or perinatal death or severe morbidity). Maternal mortality will be defined as death in pregnancy or within 42 days of delivery. Severe morbidity will be: non-lethal events of eclampsia, stroke, and coma, occurring post-randomization. Perinatal death will be: stillbirth after 27^{+6} weeks' or early neonatal death [<7d of birth]) and severe neonatal morbidity will be: non-lethal events of seizures or coma. We have chosen a combined maternal and perinatal outcome as an effective intervention should reduce the incidence of both maternal and perinatal outcomes. *Secondary outcomes* will include: miniPIERS score on initial assessment at the PHC and hospital levels, diagnosis-to-admission interval, number of women seen at PHCs, number of women admitted to hospital, PIERS combined adverse maternal outcome, PIERS combined adverse perinatal outcome, complications of labetalol and/or $MgSO_4$ therapy, identification of barriers, new implementation strategies, and health economic analysis. Also, we will assess, as *other outcomes*, the rate of non-HDP-related maternal deaths, as miniPIERS may improve outcomes for women with other illnesses in pregnancy as varied as pneumonia and appendicitis.

Both the CLIP Pilot RCT and definitive CLIP RCT require feasibility assessment to identify significant system and individual barriers and/or facilitators which may have an impact on the effectiveness and efficiency of conducting the studies.

Objective To determine the ability to implement the community- and primary health center-relevant CLIP package of care within the framework of a cluster RCT.

Hypothesis Implementing a community level package designed to reduce the incidence of pre-eclampsia-related morbidity and mortality is feasible. To prepare for this, we will conduct 1) an ***international feasibility study*** in , Nigeria and two other centers selected from Bangladesh, India, Kenya, and Uganda; and 2) a single jurisdiction ***pilot cluster RCT*** in . We have chosen these countries due to perceived need for the intervention, existing infrastructure, racial diversity, and personal relationships with, and knowledge of, local investigators and academic leaders.

TABLE 5. The CLIP Feasibility Study & Pilot cluster RCT

CLIP sub-project	Y1	Y2	Y3	Y4
CLIP Feasibility Study Pilot • Pakistan	Conduct Feasibility Study Pilot			
CLIP Feasibility Study: Site selection & set up, Africa and South Asia • Conduct study (all 3 sites) • Analyses	Select	Set up	Conduct Feasibility Study	
CLIP Pilot cRCT (Pakistan) • Set up • Conduct trial • Analyses	Set up	Conduct		
Definitive CLIP cRCT • Design • Cost • Fund	Design	Design	Cost	

The CLIP Trial Feasibility study will be completed PRIOR TO commencement of the CLIP Pilot Trial. The CLIP Feasibility Study and Pilot Trial will run in parallel. We will use the established infrastructure in Hyderabad to test and pilot our feasibility study methods and tools, while selecting additional countries in South Asia and/or sub-Saharan African. Once the countries for the feasibility study are chosen, we will establish relationships with decision makers, NGOs, and professional groups in those countries while completing the Feasibility Study Pilot in Pakistan. The Feasibility Study will then run over the same timeframe as the CLIP Pilot cRCT in Pakistan.

We anticipate being in a position to apply for funding of the definitive CLIP trial by early-to-mid year 4.

CLIP, Community Level Interventions in Pre-eclampsia; cRCT, cluster randomized controlled trial

General assumptions We assume that the results of the Pilot Feasibility Study to be conducted in will inform the Pilot CLIP trial, including costs. Therefore, the Pilot CLIP trial will not be started until the Pilot Feasibility Study is completed. We have assumed

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14

that the clinical and data coordinating center will be located at UBC, Vancouver, where the statistical analyses will also be performed. We do not anticipate any delays related to gaining IRB approval for this intervention. For the Feasibility Study, we assume that stakeholder support and involvement at the ministerial level of health care in the identified countries. We assume that each of the three stages of the Feasibility Study will be completed according to the specified timelines and budget. In addition, we have assumed the established pattern of community level cluster RCTs in will support the CLIP Pilot Trial[51-55], including community CHW-based BP control[55]. Whatever the results of the Pilot RCT, the data will be novel and important and we anticipate the acceptance of resulting paper(s) for publication. We have assumed that no natural or human-caused disaster will occur to curtail our work.

ACTIVITIES

Objective 3.1 To complete the CLIP exploratory site visits and Feasibility Study in South Asia and sub-Saharan Africa (Table 5) The Feasibility Study will first be conducted as a pilot in in preparation for the Pilot RCT (Obj 3.2 & 3.3). In we will be able to build on the previous community- and PHC-level perinatal intervention studies and trials led by Professor Bhutta[51-54]. Using that infrastructure, we will rapidly complete the stages (1-3) outlined below. The feasibility study methods and/or assessment tools will be revised as indicated by the study prior to it being conducted in the other three international jurisdictions (see below).

The *purpose* of the CLIP Feasibility Study is to determine the: 1) stakeholder support, 2) health care system organization and infrastructure capacity related to antenatal care models and pre-eclampsia/eclampsia monitoring, triage, management, maternal transfer, and PHC and referral facility pre-eclampsia/eclampsia treatment, 3) professional scope of practice regulations and/or legal barriers and potential for task shifting, 4) provider knowledge & competency related to pre-eclampsia/eclampsia and resource/informational capacity for provider training, 5) community demographics, pre-eclampsia/eclampsia prevalence rates and rates of associated maternal and perinatal morbidity and mortality, 6) data collection methods and informational systems for population surveillance, 7) cultural and/or community beliefs/practices/influences/attitudes, 8) specific barriers to conducting a RCT including recruitment feasibility, capacity to implement community intervention, and accurate data collection, 9) cost identification to conduct the Pilot CLIP trial and an adequately powered cluster RCT in the identified country, and 10) stakeholder commitment and financial/schedule feasibility to remedy indentified barriers. The feasibility study will use a mixed methods approach (quantitative, participatory/formative, community mapping[56-58]) based on the normalization process model and will utilize literature reviews, target interviews, focus groups, and survey tools. Target interviews and focus group data will be recorded and transcribed; observations and assessments will be written up as field notes. The core approach will be similar across the six study sites, but will allow for tailoring according to individual setting and cultural context. We will draw on models of how interventions are embedded in practice (e.g., the Normalization Process[59-61] and psychological theory[62]) as frameworks for this assessment, which will have three stages:

Stage 1: Consultation with multisector stakeholders (policy makers, health care providers at different levels of care, health care managers, members of the public,

15

patient organizations, NGOs, donors) in each setting to explore factors identified above. Snowball sampling will be used, drawing initially on existing networks and contacts Data collection will be achieved through observation, focus interviews, and focus group meetings. All discussions will be recorded and transcribed. Thematic analysis will be used to identify key themes and these will then be grouped, based on the models above (Table 6).

Stage 2: Assessment of the generalizability We will develop a survey tool to assess the extent to which the identified factors (Stage 1) are generalizable across study sites. The survey will be tailored for the following populations: service users, health care providers at community, PHC and referral hospital levels; and health care managers. Sampling will ensure statistical generalizability across populations. To expedite data collection and analysis, and reduce errors, interviewers will use mobile phones for data entry at the point of collection. Data will be downloaded to a central server for analysis.

Stage 3: Data cleaning, data entry, and qualitative/statistical analysis will be conducted at UBC. Data interpretation, discussion and conclusions regarding feasibility for participation in a community intervention cluster RCT will occur in conjunction with Working Group members and stakeholders of the designated jurisdictions. The final output of Obj 3.1 will be a detailed assessment of the key components that will affect the feasibility of both the Pilot and definitive CLIP trial.

Objective 3.2 To *complete the CLIP Pilot trial design & registration* We have designed a community- and PHC-level pilot cluster RCT encompassing both urban and rural settings in Hyderabad and Matiari districts in rural Sindh. The interventions, allocated by computer-generated random series, with each cluster being the unit of randomization, will be: *Study group*: active implementation of the CLIP package of care focused on the identification and management of women with pre-eclampsia (Table 7); and *Control group*: current practice. In the study group, for antihypertensive and $MgSO_4$ loading, these medications will be pre-packaged in 'boxes', as were used so successfully in the IET and Magpie[4-6]. The "boxes" will be used in communities and at PHCs in each study cluster. We plan to include 12 (6 study and 6 control) clusters in the pilot trial with a public and private sector referral facility in the area adjacent to Hyderabad and Matiari (the latter to give patients choice in terms of referral options beyond the rural health centers (RHC)). *Clusters* will be defined by their PHC (unit of randomization). The villages and basic health units (BHUs) that refer patients to that PHC will be included in the cluster (Table 8).

Site We will recruit in the catchment area of adjacent union councils of Hyderabad and Matiari, Sindh, . Using the community-level infrastructure of CHWs (called Lady Health Workers) proven effective in interventions research by Professor Bhutta[51-54] and the particular, federal Ministry of Health-mandated, relationship between AKU and the Hyderabad and Matiari district health systems, we will complete permissions and pilot feasibility assessments outlined in Obj 3.1, above. We will assess the pattern of care of women with pre-eclampsia/ eclampsia in the main Hyderabad and Matiari referral hospitals. We will not undertake a hospital level implementation trial, but rather focus on community- and PHC-level interventions. It is at those levels that the burden of disease-related risk lies. However, we will ensure that $MgSO_4$ is on formulary at RHCs, and used in >90% of women with eclampsia in all participating RHCs and the main hospitals (Table 8). In addition, effective antihypertensive therapy must be used in >80% of

16

women with severe hypertension (sBP ≥160mmHg and/or dBP ≥110mmHg).

Participants will be **all pregnant women** identified by the CHW assigned to their community. CHWs in these jurisdictions do not currently measure BP. BP measurement is likely to be a component of both miniPIERS and genPIERS (elements of the CLIP intervention). Therefore, we do not want to confound the trial by introducing an element of the intervention (BP measurement) to all clusters. In addition, we need to accrue data from the community level, as, if the intervention is effective across a population of women, fewer women may die unknown to the formal health care system, as more women will be referred to the PHC and hospital levels. It is plausible that the number of inpatient pre-eclampsia-related maternal and perinatal deaths will rise, as women and/or fetuses who previously would have died in their community might now reach hospital moribund and beyond help.

The *primary outcome* will be the rate of utilization of the CLIP package of care between clusters (utilization: number of women triaged and/or treated). The unit of analysis will be all pregnant women. The *secondary outcomes* will be those outcomes planned for the definitive CLIP Trial (page 14).

We will recruit over 18 months to assess the primary outcome (package utilization) and gather sufficient data related to the secondary outcomes to inform the design of the definitive CLIP Trial. We assume that we will achieve a *sample size* of 11,033 women (Table 8), as the number of people/cluster: 35,498; with a birth rate: 25.9/1000 population annually will result in 1379 pregnancies/cluster over 18 months. The number of clusters: 10. Assuming 20% loss to follow-up, that will leave 1103 women delivering per cluster/18 months. With an incidence of HDP: 10%, and utilization of the CLIP package at 5% in control clusters (due to cross-contamination), an intracluster correlation coefficient of 0.01, and an alpha of 0.05, we will have sufficient power (80%) to identify 80% CLIP package use in HDP women in the study clusters (0.125% [control cluster pregnant women] vs 2.0% [study cluster pregnant women]). This sample size will provide sufficient patient level data to allow us to power the definitive CLIP trial. To maximize the amount of patient level data, we will look to increase the total number of clusters to 12 (6 study clusters and 6 control clusters) after the initial site visits and a more detailed budget assessment.

The *DSMB* will be shared with Obj 1. The trial will be registered with either ISRCTN and/or clinicaltrials.gov.

Pre-recruitment phase As outlined in Obj 3.1, initially, we will conduct the CLIP Feasibility Pilot Study in X district. We will finalize a tailored intervention that will be culturally sensitive, effective at reducing barriers, and increase enthusiasm for the CLIP package amongst decision makers through respectful dialog. An educational package will be developed, and the ANMs, midwives and physicians working in the intervention clusters will be trained. To facilitate best care, we will introduce the genPIERS and fullPIERS models into the X hospitals during the pre-recruitment phase. The effect of this introduction (a minimal cost activity through in-house quality improvement activities), will be observed using a pre-/post-implementation design[29;30]. This will be an opportunistic ancillary study to provide useful data to inform the design, planning, and conduct of the definitive CLIP RCT.

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17

ANNEX 2: PROPOSAL - CLIP (COMMUNITY LEVEL INTERVENTIONS FOR PRE-ECLAMPSIA) FEASIBILITY STUDY

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Background

Worldwide every single day, 1500 women die from pregnancy or childbirth-related complications. Most of these deaths occurred in developing countries, and most were avoidable.[1] Women die from a wide range of complications in pregnancy, childbirth or the postpartum period. Most of these complications develop because of their pregnant status and some because pregnancy aggravated an existing disease. The four major killers are: severe bleeding (mostly bleeding postpartum), infections (also mostly soon after delivery), hypertensive disorders in pregnancy (eclampsia) and obstructed labour.[2] Pre-eclampsia complicates 3-5% of pregnancies and remains one of the two most common causes of maternal death in the developed and developing world. Previously, management of pre-eclampsia has merely focused on institutional level intervention with $MgSO_4$ and in-patient management of severe pregnancy hypertension[4, 5]. If the scope of pre-eclampsia management continues to be limited to its in-patient treatment, women will continue to die or be irreversibly affected prior to arriving at the in-patient facility, regardless of how efficient the care there is.

It is known that these deaths are not solely attributed to the lack of in-patient management but have a high share of the three primary delays. These are the delays in triage, transport and treatment. Such delays occur within the community, at PHC level and on admission to the health facility. In order to prevent these delays, community mobilization and community level availability of diagnostic tools is required. The CLIP (community level interventions for pre-eclampsia) trial agenda is a singular step

18

in addressing the excess maternal and perinatal deaths that derive from the failure to identify and rapidly manage pre-eclampsia at the community level.

This study undertakes the task of evaluating the feasibility of introducing a treatment package for pre-eclampsia, and in the future to perform community based studies to evaluate the treatment package. The proposed Feasibility Study looks towards identification and understanding of significant health system, community and individual barriers and/or facilitators that influence care of pregnant women in the community.

Rationale

The implementation of a large scale community intervention requires a prior assessment of the acceptability and feasibility of the intervention. In addition, it also assesses ways to achieve effectiveness and sustainability. Therefore, we propose an observational feasibility study to explore prevailing enablers and barriers for the future implementation of the proposed CLIP trial.

Overall Goal for the Study

This study aims to demonstrate the feasibility of introducing a community-based treatment package for pre-eclampsia and eclampsia in preparation for the conduct of a community-based study to test the effectiveness of this package [the Community Level Intervention for Pre-eclampsia and Eclampsia (CLIP) trial].

Objectives for the CLIP Feasibility Study: India

The specific objectives of the feasibility study are as follows:

1. To determine stakeholder support.
2. To determine health care system organization and infrastructural capacity.
3. To determine cultural and/or community beliefs /practices/influences/attitudes.
4. To determine the potential for scale up and task shifting for Community Health Extension Workers (ANMs) for use and / or administration of:
    A. A mechanism to understand the symptoms and signs of patient presenting with pre-eclampsia and eclampsia so as to define the severity of the disease.
    B. Oral antihypertensive agent, as indicated

19

C. Parenteral drugs as indicated.

5. To assess ANMs competency and resource/informational capacity for provider training and develop appropriate training package.
6. To pilot test the education and intervention package for acceptability and barriers identification.
7. To identify/develop data collection tools for community and facility surveillance assessments in both the intervention & usual care study clusters, develop a database, and obtain pre-intervention cluster level data for:
   a. maternal demographics
   b. maternal mortality & morbidity
   c. fetal mortality & morbidity
   d. neonatal mortality & morbidity
   e. pre-eclampsia/eclampsia prevalence and associated morbidities/near-misses
   f. current intervention coverage for women with pre-eclampsia/eclampsia including monitoring, anti-hypertensive agent, MgSO4, corticosteroids, timely delivery.
8. To identify potential barriers to project success and stakeholder support/commitment with the aim of remedying identified barriers.
9. To conduct a cost identification analysis to conduct the Pilot CLIP RCT and adequately powered definitive cluster RCT.

Hypothesis:

We hypothesize that it is feasible to implement a community level package, with a design to reduce the incidence of pre-eclampsia and eclampsia related morbidity and mortality within the existing health system in the future.

RESEARCH METHODOLOGY

Study Site:

This study will be conducted in select Belgaum District, Karnataka State, India. The unit of randomization will be the Primary Health Centre (Local Council). Twelve clusters have already been identified in Belgaum for conducting the CLIP study.

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20

Duration of Study:

The feasibility study is planned for one-year period

Sample size:

4 clusters are selected for the CLIP Feasibility Study. These are:

Twenty (20) Focus Group Discussions (FGD's) and 20 In-Depth Interviews (IDI's) will occur and each FGD will be conducted for a group of around 12 participants. The FGD group will include X etc. IDI's will be conducted for the selected representatives of the stakeholder's group. Snowball sampling will be used for the selection of participants for IDI's.

Census will be conducted in the selected clusters. The included clusters will be surveyed to identify maternal demographics, maternal mortality and morbidity, neonatal mortality and morbidity, prevalence of pre-eclampsia and eclampsia and associated morbidity/near misses. Women who have experienced pregnancies and those of reproductive age will be surveyed for collection of data regarding morbidities and experiences associated with the previous pregnancies like monitoring, use of antihypertensive agent i.e. MgSO4 and corticosteroids and timely delivery. The following table depicts the clusters selected and the catchment population. All the women of reproductive age in the catchment population will be included for data gathering:

Study Cluster	Major Hospitals	PHC	Catchment Population

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Study Population:

The sampling technique employed will be snowball sampling method. For FGD's and IDI's, the target population will include:

- ANMSs and nurse-midwives
- TBA's
- Community leaders
- Community Members
- Various Stake holders Group (District/ Provincial Coordinators, Facility administration/management i.e. administrative staff of the Public/Private Health Facilities, professional administrations and Karnataka State Ministry of Health.

For the census survey, the target population will be all the women of reproductive age and newborns, along with the head of the households in the selected clusters. Data will also be collected from the existing records of the government and private health facilities.

Study Design:

The Feasibility Study adopts a mixed methods approach to achieve the objectives (i.e. quantitative, participatory/formative, community mapping) based on the normalization process model and will utilize literature reviews, target interviews, focus group discussions, and survey tools for data collection. Data of target interviews and focus group discussion will be recorded and transcribed; observations and assessments will be written up as field notes. The core approach will be similar across the study sites, but will allow for tailoring according to individual setting and cultural context. Models of how the women in the community manage their pregnancy related problems are embedded in practice (e.g., the Normalization Process and psychological theory) will be drawn as frameworks for this assessment.

QUANTITATIVE METHODOLOGY

Operational Definitions

A cross sectional study incorporating a census survey will help capture the existing status of the population. This will provide us with a "snapshot" of the frequency and characteristics of maternal

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22

health related problems at this particular point in time. The data will be used to assess the status of maternal, fetal and neonatal mortality and morbidity. A survey of the above mentioned areas will be conducted to elucidate the information regarding pre-eclampsia/eclampsia prevalence. Furthermore, current intervention coverage for women with pre-eclampsia/eclampsia including monitoring, anti-hypertensive agent, anti-convulsive, corticosteroid and timely delivery, etc. will be identified. A structured questionnaire will be used to obtain the information of the indicators defined below:

1. **Maternal mortality**: death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes.
2. **Maternal morbidity**: any maternal illness from 7 months of gestation to 1 month postpartum
3. **Perinatal mortality**: the number of still births, and neonatal deaths within the first week of life, among all stillbirths and live births
4. **Stillbirth**: is defined as fetal death after 28 weeks of gestation but before delivery of the baby's head per live births.
5. **Neonatal mortality**: is defined as the number of neonatal deaths from any cause among total live births (early: in the first week of life; late: in 7-28 days of life)
6. **Complications of pregnancy**: obstructed or prolonged labor, post partum hemorrhage, posts partum infection/sepsis, eclampsia etc.

QUALITATIVE METHOD

The qualitative part of the study will be conducted in the following three stages:

STAGE 1: Consultation with Multi-sector Stakeholders

Consultation with multi-sector stakeholders (policy makers, health care providers at different levels of care, health care managers, and members of the public, patient organizations) in each setting to explore factors identified above. Snowball sampling will be used, drawing initially on existing networks and contacts. Data collection will be achieved through observation, In-depth interviews, and Focus Group discussions. All IDIs and FGDs will be recorded and transcribed. Thematic

23

analysis will be used to identify key themes and these will then be grouped, based on the models above.

Theoretical sampling will be used to ensure coverage of the three levels of care as well as of health service and contextual factors likely to impact on implementation (e.g. urban/rural setting; large/small facilities; levels of staffing and other resources etc.).

In-Depth interviews and Focus group discussions will be conducted with the following stake holders as well:

- Federation of OBGYN Societies of India (FOGSI)
- Indian Academy of Pediatrics (IAP)
- Auxiliary nurse midwives (ANMs) and administrators
- Public health facility/organization leads
- State Ministry of Health
- Obstetrics and Gynecological Consultants at the KLES Dr Prabhakar Kore Hospital & Medical Research Center, and HSK Hospital & Medical Research Center, Bagalkot
- UBC & KLES University Ethics approval Committee
- Public & Private sector facilities

Observation, Interviews, Literature/document review and Clinical review using the standard Facility Assessment Form will be conducted with Community, PHC, and facility provision for antenatal care, specifically related to pre-eclampsia/eclampsia monitoring, prevention and treatment.

1. Antenatal care funding models and/or public provision of antenatal care.
2. Criteria and mechanisms for referral to the appropriate level of care.
3. Referral Centre capacity related to pre-eclampsia/eclampsia monitoring, prevention and treatment.

STAGE 2: Exploration of Associated Factors

This stage involves the in-depth exploration of these factors in the field across the three levels of care (community, PHC, referral hospital). The approach will be largely qualitative and will involve interviews with health care providers and managers in the field and with service users; structured observations of practice, including assessment, treatment and referral; examination of existing clinical management protocols; and review of relevant supply chains. We will explore issues such as whether local health care organizations have the ability and resources to implement the intervention;

how existing provider roles, tasks and responsibilities might be affected; and how the package will fit into existing provider knowledge, skills and competencies, practices and appropriately diagnosed); human resources (lack of availability of appropriate human resources for diagnosis and management); highly skilled providers seen as necessary for $MgSO_4$ administration due to the perceived 'dangers' of the drug; lack of experience among clinicians with use of $MgSO_4$; local 'traditions' of other forms of treatment; lack of clinical leaders for the condition; availability of drugs and facilities (poor availability of appropriate treatment facilities, including facilities for the intensive monitoring of patients); inadequate distribution of $MgSO_4$ and oral anti-hypertensive drugs to all facilities; availability of guidelines; lack of evidence-based maternal health/ eclampsia policy and management guidelines; failure to disseminate and implement evidence based maternal health/ eclampsia policy and management guidelines; and training of providers and quality assurance in terms of lack of (monitored) standards for care delivery and poor accountability of clinicians in terms of adherence to best practice.

We will develop a survey tool to assess the extent to which the factors identified in Stage 1 are generalizable across study sites. The survey will be tailored for: service users, health care providers at community, PHC and referral hospital levels; and health care managers. Sampling will ensure statistical generalizability across populations. While data collection will be guided by the factors identified in Stage I, it will also attempt to identify other important factors that did not emerge earlier. To expedite data collection and analysis, and reduce errors, interviewers will use mobile phones for data entry at the point of collection.

STAGE 3: Focus Group Discussions

Target interviews and focus group data will be recorded and transcribed; observations and assessments will be written up as field notes. These data will be analyzed qualitatively, first, to develop a comprehensive description of the factors likely to affect implementation of the package of care across each setting and, second, to identify factors shared across all settings. This will facilitate the later development of 'core' and 'site specific' elements of the intervention package. In addition, we will explore the:

I) community demographics, pre-eclampsia, eclampsia prevalence rates and rates of associated maternal and perinatal morbidity and mortality;

25

2) cost identification for treatment

3) stakeholder commitment and financial/schedule feasibility to remedy identified barriers.

Data Management and Analysis:

In this research, notes will be made during interviews/discussion, and later they will be validated with transcripts of tape recording. Field notes/observation (reflective journal) will be maintained which will be the central feature of the analysis. The data will be collected in local languages and translated and transcribed in English. Qualitative data management is one of the important and, perhaps, the most difficult task, as data in bulk has to be organized. By using QSR NVivo version 10.0 computer software program the qualitative data will be analyzed. The data analysis will follow following steps:

- Organizing the data
- Generating categories, themes, patterns
- Testing emergent hypothesis
- Searching for alternative explanation

Data collection and cleaning, data entry, will be conducted at JNMC Research Unit in Belgaum, India. The University of British Columbia, Canada will be responsible for the qualitative/statistical analysis. Data will be downloaded to a central server then analyzed. Any substantive difference between the stage 2 and 3 results will be explored further using methods similar to those described for stage 2 above. Data interpretation, discussion and conclusions regarding feasibility for participation in a community intervention will occur in consultation with the Working Group members and stakeholders of the designated jurisdictions. The final output will be a detailed assessment of the key components that will affect the feasibility for future studies.

The Final Output:

The final output will be a detailed assessment of the key factors (including barriers and facilitators) that will affect the implementation of the package of care within and across the study sites. This will then provide a foundation for both an implementation strategy and a sample size calculation for the future studies on this topic.

ETHICAL CONSIDERATION:

This is an observational study and there is no intervention during the study. This will be conducted on the principles of ethical practice in medical care. Firstly the patient will have the autonomy and

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26

the right to refuse participation in the study process. Secondly the entire process is aimed at finding the feasibility of putting in place a package of care specifically targeting pregnant women who develop hypertension. Thirdly no part of the feasibility study has any intervention for harming any member of the study group. Fourthly, the feasibility study aims to find information which will help to develop care for the least privileged and the most needy/deserving women who are residing in the community. During the study the dignity of each and every one of the subjects will be upheld with the utmost sincerity and any person not wanting to participate will not be coerced. Informed consent will be taken from all the participants participating in the interviews. Those who are literate will sign the form (we will take written consent from each stake holder and individual participant) and those who cannot read or write will be counseled in their own spoken language. Verbal consent translated in local languages will be used for consent taken from such patients. There will be no monetary benefit to the study subjects by participating in the study.

The participants recruited into the study will be given a serial number, which will be used for identification for data entry. All the hard copies of questionnaires will be kept secured in locked file cabinets that will only accessible to lead investigators in the project. All the computer files in which data is entered will be password protected and kept secure. Data will be collected and entered into an anonymized database. The findings will be made available to investigators without personal identification of the individual who responded to the questionnaire.

Impact of the Findings:

This study will enable us to determine the feasibility of the proposed CLIP package not only at the community level but also at the PHC level along with the public and private health care settings. An improved understanding of the prevailing maternal mortality and morbidity status at the study sites would also help in providing useful population based data for the participating communities; and appropriate designing of the CLIP trial for enhanced validity and wider acceptability and applicability.

REFERENCES:

1. Maternal mortality in 2005: estimates developed by WHO, UNICEF, UNFPA and the World Bank. Geneva, World Health Organization, 2007

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27

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3. Steegers EAP, von Dadelszen P, Duvekot JJ, Pijnenborg R. Seminar: pre-eclempsia. Lancet 2010; 376: 631 -644.

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13. (http://www.who.int/healthinfo/statistics/indmaternalmortality/en/index.html

5. Scope and Deliverables

The following table outlines, for each of the objectives, factors within the scope of each objective, as well as the methods, deliverables, and proposed target timelines. Target dates for

28

the deliverables for each objective shall be determined by the India CLIP Feasibility PI. A Final Report of all completed deliverables for all objectives will be available for UBC by **September 30, 2013**.

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29

Objective 1.0: Stakeholder Support: To determine stakeholder support for the CLIP Pilot RCT.			
Within Scope	Methods	Deliverables	Target
1. Federation of OBGYN Societies of India (FOGSI) 2. Indian Academy of Pediatrics (IAP) 3. District Health Officers, Belgaum and Bagalkot 4. Chief Executive Officer, Zilla Panchayat (local self government), Belgaum and Bagalkot 5. Program Director, RCH, Ministry of Health and Family Welfare, Government of Karnataka, Bangalore 6. Reproductive Health and Nutrition Division, Indian Council of Medical Research, New Delhi 7. District and facility health organization leads 8. ANM program (names TBD) 9. UBC, Ethics Committees 10. JNMC Institutional Ethics Committee on Human Subjects Research 11. Health Ministry's Screening Committee, Indian Council of Medical Research 12. Public/private sector/referral facilities	• Key informant interviews with stakeholders in the health system and hospitals • Focus groups	Letters of support/MoUs	

Objective 2.0 Health Care System Organization To determine health care system organization and infrastructure capacity for the CLIP Pilot RCT			
Within Scope	Methods	Deliverables	Target
1. Community, PHC, and facility provision for antenatal care, specifically related to PRE-EMPT 2. Antenatal care funding models and/or public provision of antenatal care 3. Criteria and mechanisms for referral to the appropriate level of care 4. Referral centre capacity related to PRE-EMPT (patient volume/types of morbidities/inpatient services available at the hospitals)	• Observation (by field researchers to guide the process of subsequent data collection or modify the FGD guide) • Key informant interviews with hospital administrators and care providers • Literature/document review • Clinical review using the standard Facility Assessment Form (FAA)	Description of usual antenatal care Description of funding for antenatal care including out of pocket direct and indirect costs e.g. transport, drugs, Description of usual criteria and mechanisms for referral from primary/secondary to tertiary care hospitals Determination of whether appropriate acute care r/t CLIP is available at select facilities	

Objective 3.0 Cultural Beliefs & Practices To determine cultural and/or community beliefs/practices/influences/attitudes that may impact the CLIP Pilot RCT			
Within Scope	Methods	Deliverables	Target
1. Beliefs regarding the cause of PE/E. Determine local names for HDPs, pre-eclampsia/eclampsia 2. Beliefs and practices around traditional, alternative, home remedies, and evidence-based medicines for treatment of pre-eclampsia/eclampsia 3. Assessment of knowledge myths 4. Practices re: the time of seeking healthcare 5. Beliefs around local care 6. Beliefs around transport from community to facility 7. Beliefs around role of women in health care decision making 8. Beliefs and fears regarding MgSO4	• Literature review • Focus group discussions (FGD) (20 total) for community at large, including TBAs, married women of reproductive age (MWRA), local midwives, male and female decision makers • Key informant interviews with community leaders, peers, and/or religious leaders	Identification of any practices that may impact success the CLIP Pilot RCT	
Objective 4.0 Provincial Coordinator ANMs and nurse-midwives			

To determine the potential for scale up and task shifting for ANMs for use and/or administration of 1) miniPIERS Triage Tool, 2) oral antihypertensive agent as indicated, and 3) intramuscular $MgSO_4$ as indicated			
Within Scope	Methods	Deliverables	Target
1. Written professional practice regulations for ANMs 2. Identification of barriers to scale up and task shifting for ANMs including: a) legal b) administrative 3. Interface of ANMs with District Hospital 4. Administrative & clinical support for ANMs	• Literature review • Document review of ANMs scope of practice • Key informant and group interviews with the ANMs, district coordinators for ANMs	Letters of support from the State/National Program	

Objective 5.0 State Coordinator ANMs To assess ANM competency related to the CLIP Pilot RCT and resource/informational capacity for provider training and develop appropriate training package.			
Within Scope	Methods	Deliverables	Target
1. Assess current standard ANM Program curriculum, including: 1.1 instructional tools & training modalities used 1.2 current education related to HDPs, pre-eclampsia/eclampsia 1.3 methods used for knowledge & competency assessment 2. Determine anticipated training time required to develop knowledge and skills related to the CLIP intervention package 3. Develop CLIP training curriculum with specific content 4. Determine preferred training modalities 5. Determine competency assessment and evaluation methods in current 6. Determine instructors for training	• Key informant Individual and group interviews • Review of current ANM curriculum instructional modalities, content related to HDPs, pre-eclampsia/eclampsia, and methods of competency assessment	Documentation of current curriculum content related to PRE-EMPT Identification of training time required. Development of appropriate curriculum content for the CLIP components Development of appropriate training modalities Development of competency based assessment tools	

Objective 6.0 : State Coordinator-ANMs To pilot test the education and intervention package for acceptability and barriers identification			
Within Scope	Methods	Deliverables	Target
1. Determine timeline for pilot test 2. Development of evaluation tool and checklist 3. Analysis 4. Identify and modify barriers	• Pilot test in group of ANMs in non-study clusters	Written report	

Objective 7.0 Pre-intervention Cluster Level Data

To identify/develop data collection tools for community and facility surveillance assessments in both the intervention & usual care study clusters, develop a database, and obtain pre-intervention cluster level data:

a. maternal demographics
b. maternal mortality & morbidity in the past two years
c. fetal mortality & morbidity
d. neonatal mortality & morbidity
e. pre-eclampsia/eclampsia prevalence and associated morbidities/near-misses
f. current intervention coverage for women with pre-eclampsia/eclampsia including monitoring, anti-hypertensive agent, $MgSO_4$, corticosteroids, timely delivery

Within Scope	Methods	Deliverables	Target
1. Community-based maternal demographics, PE/E prevalence, death review (verbal autopsy) within the geographic study setting 2. Facility-based maternal demographics, PE/E prevalence, death review of referral facilities within the geographic study setting 3. Facility-based maternal morbidity/near- misses related to pre-eclampsia/eclampsia 4. Facility-based fetal and neonatal mortality & morbidity	• Adaptation of tools available from WHO Beyond the Numbers using the PDHA Survey 2007	Identification of data fields, adaptation of data collection tools, form design and translation ready for pilot testing. Development of project database Pilot testing of the data instruments Community and facility data collection Data analysis Report	

Objective 8.0 Potential Barriers

To identify potential barriers to project success and stakeholder support/commitment to remedy identified barriers

Within Scope	Methods	Deliverables	Target
1. Human resource constraints (ANMs, facilities, consultants) 2. ANM competing demands 3. General health system weakness functionality 4. Cultural beliefs & practices 5. Issues related to recruitment feasibility, capacity to implement intervention, or accurate data coll. 6. Other observed/ documented barriers 7. Support/commitment to remedy any identified barriers to participating in the CLIP Pilot study 8. Resources available to remedy barriers 9. Timelines required to remedy barriers and compatibility with project timelines 10. Contractual agreements for items 7-9, if applicable	• Literature review • Key informant meetings and interviews	Barrier analysis Written commitments for barriers modifications.	
Objective9.0: Cost identification **To conduct a cost identification analysis for conducting the Pilot CLIP RCT and an adequately powered definitive cluster RCT.**			

Within Scope	Methods	Deliverables	Target date of completion
1. The number and cost of key resources required by ANMSs for the intervention package: • Manual BP cuff • Urine dipsticks • Triage tool • Oral antihypertensive agent • Single dose MgSO4 • Cell phone 2. The educational resources required to train the ANMs in the intervention cluster 2. Human resources required for conducting the CLIP Pilot RCT 3. Central costs required for conducting the CLIP Pilot RCT (e.g. computers, vehicles, etc)	Per unit item cost identification Calculation of power required for the Pilot RCT to determine cluster size and resources required	Cost identification report	

ANNEX 3 - PRIME AGREEMENT

BILL & MELINDA GATES *foundation*

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November 5, 2010

Dean Kuusuela
Senior Manager, Research Services
The University of British Columbia
Technology Enterprise Facility
102-6190 Agronomy Road
Vancouver, British Columbia V6T 1Z3
Canada

Re: Global Health Grant Number OPP1017337
PRE-EMPT (PRE-eclampsia-Eclampsia Monitoring, Prevention, & Treatment)

Dear Mr. Kuusuela:

The Bill & Melinda Gates Foundation (the "Foundation") is pleased to award The University of British Columbia ("UBC") a grant in the amount of $6,999,991.00 for the period beginning on the date you sign this agreement (the "Start Date") to December 01, 2014 (the "Grant Period"). This agreement (the "Grant Agreement") contains the terms and conditions of this grant.

Charitable Purpose of the Grant. The charitable purpose of this grant is to test new strategies for monitoring, prevention, and treatment of pre-eclampsia in various low resource settings, as described in your proposal (the "Proposal") and budget (the "Budget") dated September 29, 2010 (together, the "Project").

Tax-Exempt Status. UBC confirms that under the United States Internal Revenue Code of 1986 (the "Code") it is exempt from federal income tax under section 501(c)(3) and is not a private foundation within the meaning of section 509(a) of the Code. You agree to advise us immediately if there is any change in your organization's exempt status during the Grant Period.

Use of Grant Funds. Grant funds may only be used for the Project. Any grant funds unexpended or uncommitted at the end of the Grant Period must be promptly returned to the Foundation. Any Budget cost category change of more than 10% must be approved in writing by the Foundation in advance. You may not use the grant funds to reimburse any expenses you chose to incur prior to the Start Date.

Investment of Grant Funds. Grant funds must be invested in highly liquid investments (such as interest-bearing bank accounts) with the primary objective of preservation of principal so that they are available for the Project. The Foundation requires you to report the amount of any interest or other income generated by the grant funds, including currency conversion gains (collectively "Interest"). Any Interest must be used for the Project. At the end of the Grant Period, any remaining Interest must be applied to another of your Foundation-funded projects (current or under consideration).

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Anti-Terrorism. You confirm that you are familiar with the U.S. Executive Orders and laws prohibiting the provision of resources and support to individuals and organizations associated with terrorism and the terrorist related lists promulgated by the U.S. Government. You will use reasonable efforts to ensure that you do not support or promote terrorist activity or related training, or money laundering.

Subgrants and Subcontracts. You have the exclusive right to select subgrantees and subcontractors for the Project. The Foundation has not earmarked the use of the grant funds for any specific subgrantee or subcontractor. You, and not the Foundation, are responsible for ensuring that all subgrantees and subcontractors use grant funds consistent with this Grant Agreement and the Proposal. Neither you nor your subgrantees or subcontractors may make any statement or otherwise imply to donors, investors, media or the general public that the Foundation directly funds the activities of any subgrantee or subcontractor. Any agreements with subgrantees and subcontractors you engage to assist with the Project must include the following language: "Your organization has been selected to participate in this Project at our discretion. You may not make any statement or otherwise imply to donors, investors, media or the general public that you are a direct grantee of the Bill & Melinda Gates Foundation ("Foundation"). You may state that University of British Columbia is the Foundation's grantee and that you are a subgrantee or subcontractor of University of British Columbia for the Project."

Payments and Reports. This table shows the deliverables (including reports) and milestones for this grant. Where indicated, the Foundation's payment is contingent on satisfaction of the listed deliverable and/or milestone. The Foundation may authorize changes to the payment and reporting schedules from time to time where appropriate. The Foundation will confirm any such changes in writing.

Payment Date	Payment Amount	Milestone or Deliverable	Due by	Reporting Period
November 2010	$2,833,574.00	----	----	
September 2011	$1,690,967.00	Progress Report; Satisfactory completion of Global Access Milestone	See below*	
September 2012	$1,182,744.00	Progress Reports	August 30, 2012	
September 2013	$1,292,706.00	Progress Report	August 30, 2013	
----	----	Final Report	February 15, 2015	
AWARD TOTAL	$6,999,991.00			

Milestones. For a report to be satisfactory, you must demonstrate meaningful progress against the milestones contained in this Grant Agreement and the Proposal. Milestones may be added or modified during the Grant Period. The Foundation will confirm any agreed changes to the milestones in writing.

*For clarification, your **September 2011 payment** is contingent upon satisfactory completion of the following:

Collaboration Agreement ("Global Access Milestone") – due April 1, 2011
Progress Report – due August 30, 2011

Report Templates. You are required to submit one or more reports regarding the expenditure of grant funds and your progress on the Project. The Foundation's report templates and submission guidelines for this grant can be found at **http://www.gatesfoundation.org/grantseeker/Documents/Progress_Guidelines-gh.doc** for Progress Reports and **http://www.gatesfoundation.org/grantseeker/Documents/Final**

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40

ReportGuidelines.doc for the final report. These templates and guidelines are subject to change. Please submit reports electronically to your Program Officer and Program Coordinator. The Foundation will send you an email with the contact information for these individuals. You also agree to submit other reports that the Foundation may reasonably request.

Record Maintenance and Inspection. The Foundation requires that you maintain adequate records for the Project to enable the Foundation to easily determine how the grant funds were expended. Your books and records must be made available for inspection by the Foundation or its designee at reasonable times to permit us to monitor and conduct an evaluation of operations under this grant.

Compliance. The Foundation has the right at its discretion to terminate or suspend the grant or withhold payment if (a) the Foundation is not reasonably satisfied with your progress on the Project; or (b) significant leadership or other changes occur that the Foundation believes may threaten the Project; or (c) you fail to comply with any term or condition of this Grant Agreement. On termination, if requested by the Foundation, you agree to promptly return to the Foundation any unspent and uncommitted grant funds (as of the date of termination) previously distributed to you by the Foundation for the Project.

Indemnification. You agree to indemnify, defend and hold the Foundation harmless from and against any and all liability, loss, and expense (including reasonable attorneys' fees and expenses) or claims for injury or damages arising out of or resulting from, or that are alleged to arise out of or result from, the actions or omissions by you or of any of your officers, agents, employees, subgrantees, contractors or subcontractors with respect to the grant. You agree that any activities by the Foundation in connection with the Project, such as its review or proposal of suggested modifications to the Project, will not modify or waive the Foundation's rights under this paragraph.

Publication. You agree that you will make available to the public the results of the research emerging from the Project, or any reports or other publications regarding the Project funded by this grant (collectively, the "Materials"), and anticipate that the Materials will be published in a treatise, thesis, trade publication, or in any other format that is available for the interested public as soon as practical, consistent with the need to first secure intellectual property rights in a manner that maximizes the benefits to developing world interests. Specifically, you are expected to use good faith efforts and work in a collaborative fashion with your subcontractors and funders associated with the Project to facilitate broad dissemination and accessibility of the Materials in the developing world.

Global Access. You acknowledge the Foundation is making this grant in furtherance of its charitable purposes and, as a condition, you agree to conduct and manage the Project, and Project technologies and information, in a manner that enables (a) the knowledge gained during the Project to be promptly and broadly disseminated, and (b) the intended product(s) to be made available and accessible at reasonable cost to people most in need within developing countries. The Foundation refers to this as "Global Access." The Foundation recognizes that you have begun to address how you anticipate achieving Global Access through descriptions provided in your Proposal and answers you provided to the Foundation during the course of pre-grant due diligence activities. In this respect, you acknowledge the Foundation is making the grant in reliance on these descriptions and answers, and you agree to comply with them.

In furtherance of Global Access, the Foundation requires you to complete no later than April 1, 2011 a fully executed Collaboration Agreement (or individual consortium agreements) with your Collaboratory partners as described in your responses to the Foundation's pre-grant due diligence questions (the "Global Access Milestone"). The Collaboration Agreement should address, at a minimum, the management of data, research materials and technologies (including the virtual data repository and sample biorepository described in your due diligence responses) so as to ensure that the Project's scientific and charitable objectives can be achieved.

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You agree that no material changes will be made to the plans and strategies contemplated in the Global Access Milestone, once accepted by the Foundation, without prior consultation with the Foundation. Your commitment to Global Access in regard to Project technologies and information will survive the Grant Period.

Research Involving Human Subjects. You agree that no funds will be expended to enroll human subjects in any research project subject to Institution Review Board (IRB) or independent ethics committee (IEC) approval until such approval has been obtained for each site.

Clinical Trials. Since the Project will involve clinical trials on human subjects, a condition of this grant is your agreement that the appropriate Institutional Review Boards ("IRBs") and ethical committees will review and approve the clinical protocols prior to trial initiation. You further agree to conduct clinical trials associated with the project under the generally accepted principles of "Good Clinical Practices" as defined by the International Conference on Harmonization (ICH) E-6 Standard, the United States Food and Drug Administration (FDA) or the European Agency for the Evaluation of Medicinal Products (EMEA), as applicable. You acknowledge and agree that, as between you and the Foundation, you take and will have full responsibility for all compliance, data safety, monitoring, and audit requirements of the relevant regulatory agencies, both for yourself and all other sites included in the project, including those activities conducted through subgrants, subcontracts or other collaborative efforts. You acknowledge and agree that any activities by the Foundation as the grantor funding the Project, including its review of the Proposal or suggested modifications to the Project, does not modify the provisions of this paragraph or constitute the basis for any claim by you against the Foundation.

Coverage for all Sites. You agree that for each venue in which any part of the Project is conducted (either by your organization or a subgrantee or subcontractor) all legal and regulatory approvals for the activities being conducted will be obtained in advance of commencing the regulated activity. You further specifically agree that no funds will be expended to enroll human subjects until the necessary regulatory and ethical bodies' approvals are obtained.

Institutional Review Board (IRB) and Other Ethical Committee Approval. You agree to obtain the review and approval of all final protocols by the appropriate IRBs and ethical committees prior to enrollment of the first human subject. A similar provision applies to Institutional Animal Care and Use Committee approval of studies involving animals, and Institutional Biosafety Committee for biohazards and recombinant DNA. You agree to provide prompt notice to the Foundation if the facts and circumstances change regarding the approval status of the IRBs or ethical committees for any final protocol(s).

Provision of Care for Human Subjects Research. In keeping with "Good Clinical Practice" standards, you will disclose to subjects and the IRBs what care and/or referrals will be available through participation in the study. Institutional policies regarding what care will be provided to personnel who are injured as a result of their work on the Project should be similarly be developed, approved and implemented with notice to the employees.

Grant Announcements, Public Reports and Use of Foundation Name and Logo. The Foundation will include information on this grant in our periodic public reports and may make grant information public at any time on its web page and as part of press releases, public reports, speeches, newsletters, and other public documents. If you wish to issue a press release or announcement regarding the award of this grant, you must obtain advance approval from the Foundation of the press release and the date of release. You also agree to obtain advance approval from the Foundation for any other use of the Foundation's name or logo. The Foundation requests an opportunity to review and comment on subsequent press releases or

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reports that are directly related to the grant. Please contact **GH.Partner.Request@gatesfoundation.org** at least two weeks before any press release, announcement or other publication date. The Foundation shall review and approve an announcement by You that identifies the title of the Project, the parties to this Grant Agreement (and clearly describing CWHC as an affiliated party of UBC but not the grantee), the Grant Period and the amount of funding provided by the Foundation for the Project that can be used without further Foundation consent or approval for the following purposes:–1) as required by law or regulation; 2) as required by any applicable granting agency or council or regulations of UBC Board of Governors; or 3) for administrative and other UBC purposes, such as the use of such information as part of a public compendium of UBC/affiliated hospitals research, or as part of a curriculum vitae of Principal Investigator, or for other such use.

Counterparts; Original. This Grant Agreement, including any amendments, may be executed in counterparts which, when taken together, will constitute one Grant Agreement. Copies of this Grant Agreement will be equally binding as originals and faxed or scanned and emailed counterpart signatures will be sufficient to evidence execution, though the Foundation may require you, the grantee, to deliver original signed documents.

Assignment. This Grant Agreement or any of the rights or obligations under this Grant Agreement may not be assigned without the Foundation's prior written consent. An assignment includes (a) any transfer of the Project; (b) an assignment by operation of law, including a merger or consolidation; or (c) the sale or transfer of all or substantially all of your organization's assets.

Entire Agreement, Severability and Amendment. This Grant Agreement is our entire agreement and supersedes any prior oral or written agreements or communications between us regarding its subject matter. The provisions of this Grant Agreement are severable so that if any provision is found to be invalid, illegal, or unenforceable, such finding shall not affect the validity, construction, or enforceability of any remaining provision. This Grant Agreement may be amended only by a mutual written agreement of the parties.

Please sign and return this Grant Agreement to Meigs Naylor, Grants Coordinator. Please keep a copy for your records. If you have questions, please contact Tammy Banua, Grants Manager at **ghgm@gatesfoundation.org** or 206-709-3141.

On behalf of the Foundation, may I extend every good wish for the success of your work.

Sincerely,

Gary Darnstadt
Director, Family Health
Global Health Program

43

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ANNEX 4

Major Line Items	Designation with % time on project	Unit Cost $/Per year	%FTE	Rate per month	Year 1		Total Cost	
					No. of Mths	1 Year (12 mths)	Total (USD)	Total (INR) @ 45=1USD
Personnel Cost								
M.B.Bellad	Principal Investigator	36160	20	602.67	12	7,232.00	7,232.00	325,440.00
Shivaprasad S. Goudar	Co-Principal Investigator	37930	5	158.04	12	1,896.50	1,896.50	85,343.00
Ashalata Mallapur	Co-Principal Investigator	36160	15	452.00	12	5,424.00	5,424.00	244,080.00
TBD	Training Coordinator	18000	30	450.00	12	5,400.00	5,400.00	243,000.00
TBD	Data Coordinator	18000	30	450.00	12	5,400.00	5,400.00	243,000.00
TBD	Project Coordinator	18000	50	750.00	12	9,000.00	9,000.00	405,000.00
TBD	Field Research Officers	10098	20	168.30	12	2,019.60	2,019.60	90,882.00
TBD	Field Research Officers	10098	20	168.30	12	2,019.60	2,019.60	90,882.00
TBD	Data Management & IT Support	17212	25	358.58	12	4,303.00	4,303.00	193,635.00
TBD	Budget Administrator	14066	25	293.04	12	3,516.50	3,516.50	158,243.00
TBD	Office Secretary	2604	100	217.00	12	2,604.00	2,604.00	117,180.00
TBD	Data Entry Clerk	2604	100	217.00	12	2,604.00	2,604.00	117,180.00
TBD	Data Entry Clerk	2604	100	217.00	12	2,604.00	2,604.00	117,180.00
Consultants								
B S Kodkany	**Consultant - donated time**							
Richard J Derman	**Consultant - donated time**							
DHO, Belgaum	Administrative Consultant			111.00	12	1,332.00	1,332.00	59,940.00
RCH, Belgaum	Administrative Consultant			111.00	12	1,332.00	1,332.00	59,940.00
DHO, Bagalkot	Administrative Consultant			111.00	12	1,332.00	1,332.00	59,940.00
RCH, Bagalkot	Administrative Consultant			111.00	12	1,332.00	1,332.00	59,940.00
MOHs of PHCs	PHC Medical Officer @ $ 222 x 4			888.00	12	10,656.00	10,656.00	479,520.00

Travel and Per Diem	Designation with % time on project	Unit Cost $/Per year	%FTE	Rate per month	No. of Mths	1 Year (12 mths)	Total (USD)	Total (INR) @ 45=1USD
Travel to Delhi & Bangalore	PI and CoPI				0	7,360.00	7,360.00	331,200.00
Purchase of Vehicles	Innova			29,000.00		29,000.00	29,000.00	1,305,000.00
Fuel /Maintenance of Vehicles /	36000 Kms running fuel cost @ 4 rs per kms+Rs 30000 for year tyre change +Rs 30000 for maintenance			200.00	12	2,400.00	2,400.00	108,000.00
Vehical Insurance	Rs 28000 per year @ Approx $650				12	650.00	650.00	29,250.00
Driver Cost full time	$113 per month			113.00	12	1,356.00	1,356.00	61,020.00
Travel for data collection.				200.00	12	2,400.00	2,400.00	108,000.00
Travel to all Facilities Level 1 +Level 2 both public and private	travel for the FRO for the Data collection of Facility Survey and audit every 3 months			90.00	12	1,080.00	1,080.00	48,600.00
Workshop and Training costs								
Ethical Conduct training & GCP Study Personnel 3 days	Food& Stay & training Material			32.00		1,000.00	1,000.00	45,000.00
Stake Holders Meeting at Belgaum One day	Representatives from ICMR, State Government , Society of OB&GYN ,for 50 People (with accommodation and travel)					12,000.00	12,000.00	540,000.00
Monthly Monitoring Meetings-	12 Meetings + Includes Food +TA for 40 Participants (At Belgaum)			333.00	12	3,996.00	3,996.00	179,820.00

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45

Workshop and Training costs cont.	Designation with % time on project	Unit Cost $/Per year	%FTE	Rate per month	No. of Mths	1 Year (12 mths)	Total (USD)	Total (INR) @ 45=1USD
Orientation and Planning Meeting with stake holders +Medical officers and the Community leaders	4 Meeting in the community @ $ 1000 per meeting	1000				4,000.00	4,000.00	180,000.00
Orientation and Planning Meeting with CHW	Members of DHO office +ADHO of Belgaum +Bagalkote +Medical officers +referral facility Doctors + private Doctors meet at Belgaum (130 Members)	4000				4,000.00	4,000.00	180,000.00
Focus \Group and community Mobilization in-depth interviews	$30 for refreshments X 10 meetings+DA for focus group member $111 X10					1,410.00	1,410.00	63,450.00
Travel Cost for focus group Interviews	20 intervies for 10 focus groupsX $67per trip			67.00		670.00	670.00	30,150.00
Translation cost for tapes of Meetings with Focus Group for 40 Hours of tape	Translation only -Rs 4500 per hour typed in English $4500X 30 hours					3,000.00	3,000.00	135,000.00
Project Supplies and Equipment								
Printing of Forms					12	6,150.00	6,150.00	276,750.00
Office Supplies	Paper , Printer toner , other Stationeries				12	3,250.00	3,250.00	146,250.00
Recorders for Focus Group meetings	Used for recording meeting of Focus group meetings				12	400.00	400.00	18,000.00

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46

Other Direct Project Costs	Designation with % time on project	Unit Cost $/Per year	%FTE	Rate per month	No. of Mths	1 Year (12 mths)	Total (USD)	Total (INR) @ 45=1USD
DMS Developing & Testing Fees,With reporting & tracking reports - For Paper based Data Collection					6	5,500.00	5,500.00	247,500.00
Computer	2 Laptop					3,000.00	3,000.00	135,000.00
Digital Camera (geo tagging)				1.00		556.00	556.00	25,020.00
Field office Renovation	2chairs ,2tables , 5 steel Cupbords for 2 regional centers with 5 plastic charis					1,780.00	1,780.00	80,100.00
Telephone Connection & Communication Charges				400.00	12	4,800.00	4,800.00	216,000.00
Total Direct Costs						**169,765.20**	**169,765.20**	**7,639,435.00**
Indirect Costs (15%)						**25,465.00**	**25,465.00**	**1,145,915.00**
Total						**195,230.20**	**195,230.20**	**8,785,350.00**

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47

Appendix A - Table A.1: Goal, Objectives, Activities, and Milestones

BILL & MELINDA GATES *foundation*

Organization Name	**The University of British Columbia**
Goal: CLIP INDIA	**To reduce the burden of life-ending, life-threatening, and life-altering maternal and perinatal complications of pre-eclampsia/ec**

Objective 3	Community Level Interventions for Pre-eclampsia - India
Critical Milestones	1 CLIP Feasibility Completed, August 31 2013 2 CLIP Pilot Complete, August 31 2014 3 CLIP Definitive Trial Complete, August 31 2016
Activity 3.1	CLIP Feasibility
Activity Milestones	1 CLIP Feasibility Interim Report, March 31, 2013 2 CLIP Feasibility Final Report, September 31, 2013
Activity 3.2	CLIP Pilot
Milestones	1 CLIP Pilot Recruitment Begins, September 1, 2013 2 CLIP Pilot Analysis begins, May 1 2014 3 CLIP Pilot Analysis is complete, October 31 2014 4 CLIP Pilot Analysis report, December 31 2014
Activity 3.3	CLIP Census
Activity Milestones	1 CLIP Census Baseline Assesment, April - Aug 2013

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48

CLINICAL STUDY SUB-SITE AGREEMENT

This clinical study sub-site agreement (the "**Agreement**") is made effective as of September 2, 2013 (the "**Effective Date**")

AMONG:

THE UNIVERSITY OF BRITISH COLUMBIA, a corporation continued under the *University Act* of British Columbia with offices at 103 - 6190 Agronomy Road, Vancouver, British Columbia, Canada V6T 1Z3 ("**UBC**"), and **CHILDREN'S & WOMEN'S HEALTH CENTRE OF BRITISH COLUMBIA BRANCH**, a public hospital having its administrative offices at 4500 Oak Street, Vancouver, British Columbia, Canada V6H 3N1 ("**C&W**")

(UBC and C&W will be referred to in the Agreement collectively as the "**Coordinating Institution**")

AND:

DR. PETER VON DADELSZEN, having an address at Rm V3-339, 950 West 28th Avenue, Vancouver, British Columbia, Canada V5Z 4H4 (the "**Principal Investigator**")

AND:

KLE UNIVERSITY'S JAWAHARLAL NEHRU MEDICAL COLLEGE, WOMEN'S AND CHILDREN'S HEALTH RESEARCH UNIT BELGAUM, having its administrative offices at Jawaharlal Nehru Medical college Nehru Nagar Belgaum 590010, Karnataka India (the "**Site**")

AND:

Dr. M.B. BELLAD, having an address at Department of OBGYN, KLE University's J N Medical College, Belgaum, 590010 Karnataka India

AND:

DR. SHIVAPRASAD S. GOUDAR, having an address at Department of Physiology, KLE University's J N Medical College, Belgaum, 590010 Karnataka India

(Dr. M.B. Bellad and Dr. Shivaprasad S. Goudar will be referred to in the Agreement collectively as the "**Site Investigator**")

(the Coordinating Institution, the Principal Investigator, the Site, and the Site Investigator are referred to in the Agreement individually as a "**Party**" and collectively as the "**Parties**")

WHEREAS:

The term "UBC" includes both UBC-Vancouver and UBC-Okanagan campuses.

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It is UBC's objective to exploit its technology for the public benefit in harmony with the UBC Global Access Principles, outlined at www.uilo.ubc.ca/global.asp, and to generate further research in a manner consistent with UBC's status as a non-profit, tax-exempt educational institution. Under UBC research policy and in agreement with its affiliated hospitals, UBC owns inventions, results, and/or data that arise from research performed by UBC and which are conceived and/or made by researchers who have an appointment with UBC.

The Principal Investigator designed and developed the protocol for a clinical study titled "**The CLIP (Community Level Interventions for Pre-eclampsia) Cluster Randomized Controlled Trial**" (the "**Study**").

UBC has received a grant for the Study from the Bill & Melinda Gates Foundation (the "**Foundation**").

The Principal Investigator and the Coordinating Institution wish to engage the services of the Site Investigator and the Site for the Study, and the Site Investigator and the Site wish to be so engaged.

THE PARTIES AGREE AS FOLLOWS:

1.0 **Definitions**

1.1 In the Agreement:

(a) "**Confidential Information**" means the Protocol (as defined below) and all information, regardless of its form, that is disclosed by one Party (the "**Discloser**") to another Party (the "**Recipient**") and which is clearly identified in writing as being confidential either at the time of disclosure, or if disclosed other than in writing, then the Discloser will identify such information as confidential at the time of disclosure and will summarize such disclosure in writing and label it "Confidential" within 30 days of the original disclosure, except that Confidential Information does not include information:

(i) possessed by the Recipient prior to receipt from the Discloser, other than through prior confidential disclosure by the Discloser, as evidenced by the Recipient's business records;

(ii) published or otherwise made available to the general public, other than through a breach of the Agreement;

(iii) obtained by the Recipient from a third party with a valid right to disclose it, provided that the third party is not under a confidentiality obligation to the Discloser in respect of the same; or

(iv) □ndependently developed by employees, agents, or consultants of the Recipient who had no knowledge of or access to the Discloser's information, as evidenced by the Recipient's business records.

□ "**Contract Period**" means the time period ranging from the Effective Date

(b) "**Contract Period**" means the time period ranging from the Effective Date through May 31, 2017 (the "**End Date**").

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50

(c) "**Data**" means any and all data generated or collected during the Contract Period in the performance of the Study, including, but not limited to, medical information, diagnoses, and analyses of medical records.

(d) "**Data Collection Forms**" means the documents attached to the Agreement as Schedule "A", as well as the mHealth data fields embedded in PIERS on the Move, as per the Protocol (defined below). The full implementation of PIERS on the Move on the mHealth platform is contingent on its feasibility as assessed during the CLIP Pilot Study.

(e) "**Inventions**" means any and all knowledge, know-how, techniques, technologies, or other intellectual property that is conceived, invented, developed, improved, or acquired during the Contract Period in the performance of the Study.

(f) "**Protocol**" means the protocol for the Study that is attached to the Agreement as Schedule "B".

(g) "**Site Data**" means all Data solely generated or developed by the Site Investigator or the Site Researchers (as defined below).

(h) "**Site Researchers**" means any agents, employees, representatives, or sub-investigators of the Site.

(i) "**Study Budget**" means the description of compensation that is attached to the Agreement as Schedule "C".

2.0 SCOPE OF WORK AND FUNDING

2.1 The Site Investigator will conduct the Study at the Site in accordance with the Protocol and any approved amendments, which will form an integral part of the Agreement. The Principal Investigator and/or the Coordinating Institution may amend the Protocol from time to time during the Contract Period, and a copy of any such amendment will be promptly provided by the Principal Investigator to the Site Investigator. The implementation of any such amendment by the Site Investigator and the Site will be preceded by any approval that may be required by the Site's Research Ethics Board ("**REB**").

2.2 The Site and Site Investigator will also ensure that the Study is conducted in accordance with the Protocol and any approved amendments at S. N. Medical College, Bagalkot ("**SNMC**"). The Site and Site Investigator will enter into an agreement (the "**SNMC Agreement**") with SNMC and investigators participating in the Study at SNMC (the "**SNMC Investigators**"), as applicable, and otherwise ensure that SNMC and the SNMC Investigators (a) are bound by the same obligations and responsibilities by which the Site and Site Investigator are bound under the Agreement; (b) agree to the terms and conditions of the Agreement as if SNMC and the SNMC Investigators were parties to the Agreement; (c) fulfill all their obligations in order to allow the Site and Site Investigator to fulfill their obligations under the Agreement.

2.3 The Coordinating Institution will provide funds to the Site for the performance of the Study by the Site Investigator in accordance with the Study Budget. The Principal Investigator and the Coordinating Institution, acting reasonably, reserve the right to withhold payment or request the return of funds to the extent that Study participants were not properly enrolled under the terms of the Protocol or the Study was otherwise not conducted in accordance with this Agreement or the Protocol. The Parties acknowledge and agree that the funding of the Site is contingent upon the receipt of grant funding from the Foundation by the Coordinating Institution.

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51

The funding provided by the Coordinating Institution to the Site will be deemed inclusive of costs associated with the research at the Site, including any indirect costs or administrative charges of the Site.

2.4 By January 15 of each year during the Contract Period, the Site will submit to the Coordinating Institution, and will ensure that SNMC will submit to the Coordinating Institution, a CLIP Annual Progress Report and completed Budget Report for the previous fiscal year (November 1 to October 31) in accordance with the Foundation reporting format requirement included in the Study materials provided to the Site.

2.5 The Site has been selected to participate in the Study at UBC's discretion. The Site may not make, and will ensure that SNMC does not make, any statement or otherwise imply to donors, investors, media, or the general public that the Site is a direct grantee of the Foundation. The Site may state that UBC is the Foundation's grantee and that the Site is a subgrantee or subcontractor of UBC for the Study.

2.6 Except as stated above, the Site may not issue, and will ensure that SNMC will not issue, a press release or announcement regarding the award of the subgrant by UBC to the Site or SNMC, or a press release or announcement that is directly related to the subgrant, without obtaining advance approval from the Coordinating Institution of the press release or announcement and the date of release. The Site also agrees to obtain, and will ensure that SNMC agrees to obtain, advance approval from the Coordinating Institution for any other use of the Foundation's name or logo.

2.7 The Site and Site Investigator will not expend, and will ensure that neither SNMC nor the SNMC Investigators expend, any funds to enroll human subjects in the Study until the necessary ethical bodies' approvals are obtained by the Site, the Coordinating Institution, and SNMC, and copies of the Site's and SNMC's approvals are provided to the Coordinating Institution.

2.8 Funding provided by UBC to the Site may be used only for the Study. Any funds unexpended or uncommitted at the end of the Contract Period must be promptly returned to UBC. Any budget cost category change of more than 10% must be approved in writing by the Coordinating Institution in advance. No funds may be used to reimburse expenses incurred prior to the Effective Date.

2.9 Funds originating from the Foundation may be invested in highly liquid investments with the primary objective of preservation of principal so that they are available for the Study. The Coordinating Institution requires that the Site report the amount of any interest or other income generated by the grant funds, including currency conversion gains (collectively "**Interest**"). Any Interest must be used for the Study.

2.10 The Site and Site Investigator will maintain, and will ensure that SNMC and the SNMC Investigators maintain, adequate financial records for the Study in order to enable the Coordinating Institution to easily determine how the Study funds were expended. The Parties agree that the Site and Site Investigator's books and records must be made available for inspection, and that the Site and Site Investigator will ensure that the SNMC and SNMC Investigators' books and records are made available for inspection, by the Coordinating Institution or its designee at reasonable times to permit the Coordinating Institution to monitor and conduct an evaluation of operations under the Study.

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3.0 PERIOD OF PERFORMANCE

3.1 The Agreement will continue in full force and effect for the duration of the Contract Period; or if the Study is completed prior to the End Date, until the date on which the Study is completed at the Site; or if the Parties agree to extend the Study at the Site beyond the End Date, until such date as is mutually agreed upon in writing; or if the Study is terminated in accordance with Section 10.0 of the Agreement, until the date on which the Study is terminated.

4.0 RESPONSIBILITIES OF THE SITE AND/OR SITE INVESTIGATOR

4.1 The Site and/or Site Investigator, as applicable, will, and will ensure that SNMC and the SNMC Investigators will:

(a) comply with the Protocol and with all applicable laws, rules, guidelines, and regulations in the performance and documentation of the Study, including, but not limited to: the generally accepted principles of "Good Clinical Practices" as defined by the International Conference on Harmonisation (ICH) E-6 Standard (the "ICH/GCP"), the United States Food and Drug Administration, or the European Agency for the Evaluation of Medicinal Products, as applicable; the Canadian Institutes of Health Research: Best Practices for Protecting Privacy in Health Research; the Declaration of Helsinki; the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans; and all applicable Health Canada regulations and other applicable federal, provincial, and local laws, rules, regulations, procedures, and guidelines.

(b) provide to the Coordinating Institution, prior to screening Study participants or enrolling Study participants into the Study: (i) a copy of the Study participant informed consent form, written in the Site's local language, that will be used in the Study and that has been approved by the Site's REB (the "**ICF**"), as well as a copy of the ICF that has been translated into English and a signed certificate of translation which certifies that the ICF in English is a true and accurate translation of the ICF in the Site's local language; and (ii) a copy of the Data Collection Forms formatted for the local site and written in the English language that will be used in the Study and that has been approved by the Site's REB. Any changes to the ICF or Data Collection Forms will be reported to the Coordinating Centre, with justification for each change, prior to the UBC REB renewal.

(c) provide to the Coordinating Institution, prior to screening Study participants or enrolling Study participants into the Study, a copy of the *curriculum vitae* of the Site Investigator, SNMC Investigators, and any key Study personnel at the Site and SNMC; and written evidence of all applicable legal, regulatory, and ethical bodies' approvals for the Study, including written approval from the appropriate REB and ethical committee for the Protocol and the conduct of the Study at the Site and SNMC. The Site will promptly notify, and will ensure that SNMC will promptly notify, the Coordinating Centre if the facts and/or circumstances change regarding the approval status of the REB or ethical committee for the Protocol.

(d) provide to the Coordinating Institution, for trial monitoring purposes, the certificate of analysis for the drugs to be used in the Study (the "**Study Drugs**"; methyldopa, $MgSO_4$), including the batch number, expiry date, where the Study Drugs will be stored, and who will be responsible for handling the Study Drugs (e.g., pharmacist).

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Registrar 53
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(e) assume responsibility for the conduct of the Study at the Site or SNMC, as applicable, and conduct the Study at the Site or SNMC, as applicable, in accordance with the Protocol (subject to any amendments approved by the Site's REB or SNMC's REB, as applicable). Any changes in procedure set out in the Protocol will be made by the Site Investigator only if considered necessary by the Site Investigator to protect the safety, rights, or welfare of Study participants, provided that the Site Investigator promptly notify the Principal Investigator of any such deviation. Such deviations from the terms of the Protocol will not constitute negligence, error, omission, malfeasance, or material breach of the Agreement on the part of the Site Investigator or the Site.

(f) ensure that any sub-investigators and any support staff who are participating in the Study at the Site and SNMC will comply with the terms of the Protocol and any amendments to the same extent as the Site Investigator. The Site Investigator will take appropriate steps to inform, and will ensure that the SNMC Investigators will take appropriate steps to inform, each such person of his/her obligations and to obtain his/her agreement to abide by the terms and conditions of the Agreement.

(g) complete accurately and promptly the Data Collection Forms in accordance with the Protocol and submit completed Data Collection Forms and any other Study data on a timely basis through the customized Study database. Clinical PIERS on the Move cleaned data will be sent monthly, and Surveillance cleaned data will be sent at the completion of each Surveillance cycle. The Site will provide all translation services for paper copy and mHealth Data Collection Forms.

(h) disclose to Study participants and the REB what care and/or referrals will be available through participation in the Study. Institutional policies regarding what care will be provided to personnel who are injured as a result of their work on the Study should be similarly developed, approved, and implemented with notice to the employees.

(i) conduct and manage the Study, and Study technologies, biological samples, and information, in a manner that enables (i) the knowledge gained during the Study, including but not limited to data and biological samples, to be promptly and broadly disseminated, and (ii) the intended product(s) to be made available and accessible at reasonable cost to people most in need within developing countries.

(j) agree that the Site and/or Site Investigator, as applicable, will source and purchase, in country, all Study package materials, including (i) all Study Drugs, and (ii) all devices and equipment to be used in the Study (collectively, the "**Study Devices**"). The Study Devices will exclude blood pressure monitoring devices (BP 3AS-2), which will be purchased from Microlife by the Coordinating Institution and provided by the Coordinating Institution to the Site for use in the Study. The blood pressure monitoring devices will be provided by the Coordinating Institution to the Site in quantities sufficient for use in the Study. The Site will be responsible for replacing any blood pressure monitoring devices and mobile devices that are misplaced, stolen, damaged, or lost. All Study Drugs and Study Devices sourced and purchased by the Site must meet quality standards established by the Coordinating Institution. The Coordinating Institution will reimburse the Site for the Study Drugs and Study Devices listed in Table A below. The Coordinating Institution will pay to the Site up to the Amounts specified in Table A plus 15% in indirect costs upon invoice, with the exception of cell phone minutes/data plan, indicated in Table A as "Mobile Minutes", for which the Coordinating Institution will provide to the Site a one-time payment in the amount of $22,500 USD (including indirect

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54

costs) at the first quarterly invoice. The Coordinating Institution will also provide the Site with funds plus 15% in indirect costs to purchase the Android operating system-based mobile devices and SD cards upon receipt of the quote from the mobile device vendor. In the event that the Coordinating Institution is able to purchase the mobile devices directly, the Coordinating Institution will notify the Site. Accurate records of the costs of all Study Drugs and Study Devices, including receipts, will be provided by the Site to the Coordinating Institution upon request by the Coordinating Institution for the purposes of (i) reimbursement, and (ii) conducting the Study cost analysis. The Coordinating Institution will reimburse the Site on a quarterly basis for the Study Devices within sixty (60) days of receipt of an invoice with receipts. The total payment by the Coordinating Institution to the Site for the direct costs of the Study Drugs and Study Devices will not exceed $33,454 USD. The total payment by the Coordinating Institution to the Site for the indirect costs of the Study Drugs and Study Devices will not exceed $1,643 USD.

Table A

Sl.NO	Particulars	Quantity	Rate (in Rupees)	Amount (in Rupees)	Amount (in USD)	
1	Clip Box	50	200	10000	167	
2	Clip Box Cardboard box with Stickers	1500	30	45000	750	
3	Stickers Cardboard box	1500	30	45000	750	
4	Gloves Pair	1500	20	30000	500	
5	Syringe 10ml *3	4500	20	90000	1500	
6	Magnesium sulfate 10ml 2	3000	40	120000	2000	
7	Methyldopa, 3 tablet per Women	4500	3	13500	225	
8	Alcohol swabs	4500	1.5	6750	113	
9	Community engagement handbook or Pamplet 3 Fold	2000		30000	500	
10	PHC Posters- 200 quantity , Size 2'X4' flex Color	200	150	30000	500	
11	Paper Posters A3 size	1000	15	15000	250	
12	Fram with board for 200 Paperposter A3 Size	200	100	20000	333	

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Belagavi-590 010, Karnataka

13	Mobile Minutes - 2gb Limited usage Rs 250 for 3g Plan for 150 Devices over a period on 36 months	150	250	1350000	22500	
14	Dip Sticks (Protin)	1500	100	150000	2500	
15	CLIP Protocol Over View	600	30	18000	300	
16	LMP EDD Card	600	30	18000	300	
17	Sharps Box for Syringe Disposal	40	400	16000	267	
			In Rupees	**2,007,250**	In United States Dollars	**$33,454**

5.0 RECORD KEEPING

5.1 The Site and Site Investigator will maintain, and will ensure that SNMC and the SNMC Investigators maintain, adequate and accurate records relating to the Study, including the Study participant informed consent and treatment records of the Study participants, for the minimum period following completion or termination of the Study that is required by Health Canada regulations or such other period required by local laws, regulations, or guidelines.

6.0 CONFIDENTIALITY

6.1 The Recipient will keep and use the Discloser's Confidential Information in confidence and will not, without the Discloser's prior written consent, disclose the Discloser's Confidential Information to any person or entity, except to the Recipient's directors, officers, employees, faculty, students, and professional advisors who require the Confidential Information in order to assist the Recipient in performing its obligations and/or exercising its rights under the Agreement.

6.2 If the Recipient is required by judicial or administrative process to disclose the Discloser's Confidential Information, the Recipient will promptly notify the Discloser of the requirement and allow the Discloser reasonable time to oppose the process before disclosing the Confidential Information.

6.3 The Parties agree that the provisions of this Section 6.0 will not prevent the Recipient from disclosing the Discloser's Confidential Information to: (i) the Recipient's REB; (ii) the REB of another site participating in the Study if it is necessary for the performance of the Study or for the safety of Study participants, provided that the Recipient notifies the Discloser in writing in advance of the Recipient's intention to do so; or (iii) Study participants, their doctors, or their legal representatives if required for the clinical or medical care or safety of the Study participants.

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6.4 Notwithstanding any termination or expiration of the Agreement, the obligations set out in this Section 6.0 survive and continue to bind the Parties and their successors and assigns until 5 years after the date of such termination or expiration.

7.0 PRIVACY

7.1 The Parties agree that all personal information and personal health information (the "**Information**") provided by a Party to any other Party under the Agreement is subject to Canada's *Personal Information Protection and Electronic Documents Act* ("**PIPEDA**"), the text of which is available at the following web address: http://laws-lois.justice.gc.ca/PDF/P-8.6.pdf. Each Party warrants that the Party and its employees and designee(s) will adhere to and comply with all applicable laws and regulations regarding protection of the Information, including but not limited to PIPEDA. In the event that a Party is subject to a substantially similar provincial legislation as acceptable under the terms of PIPEDA, the Party will comply with such provincial legislation in its use, retention, and destruction of all Information provided to it under the Agreement. Notwithstanding anything to the contrary in the Agreement, the Parties will treat as confidential, and will continue to treat as confidential following the ending or termination of the Agreement, all the Information of Study participants as set out in this Section 7.1 and as required by law.

8.0 DATA AND INVENTIONS

8.1 Subject to Section 9 (Publication), the Parties agree, and the Site and Site Investigator will ensure that SNMC and the SNMC Investigators agree, that the Coordinating Institution and the Principal Investigator own all right, title, and interest in any and all Data, Site Data, Data Collection Forms, and Data generated or developed by SNMC, SNMC Investigators, and any agents, employees, representatives, or sub-investigators of SNMC (the "**SNMC Researchers**").

8.2 The Coordinating Institution and the Principal Investigator hereby grant to the Site and the Site Investigator a non-exclusive, royalty-free, irrevocable, perpetual right to use any and all Site Data for the purpose of the Study and internal and academic research purposes.

8.3 The Site and the Site Investigator will promptly disclose, and will ensure that SNMC and the SNMC Investigators will promptly disclose, to the Principal Investigator and the Coordinating Institution any Inventions made or conceived by the Site Investigator and/or the Site Researchers. Inventorship will be determined in accordance with United States patent law and ownership will follow inventorship. Where a joint Invention is made by naming at least one entity as inventor from each Party, the Site and the Site Investigator agree, and will ensure that SNMC and the SNMC Investigators agree, to enter into an agreement with the Coordinating Institution to administer such joint Inventions (the "**Joint Inventions Agreement**"). The Joint Inventions Agreement will specify, among other terms, the respective responsibilities of the Parties regarding patent costs and other reasonable costs, and a reasonable and equitable revenue sharing mechanism.

8.4 Each Party hereby grants to the other Parties a non-exclusive, royalty-free license to use Inventions for internal and academic research purposes.

9.0 PUBLICATION

9.1 The Parties agree, and the Site and Site Investigator will ensure that SNMC and the SNMC Investigators agree, that one publication of the Study will be a joint, multi-centre

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publication involving all the investigators and sites that participated in the Study, and that authorship of the multi-centre publication will be determined in accordance with academic standards for authorship. Prior to this multi-site publication, the Site Investigator may publish any Site Data, and the Parties agree that the SNMC Investigators may publish all Data solely generated or developed by the SNMC Investigators (the "**SNMC Data**"), in accordance with Section 9.2. The Site Investigator will have the right to disclose information resulting from the Study or any background information provided by the Principal Investigator or the Coordinating Institution that is necessary to allow other scholars to verify research results.

9.2 Subject to Section 9.1, the Site Investigator and the Site Researchers will not be restricted from presenting Site Data, and the Parties agree that the SNMC Investigators will not be restricted from presenting the SNMC Data, at symposia or national or regional professional meetings or from publishing Site Data or SNMC Data, as applicable, in journals or other publications (collectively, the "**Proposed Disclosure**"), provided that any Proposed Disclosure is submitted to the Principal Investigator for review for Confidential Information and for comment at least 30 days before the date of presentation of the Proposed Disclosure or the date of submission of the Proposed Disclosure for publication. The Parties agree, and the Site and Site Investigator will ensure that SNMC and the SNMC Investigators agree, that any information identified by the Principal Investigator or the Coordinating Institution as being Confidential Information will be deleted from the Proposed Disclosure, provided that the Principal Investigator and the Coordinating Institution will not request the deletion of, and the Site Investigator, the Site Researchers, or the SNCM Investigators will not be required to delete, any data, results, or information related to research methods used in the Study. The Parties agree, and the Site and Site Investigator will ensure that SNMC and the SNMC Investigators agree, that at the request of the Principal Investigator or the Coordinating Institution, any Proposed Disclosure will be delayed for a further period not exceeding 60 days to enable the Coordinating Institution to protect its rights in such Confidential Information. If the Site Investigator, the Site Researchers, or the SNMC Investigators do not wish to delay the Proposed Disclosure, the Site Investigator, the Site Researchers, or the SNMC Investigators, as applicable, will delete the Confidential Information identified by the Principal Investigator or the Coordinating Institution from the Proposed Disclosure prior to its presentation or submission for publication.

9.3 Other than with respect to Confidential Information, nothing in the Agreement will be construed as granting to the Principal Investigator or the Coordinating Institution any right to edit the Proposed Disclosure. The final analysis and interpretation of the Site Data remain with the Site Investigator and the Site Researchers.

9.4 The Parties agree that any publication that arises from the Study will be in accordance with Schedule "D" ("Community Level Interventions for Pre-Eclampsia (CLIP) Authorship Agreement").

10.0 TERMINATION

10.1 The Parties agree, and the Site will ensure that SNMC agrees, that any Party may terminate the Agreement upon 30 days' prior written notice to the other Parties and that the 30-day notice will not be required if the Party wishing to terminate the Agreement, in its sole opinion, deems that the safety of the Study participants is a concern, provided that the Party wishing to terminate the Agreement due to safety concerns promptly notifies the other Parties of its decision to do so.

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

10.2 If a Party (the "**Breaching Party**") breaches the Agreement, the Agreement will be terminated, provided that a non-breaching Party provides written notice of the breach to the Breaching Party and the Breaching Party fails to remedy such breach within 15 days after receiving such notice, or such longer period as the Parties may agree to in writing, acting reasonably and giving consideration to the nature of the breach and time reasonably required to cure the same.

10.3 No termination of the Agreement, however effectuated, will release the Parties from their rights and obligations under Sections 5.0 (Record Keeping), 6.0 (Confidentiality), 7.0 (Privacy), 8.0 (Data and Inventions), 9.0 (Publication), 10.3, 10.4, 11.0 (Disclaimer of Warranty and Liability), 12.0 (Insurance), 13.0 (Use of Name), and 15.0 (General).

10.4 In the event of termination, the Coordinating Institution will reimburse the Site for all payments owing to the Site up to the Site's receipt of the written notice of termination, in accordance with the Study Budget, except that no such payment will be made in the event that the Agreement is terminated because of the Site's, Site Investigator's, SNMC's, or the SNMC Investigators' failure to adhere to the Protocol. The Site shall take all reasonable steps to minimize further costs after receiving notice of termination, regardless of the grounds for such termination.

11.0 DISCLAIMER OF WARRANTY AND LIABILITY

11.1 The Parties will perform the Study in accordance with the Protocol and the terms of the Agreement. However, no Party promises success in achieving any particular result. Except as expressly provided in the Agreement, no Party gives any warranty whatsoever, express or implied, as to any matter, including, without limitation, as to the results of the Study or regarding Confidential Information that a Party may disclose to another Party. No Party will be responsible for any lost profits, lost opportunities, or other indirect or consequential damages suffered by any other Party as a result of the conduct of the Study or the performance of the Agreement.

11.2 The Parties acknowledge and agree that each Party will be responsible and liable for any damage or loss to the extent that such damage or loss arises as a result of its own negligence or willful or wrongful acts or omissions in conducting the Study, such as a failure by that Party to: (a) adhere to the material terms of the Protocol; (b) comply with applicable governmental requirements or regulations of Canada or the province in which a Party operates; and (c) conduct the Study in accordance with the medical standards set out in the ICH-GCP. No Party ("the **First Party**") will be liable to any other Party (the "**Second Party**") or third party for any damage or loss that results from the use by the Second Party or third party of the Data or Inventions developed under the Agreement, Protocol, or Study, except to the extent that the damage or loss arises from the gross negligence or willful misconduct of the First Party.

11.3 The Site assumes liability, or will otherwise require that SNMC assumes liability, for any costs, suits, or claims on account of injuries (including death) to persons participating in the Study at SNMC arising from their participation in the Study or damage to property which may arise as a result of SNMC's or the SNMC Investigators' participation in the Study. Neither the Coordinating Institution nor the Principal Investigator will assume liability for any costs, suits, or claims on account of injuries (including death) to persons participating in the Study or damage to property which may arise as a result of the participation of SNMC or the SNMC Investigators in the Study.

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

12.0 INSURANCE

12.1 The Coordinating Institution and the Site will each maintain, and the Site will ensure that SNMC will maintain, appropriate policies of liability insurance against any and all foreseeable risks of loss arising out of the Agreement or the Study, with the Coordinating Institution having limits of no less than $3,000,000 CAD per occurrence, the Site having limits of no less than INR 10,000,000 per occurrence, and SNMC having limits of no less than INR 4,000,000 per occurrence, to cover the activities of their directors, officers, employees, faculty, students, and agents. The Coordinating Institution and the Site will provide, and the Site will ensure that SNMC will provide, evidence of such insurance to each other upon written request, and will provide each other 30 days' prior written notice of cancellation or non-renewal of their respective coverage.

12.2 The Site Investigator represents and warrants that they are, and that any other licensed physician involved in the Study at the Site, including any co-investigator and sub-investigator, is, a member in good standing of the applicable professional medical organization and will maintain such standing during the conduct of the Study. The Site will also ensure that the SNMC Investigators represent and warrant that they are, and that any other licensed physician involved in the Study at SNMC, including any co-investigator and sub-investigator, is, a member in good standing of the applicable professional medical organization and will maintain such standing during the conduct of the Study.

13.0 USE OF NAME

13.1 Notwithstanding anything to the contrary in the Agreement and without further notice, the Parties agree that each Party may disclose the existence of the Agreement, the Contract Period, the Parties to the Agreement, the amount of funding received by the Site from the Coordinating Institution and the title of the Study in annual reports or in any publication or presentation relating to the results of the Study. However, no Party may use the name, trademarks, or insignia of any other Party in any publication, news release, promotion, advertisement, or other public announcement, whether written or oral, that endorses services, organizations, or products, or for any other purpose other than that expressly permitted by the Agreement, without the other Party's prior written consent.

14.0 NOTICES

14.1 All payments, reports, notices, or other documents that a Party is required or wishes to deliver to any other Party will be delivered:

(a) in writing, and

(b) either by personal delivery or by registered or certified mail (with all postage and other charges prepaid) at the address for the receiving Party as set out in Section 14.2 or as varied by any notice.

Any notice that is personally delivered is deemed to have been received at the time of delivery. Any notice that is mailed in accordance with this Section 14.0 is deemed to have been received at the end of the fifth business day after it is posted.

14.2 Addresses for delivery of notices:

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

To the Coordinating Institution
If to UBC:

Managing Director, UILO
UBC File No.
The University of British Columbia
University-Industry Liaison Office
#103 - 6190 Agronomy Road
Vancouver, British Columbia
Canada V6T 1Z3
Tel: (604) 822-8580
Fax: (604) 822-8589

If to C&W

Dr. Michael O'Shaughnessy
Acting Executive Director, Child and Family Research Institute
Children's and Women's Health Centre of B.C. Branch
A2-146
950 West 28th Avenue
Vancouver, British Columbia
Canada V5Z 4H4
Tel: (604) 875-2404
Fax: (604) 875-2496

To the Principal Investigator

Dr. Peter von Dadelszen
Rm V3-339, 950 West 28th Avenue
Vancouver, British Columbia
Canada V5Z 4H4
Tel: (604) 875-3054
Fax: (604) 875-3212

To the Site:

KLE University's
Jawaharlal Nehru Medical College
Women's and Children's Health Research Unit
Belgaum 590010 Karnataka India
Tel: 91-831-2474200
Fax: 91-831-2472891

To the Site Investigator:

Dr. M.B. Bellad
Professor, Department of OBGYN,
KEL University' J N Medical College
Belgaum, 590010 Karnataka India
Tel: 91+94481 24893
Fax: 91-831-2472891

Dr. Shivaprasad S Goudar
Professor, Department of Physiology
KEL University' J N Medical College
Belgaum, 590010 Karnataka India
Tel: 91+94481 26371
Fax: 91-831-2472891

15.0 GENERAL

15.1 Nothing contained in the Agreement is to be deemed or construed to create between the Parties a partnership or joint venture. No Party has the authority to act on behalf of any other Party, or to commit any other Party in any manner at all or cause any other Party's name to be used in any way not specifically authorized by the Agreement.

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

15.2 The Agreement is governed by, and will be construed in accordance with, the laws of British Columbia and the laws of Canada in force in that province, without regard to its conflict of law rules. The Parties agree that by executing the Agreement, they have attorned to the exclusive jurisdiction of the Supreme Court of British Columbia.

15.3 No condoning, excusing, or overlooking by any Party of any default, breach, or non-observance by any other Party at any time or times regarding any terms of the Agreement operates as a waiver of that Party's rights under the Agreement. A waiver of any term or right under the Agreement will be in writing signed by the Party entitled to the benefit of that term or right, and is effective only to the extent set out in the written waiver.

15.4 No exercise of a specific right or remedy by any Party precludes it from or prejudices it in exercising another right or pursuing another remedy or maintaining an action to which it may otherwise be entitled either at law or in equity.

15.5 No right or license is granted under the Agreement by any Party to any other Party either expressly or by implication, except as specifically set out in the Agreement. Nothing contained in the Agreement will impose an obligation of exclusivity on one Party by any other Party. Each Party reserves the right to enter into and participate in other activities (either alone or with a third party), including, but not limited to, clinical trials and other research projects.

15.6 All terms in the Agreement which require performance by the Parties after the expiry or termination of the Agreement will remain in force despite the Agreement's expiry or termination for any reason.

15.7 Part or all of any section of the Agreement that is indefinite, invalid, illegal, or otherwise voidable or unenforceable may be severed from the Agreement, and the balance of the Agreement will continue in full force and effect.

15.8 Each Party will execute and deliver such further agreements and other documents and do such further acts and things as the other Parties reasonably request to evidence, carry out, or give full force and effect to the intent of the Agreement.

15.9 The Agreement and the Schedules set out the entire understanding between the Parties and no changes to the Agreement are binding unless in writing and signed by the Parties to the Agreement. The Parties will be bound by the Schedules, except to the extent that they may conflict with the terms and conditions contained in the Agreement, in which case the terms and conditions of the Agreement will govern.

15.10 The Parties are independent contractors. No Party has the authority to act on behalf of any other Party, or to commit any other Party in any manner at all.

15.11 Each Party acknowledges that it/he/she has been advised by the other Parties to seek independent legal advice with respect to the Agreement and that it/he/she has not relied upon any of the other Parties for any advice, whether legal or otherwise, with respect to the Agreement.

15.12 The Agreement may be executed in counterparts by the Parties, either through original copies or by facsimile or electronically, each of which will be deemed an original and all of which will constitute the same instrument.

15.13 In the Agreement, the term "days" means calendar days, unless otherwise indicated.

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

SIGNED BY THE PARTIES AS AN AGREEMENT and effective as of the Effective Date.

Signed for and on behalf of
THE UNIVERSITY OF BRITISH COLUMBIA
by its authorized signatories:

Signature

Name: MARIO A. KASAPI
Title: Associate Director
University - Industry Liaison Office

Sept. 16, 2013
Date

Signature

Name: J. P. Heale, PhD, MBA
Title: Associate Director
University-Industry Liaison Office

Sept 12/13
Date

Signed for and on behalf of
CHILDREN'S & WOMEN'S HEALTH CENTRE OF BRITISH COLUMBIA BRANCH by its authorized signatory:

Stuart Turvey
Director of Clinical Research
Child & Family Research Institute

Signature

Name: Dr. Michael O'Shaughnessy
Title: Acting Executive Director
CFRI

18 Sept. 2013
Date

PRINCIPAL INVESTIGATOR

Signature

Name: Dr. Peter von Dadelszen

Date

Signed for and on behalf of
KLE UNIVERSITY'S JAWAHARLAL NEHRU MEDICAL COLLEGE, WOMEN'S AND CHILDREN'S HEALTH RESEARCH UNIT BELGAUM
by its authorized signatory:

Signature

Name: Dr. Ashok S. Godhi
Title: Principal

Date

SITE INVESTIGATOR

Signature

Name: Dr. M. B. Bellad
Title: Professor

Date

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

SIGNED BY THE PARTIES AS AN AGREEMENT and effective as of the Effective Date.

Signed for and on behalf of
THE UNIVERSITY OF BRITISH COLUMBIA
by its authorized signatories:

Signature

Name:
Title:

Date

Signature

Name:
Title:

Date

Signed for and on behalf of
CHILDREN'S & WOMEN'S HEALTH CENTRE OF BRITISH COLUMBIA BRANCH
by its authorized signatory:

Signature

Name:
Title:

Date

PRINCIPAL INVESTIGATOR

Signature

Name: Dr. Peter von Dadelszen

September 13/2013
Date

Signed for and on behalf of
KLE UNIVERSITY'S JAWAHARLAL NEHRU MEDICAL COLLEGE, WOMEN'S AND CHILDREN'S HEALTH RESEARCH UNIT BELGAUM
by its authorized signatory:

Signature

Name: Dr. Ashok S. Godhi
Title: Principal

Date

SITE INVESTIGATOR

Signature

Name: Dr. M. B. Bellad
Title: Professor

Date

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

SIGNED BY THE PARTIES AS AN AGREEMENT and effective as of the Effective Date.

Signed for and on behalf of
THE UNIVERSITY OF BRITISH COLUMBIA
by its authorized signatories:

Signature

Name:
Title:

Date

Signature

Name:
Title:

Date

Signed for and on behalf of
CHILDREN'S & WOMEN'S HEALTH CENTRE OF BRITISH COLUMBIA BRANCH by its authorized signatory:

Signature

Name:
Title:

Date

PRINCIPAL INVESTIGATOR

Signature

Name: Dr. Peter von Dadelszen

Date

Signed for and on behalf of
KLE UNIVERSITY'S
JAWAHARLAL NEHRU MEDICAL COLLEGE,
WOMEN'S AND CHILDREN'S HEALTH RESEARCH UNIT BELGAUM
by its authorized signatory:

Signature

Name: Dr. Ashok S. Godhi
Title: Principal

September 21, 2013
Date

SITE INVESTIGATOR

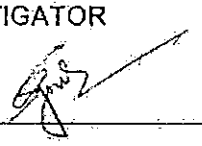
Signature

Name: Dr. M. B. Bellad
Title: Professor

September 21, 2013.
Date

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

SITE INVESTIGATOR



Signature

Name: Dr. Shivaprasad S. Goudar
Title: Professor

September 23, 2013

Date

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

पी.ए.बी.एक्स./PABX : 26588980, 26588707, 26589336, 26589745,
26589873, 26589414
फैक्स/FAX : 011-26588662, 011-26589791, 011-26589258

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

भारतीय आयुर्विज्ञान अनुसंधान परिषद्

INDIAN COUNCIL OF MEDICAL RESEARCH

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

Dr Shalini Singh
Scientist D, Div of RHN
Email: shalinisingh_icmr@yahoo.co.in
Ph : 011-26589493, 9811615561
Fax: 011-26588755

No. 5/7/859/12-RHN
Dated: 27.9.2012

Subject : Project titled "The CLIP (Community Level Interventions for Pre-Eclampsia) Cluster Randomized Controlled Trial".

Dear Dr Bellad,

This is to inform you that the Health Ministry's Screening Committee (HMSC) at Indian Council of Medical Research, New Delhi has approved the above mentioned proposal. However, the pre-conditions indicated by the Govt. of Karnataka in the permission letter may be taken care of by the PI.

With best wishes,

Yours sincerely,

(SHALINI SINGH)
for Director General

Dr MB Bellad,
Prof, Dept of Obst & Gynae
J N Medical College
Belgaum - 590010

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

FIZ - COUSA

SUB-GRANT AGREEMENT (July 16, 2012)

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

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

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

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

The Sub-grant Agreement between the Parties comprises:

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

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

III. Responsibility

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

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

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

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

IV. Financial arrangements

1. Schedule of payments

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

2. Payment of the contribution

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

ACCOUNT DETAILS FOR USD PAYMENT

CORRESPONDENT BANK NAME AND ADDRESS:

BENEFICIARY BANK
NAME AND ADDRESS:

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

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

DEUTSCH BANK TRUST COMPANY AMERICAS NEWYORK

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

ACCOUNT NUMBER: **05043030000042**

3. Utilization of funds and accounting

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

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

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

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
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obligations by SUB-AWARDEE prior to expiration or termination have been fully liquidated, shall be repaid to UBC.

V. Implementation

1. Period of implementation

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

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

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

2. Completion of Deliverables

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

VI. Reporting

1. Technical

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

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

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

2. Financial

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

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

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

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

VII. Audit

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

VIII. Change of SUB-AWARDEE Co-Principal Investigators

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

IX. Acknowledgement

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

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

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

X. Termination

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

XI. Global Access

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

XII. Publications

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

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

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

XIII. Intellectual Property Rights

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

XIV. Data Sharing

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

XV. Human Subjects

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

XVI. Terrorism

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

XVII. Liability

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

XVIII. Independent Contractor

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

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

and shall be deemed to be, an independent contractor and not an agent or employee of the other Party. Neither Party shall have authority to make any statements, representations, nor commitments of any kind, or to take any action, which shall be binding on the other Party, except as may be explicitly provided for herein or authorized by the other Party in writing.

XIX. Assignment

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

XX. Settlement of disputes

Any dispute relating to the interpretation or application of this Agreement shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the Parties, or in the absence of agreement, with the rules of arbitration of the International Chamber of Commerce. The Parties shall accept the arbitral award as final.

XXI. Contact Information

Administrative Contacts

SUB-AWARDEE

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

sgoudar@jnmc.edu; +91 94481 26371

UBC

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

Scientific Contacts

SUB-AWARDEE

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

sgoudar@jnmc.edu; +91 94481 26371

UBC

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

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

July 16, 2012

XXII. Entire Agreement

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

Accepted on behalf of the
The University of British Columbia:

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

Date: July 31/12

By:
Name:
Title:

Date: Aug 2/12

LEGAL APPROVED

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

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

Date: July 20, 2012

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

Date: 20/7/2012

7

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

BT/IN/DBT-MRC/DFID/22/SSG/2015-16
Ministry of Science & Technology
Department of Biotechnology
Government of India

Block 2, 8th Floor
CGO Complex, Lodhi Road
New Delhi 110 003
Dated: 04th March, 2016

ORDER

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

2.0 The Project :

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

2.2 Investigators :

A. Indian Investigators:

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

B. UK Investigators:

a. Professor Andrew Shennan, King's College, London.
b. Dr. Lucy Chappell, Hannah L Nathan, King's College, London.
c. Dr. Adrian Brown, Public Health England, London.

2.3 Project Objectives:

i. The main objective is to reduce (all-cause) maternal mortality and major morbidity by 25% or more, by introducing the Micro life CRADLE Vital Sign Alert (VSA) device, a novel semi-automated vital-sign measuring device, alongside a simple training programme for device-users, to community and facility levels in low- and middle-income countries (LMICs).
ii. This will be achieved in a stepped-wedge randomized controlled trial at eight low-income country areas (Zimbabwe, Zambia (x2 areas), Sierra Leone, Uganda (X2 areas), Haiti, Malawi and Ethiopia), and in one Indian, over 21 months. The primary outcome will be a composite of maternal mortality and major morbidity (one of maternal death, ICU admission, eclampsia, stroke, or hysterectomy, with no double counting).
iii. A secondary objective is to qualitatively evaluate the acceptability, usability and feasibility of the CRADLE device, through one-to-one interviews and observations of healthcare providers (HCPs) using the device.
iv. A third objective will be to evaluate the economic impact of device implementation in these areas, to inform the subsequent scale-up of device implementation.

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

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

2.6 The expenditure for recurring is debitable to:

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

Contd. 2/-

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

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

Recurring:

(Rs. in lakhs)

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

Total Budget of the project = Rs. 72.58 lakhs

***Travel budget would include:**

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

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

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

3.1 A Memorandum of Agreement (MOA) will be signed between the Department of Biotechnology and the grantee institution on Non-Judicial stamp paper Rs. 100/- in the enclosed format and the second release/ installment will be made only after signing of MOA by the grantee institutions and its acceptance by DBT. A format of the MOA is enclosed in Annexure-IV.

3.2 The Institute/ Agency will keep the whole of the grant in a Bank Account earning interest, and the interest so earned should be reported to DBT in the Utilization Certificate and Statement of Expenditure. The interest so earned will be treated as created to the Institute/ Agency and shall be adjusted towards further installment of the grant and or at the time of Final Settlement of Accounts.

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

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

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

Contd. 3/-

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

7. This issues under the powers delegated to this Department and with the concurrence of IFD vide their Dy. No. 102 IFD SANC 1353 2015-2016 dated 02.03.2016.

8. This sanction order has been noted at Serial No. 156 in the Register of Grants

(Dr. Sanjay Kalia)
Scientist 'D'

To

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

Copy to:

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

(Dr. Sanjay Kalia)
Scientist 'D'

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

Annexure – I

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

Manpower-

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

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

BT IN DBT-MRC DPID 22/SSG/2015-16
Ministry of Science & Technology
Department of Biotechnology
Government of India

Block 2, 8th Floor
CGO Complex, Lodhi Road
New Delhi 110 003
Dated: 24 May, 2016

ORDER

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

Recurring Head

(Rs. in lakhs)

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

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

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

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

Name of the Bank	:	Syndicate Bank, K.L.E. University, Jawaharlal Nehru Medical College Campus, Belgaum, Karnataka
Bank A/c No	:	05042170000039
IFSC Code	:	SYNB0000504
MICR Code	:	590025005

4. As per rule 212(1) of GFR, the accounts of all grantee Institutions shall be open to inspection by the sanctioning authority and/

Contd. 2/-

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

5. The expenditure involved is debitable to:

Demand No.79	:	Department of Biotechnology
3425	:	Other Scientific Research (Major Head)
60	:	Others (Sub Major Head)
60.200	:	Assistance to other scientific bodies
60.200.29	:	Biotechnology Research and Development
60.200.29.17	:	Assistance for Research and Development
60.200.29.17.31		Grant in aid General 2016-17 (Plan)

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

7. In case the whole or a part of the amount of the grant-in-aid is being refunded, as an interest at the rate of ten per cent per annum thereon shall be recovered.

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

9. This sanction order has been entered at Serial No. 4/5 in the register of grants.

(Dr. Sanjay Kalia)
Scientist 'D'

To

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

Copy to:

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

(Dr. Sanjay Kalia)
Scientist 'D'

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

BT/IN/DBT-MRC/DFID/22/SSG/2015-16
Ministry of Science & Technology
Department of Biotechnology
Government of India

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

ORDER

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

Recurring Head

(Rs. in lakhs)

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

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

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

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

Name of the Bank	:	Syndicate Bank, K.L.E. University, Jawaharlal Nehru Medical College Campus, Belgaum, Karnataka
Bank A/c No.	:	05042170000039
IFSC Code	:	SYNB0000504
MICR Code	:	590025005

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

Contd. 2/-

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

5. The expenditure involved is debitable to:

Demand No.79	:	Department of Biotechnology
3425	:	Other Scientific Research (Major Head)
60	:	Others (Sub Major Head)
60.200	:	Assistance to other scientific bodies
60.200.29	:	Biotechnology Research and Development
60.200.29.17	:	Assistance for Research and Development
60.200.29.17.31	:	Grant in aid General 2016-17 (Plan)

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

7. In case the whole or a part of the amount of the grant-in-aid is being refunded, as an interest at the rate of ten per cent per annum thereon shall be recovered.

8. This issues under the powers delegated to this Department with the concurrence of IFD, DBT vide their Dy. No. 1024/IFD/SAN/ 199 /2016-2017 dated 26.04.2016.

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

(Dr. Sanjay Kalia)
Scientist 'D'

To

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

Copy to:

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

(Dr. Sanjay Kalia)
Scientist 'D'

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

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

भारतीय आयुर्विज्ञान अनुसंधान परिषद
Indian Council of Medical Research

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

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

Dear Dr Kodkany,

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

With warm regards,

Yours sincerely

(K. Satyanarayana)

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

Tele : (O) 26589258 PABX 26589334, 26589335, 26589336 Extn 286
(R) 25082707 Fax : 26589497

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

पी.ओ.बी.नम्बर/PABX : 26588980, 26588707, 26589036, 26589745,
26589873, 26589414
फैक्स/FAX 011-26588662, 011-26589791, 011-26589258

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

भारतीय आयुर्विज्ञान अनुसंधान परिषद्

INDIAN COUNCIL OF MEDICAL RESEARCH

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

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

No. 5/7/624/11-RHN
Dated: Oct 7th, 2011

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

Dear Dr Kodkany,

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

With warm regards,

Yours sincerely,

(SHALINI SINGH)
for Director General

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

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

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26589873, 26589414
फैक्स/FAX : 011-26588662, 011-26589791, 011-26589358

तार / GRAM : विज्ञापी / SCIENTIFIC
Website : www.icmr.nic.in
E-mail : icmrhqd@ren.nic.in

भारतीय आयुर्विज्ञान अनुसंधान परिषद्
INDIAN COUNCIL OF MEDICAL RESEARCH

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

Dr. Vasantha Thavaraj
DDG(SG)
Division of RHN
Telefax : 011 – 26589356

Fax (work): +91 831 247 2891

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

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

Dear Dr. Goudar,

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

With kind regards,

Yours sincerely,

(Vasantha Thavaraj)

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

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

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

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

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

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

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

Approved.

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

Approved.

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

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

Approved.

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

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

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

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

Approved.

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

SUBCONTRACT
AMENDMENT NUMBER FOUR (4)

Prime Recipient	Subcontractor	
Institution/Organization ("Prime Recipient") Name: Regents of the University of Colorado, a body corporate, for and on behalf of the **University of Colorado Denver** Address: University of Colorado Denver, Office of Grants and Contracts, Anschutz Medical Campus Bldg. 500, W1126, 13001 E 17th Place, Mail Stop F428, Aurora, Colorado 80045	Institution/Organization ("Subcontractor") Name: **Jawaharlal Nehru Medical College** Address: Nehru Nagar, Belgaum Karnataka, India, PIN 590010	
Prime Award No. OPP1055867_YR4	Subcontract No. FY13.040.002	Amount Funded This Action: US$442,578
Prime Recipient's Principal Investigator Nancy Krebs, MD (PI Change)	Amendment No. FY16.115.004 AMD4	Project No. 2-5-81932

This Amendment modifies the following to the Original Terms and Conditions

1. PERIOD

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

2. COMPENSATION

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

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

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

2. PAYMENT

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

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

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

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

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

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

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

SUBCONTRACT
AMENDMENT NUMBER FIVE (5)

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

1. **PERIOD**

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

2. **COMPENSATION**

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

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

3. **PAYMENT**

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

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

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

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

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

4. **REVISED TERM**

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

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

UNIFORM GUIDANCE/FULL FORCE AND EFFECT

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

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

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

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

90

Non-Federal Research Subcontract Amendment

Contractor	Subcontractor
Institution/Organization ("Contractor") **Name:** Regents of the University of Colorado, a body corporate, for and on behalf of the **University of Colorado Denver** **Address:** University of Colorado Denver, Office of Grants and Contracts, Anschutz Medical Campus Bldg. 500, W1126, 13001 E 17th Place, Mail Stop F428, Aurora, Colorado 80045-2571	**Institution/Organization** ("Subcontractor") **Name:** Jawaharlal Nehru Medical College **Address:** Nehru Nagar, Belgaum, Karnataka, India, PIN 590010 Award: OPP1055867
Contractor Principal Investigator: Nancy Krebs, MD	**Subcontractor Principal Investigator:** Dr. Shivaprasad S. Goudar
Amendment No.: FY18.115 011_AMD6	**Subcontract No.:** FY13.040.002 / **Contractor Project No.:** 2-5-81932
Project Title: Implementing Integrated Maternal Nutrition Interventions	
Subcontract Period of Performance: **Budget Period:** Start: 11/1/2017 End: 10/31/2018 **Total Anticipated Project Period:** Start: 12/1/2012 End: 10/31/2018	**Contract Value:** Funding This Action: $ 144,176 (USD) Total Funding to Date: $ 1,767,867 (USD)

Amendment(s) to Original Terms and Conditions

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

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

By an **Authorized Official** of Contractor:

Ryan Holland — Digitally signed by Ryan Holland, DN: cn=Ryan Holland, o=University of Colorado Denver, ou=Office of Grants and Contracts, email=ryan.holland@ucdenver.edu, c=US, Date: 2018.01.04 12:14:03 -07'00'

01/04/18
Date

By an Authorized Official of **Subcontractor:**

4/12/17
Date

Acknowledged by Contractor **Principal Investigator:**

12/14/17
Date

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

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

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

Non-Federal Research Subcontract Amendment

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

Amendment(s) to Original Terms and Conditions

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

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

By an **Authorized Official** of Contractor: Ryan Holland Digitally signed by Ryan Holland DN: cn=Ryan Holland, o=University of Colorado Denver, ou=Office of Grants and Contracts, email=ryan.holland@ucdenver.edu, c=US Date: 2018.10.26 15:58:45 -06'00' 10/26/18 Date	By an Authorized Official of **Subcontractor:** (Dr VKS Mahantshetti) Date 5/10/18
Acknowledged by Contractor **Principal Investigator:** 10-20-18 Date	

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

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

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

Non-Federal Research Subcontract Amendment

Contractor	Subcontractor
Institution/Organization ("Contractor") **Name:** Regents of the University of Colorado, a body corporate, for and on behalf of the **University of Colorado Denver** **Address:** University of Colorado Denver, Office of Grants and Contracts, Anschutz Medical Campus Bldg. 500, W1126, 13001 E 17th Place, Mail Stop F428, Aurora, Colorado 80045-2571	**Institution/Organization** ("Subcontractor") **Name:** Jawaharlal Nehru Medical College **Address:** Nehru Nagar, Belgaum, Karnataka, India, PIN 590010 Award: OPP1055867
Contractor Principal Investigator: Nancy Krebs, MD	**Subcontractor Principal Investigator:** Dr. Shivaprasad S. Goudar
Amendment No.: FY19.115.011 AMD8	**Subcontract No.:** FY13.040.002 / **Contractor Project No.:** 2-5-81932
Project Title: Implementing Integrated Maternal Nutrition Interventions	
Subcontract Period of Performance: **Budget Period:** Start: 11/1/2018 End: 10/31/2019 **Total Anticipated Project Period:** Start: 12/1/2012 End: 10/31/2019	**Contract Value:** Funding This Action: $ 16,100 (USD) Total Funding to Date: $ 1,813,269 (USD)

Amendment(s) to Original Terms and Conditions

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

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

By an Authorized Official of Contractor:

Eric Maize — 4/3/2019
Date

Acknowledged by Contractor **Principal Investigator:**

3/29/19
Date

By an Authorized Official of **Subcontractor:**

(DR. M.S. MANNIKSHETTI) — 28/03/2019
Date

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

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

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

Non-Federal Research Subcontract Amendment

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

Amendment(s) to Original Terms and Conditions

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

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

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

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

World Health Organization

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

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

COVERING LETTER
LETTRE D'ACCOMPAGNEMENT

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

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

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

We are enclosing the Technical Services Agreement between the World Health Organization and PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM (JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM), KARNATAKA, in the amount of INR 12,348,393.12 (Twelve Million Three Hundred Forty-Eight Thousand Three Hundred Ninety-Three), for conducting the above-mentioned work. We also enclose three attachment(s) referenced in the Agreement.

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

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

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

WHO Global Service Centre

Cc: WHO Representative, India

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

Veuillez trouver ci-joint l'Accord de Services Techniques entre l'Organisation Mondiale de la Santé et PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM (JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM), KARNATAKA, pour un montant de INR 12,348,393.12 (Twelve Million Three Hundred Forty-Eight Thousand Three Hundred Ninety-Three), vous permettant de mener à bien le travail susmentionné. Veuillez également trouver three pièces jointes mentionnées dans l'Accord.

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

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

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

Centre de Soutien Administratif Mondial de l'OMS

Cc: Représentant de l'OMS, India

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

98

World Health Organization

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

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

TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

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

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

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

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

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

Summary of work/ *Description sommaire des travaux:*

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

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

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

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

Financial Arrangements/ *Dispositions financiers:*

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

	Deliverable/ Résultat	Due Date/ *Date Remise*	%	Currency Amount/ *Montant en Devise*
1	Upon receipt of countersigned contract	15-JUN-2014	100.00	12,348,393.12
2	Upon receipt financial report	30-NOV-2015	0.00	0.00
3	Upon receipt of technical report	30-NOV-2015	0.00	0.00

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

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

Annexes

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

Annex	File Description/Description de fichier
1	Cover letter for TSA issued for clinical trial from Legal Office
2	Main protocol
3	Project budget

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

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

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

99

World Health Organization

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

WHO Reference/ *Référence OMS*

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

TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

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

General
The parties accept the "General Conditions" overleaf, which constitute an integral part of this Agreement. The Institution certifies the correctness of the banking instructions provided on Page 1.
All necessary arrangements to comply with national regulations relating to this project and relevant to the Institution's responsibilities shall have been under-taken by the Institution; failure to do so will nullify this Agreement. The responsibility of the World Health Organization is limited only to the financial support as specified in this Agreement.

Généralités
Les parties acceptent les "Conditions générales" reproduites au verso, lesquelles font partie intégrante du présent accord. L'Institution certifie l'exactitude des instructions bancaires indiquées à la page 1.
Toutes les dispositions relevant des responsabilités de l'Institution et nécessaires à la mise en conformité de ce Projet avec la réglementation nationale, devront avoir été prises par l'Institution, faute de quoi l'accord sera nul. La responsabilité de l'Organisation Mondiale de la Santé se limite au soutien financier spécifié dans le présent accord.

ON BEHALF OF WHO/ *POUR L'OMS*

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

Mariana Widmer
Technical Officer
HQ/RHR - Reproductive Health and Research

Responsible Divisional Director
Directeur de division responsable

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

Authorized Signatory:
Signataire autorisé:

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

Motohiro Ogita
Coordinator
HQ/GSC Global Service Centre
13-JUN-2014

PRINCIPAL INVESTIGATOR/ *CHERCHEUR PRINCIPAL*

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

Signature : .....
Dr Shivaprasad Goudar

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

Responsible Administrative Authority*
*Autorité administrative responsable**

Signature : .....
Name/*nom* : Dr. A. S. Godhi
Division : .....
Date : 13/06/2014

PRINCIPAL
JNMC, BELGAUM

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

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

100

World Health Organization

COVERING LETTER
LETTRE D'ACCOMPAGNEMENT

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

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

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

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

Re: CHAMPION TRIAL

We are enclosing the Technical Services Agreement between the World Health Organization and PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM (JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM), KARNATAKA, in the amount of USD 302,410.00 (Three Hundred Two Thousand Four Hundred Ten), for conducting the above-mentioned work. We also enclose two attachment(s) referenced in the Agreement.

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

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

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

WHO Global Service Centre

Cc: WHO Representative, India

Concerne: CHAMPION TRIAL

Veuillez trouver ci-joint l'Accord de Services Techniques entre l'Organisation Mondiale de la Santé et PRINCIPAL, J.N. MEDICAL COLLEGE, BELGAUM (JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM), KARNATAKA, pour un montant de USD 302,410.00 (Three Hundred Two Thousand Four Hundred Ten), vous permettant de mener à bien le travail susmentionné. Veuillez également trouver two pièces jointes mentionnées dans l'Accord.

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

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

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

Centre de Soutien Administratif Mondial de l'OMS

Cc: Représentant de l'OMS, India

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

101

World Health Organization

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

WHO Reference/ *Référence OMS*

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

TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

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

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

Principal Investigator: DR.Shivaprasad Goudar
Telephone:
Fax:
Email/Courriel: sgoudar@jnmc.edu

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

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

Summary of work/ *Description sommaire des travaux:*

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

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

Objective: To implement trial A65870 according to GCP guidelines.

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

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

Financial Arrangements/ *Dispositions financiers:*

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

	Deliverable/ Résultat	Due Date/ *Date Remise*	%	Currency Amount/ *Montant en Devise*
1	Countersigned contract	25-JUL-2016	100.00	302,410.00
2	Receipt of final financial report	24-JUL-2017	0.00	0.00
3	Receipt of final technical report	24-JUL-2017	0.00	0.00

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

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

Annexes

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

Annex	File Description/Description de fichier
1	2016/647688 | Contractual - Budget Breakdown |
2	2016/647688 | Contractual - Terms of Reference |

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

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

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

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

102

World Health Organization

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

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

TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

Research Serv.

General
The parties accept the "General Conditions" overleaf, which constitute an integral part of this Agreement. The Institution certifies the correctness of the banking instructions provided on Page 1.
All necessary arrangements to comply with national regulations relating to this project and relevant to the Institution's responsibilities shall have been under-taken by the Institution; failure to do so will nullify this Agreement. The responsibility of the World Health Organization is limited only to the financial support as specified in this Agreement.

Généralités
Les parties acceptent les "Conditions générales" reproduites au verso, lesquelles font partie intégrante du présent accord. L'Institution certifie l'exactitude des instructions bancaires indiquées à la page 1.
Toutes les dispositions relevant des responsabilités de l'Institution et nécessaires à la mise en conformité de ce Projet avec la réglementation nationale, devront avoir été prises par l'Institution, faute de quoi l'accord sera nul. La responsabilité de l'Organisation Mondiale de la Santé se limite au soutien financier spécifié dans le présent accord.

ON BEHALF OF WHO/ *POUR L'OMS*

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

Mariana Widmer
Technical Officer
HQ/RHR - Reproductive Health and Research

Responsible Divisional Director
Directeur de division responsable

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

Authorized Signatory:
Signataire autorisé:

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

Motohiro Ogita
Coordinator
HQ/GSC Global Service Centre
21-JUL-2016

PRINCIPAL INVESTIGATOR/ *CHERCHEUR PRINCIPAL*

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

Signature : .....
DR.Shivaprasad Goudar

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

Responsible Administrative Authority*
*Autorité administrative responsable**

Signature : .....
Name/*nom* : Dr N S MAHANTSHETTI
Division : PRINCIPAL
Date : 22 July 2016

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

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

World Health Organization

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

WHO Reference/ *Référence OMS*

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

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.

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

104

World Health Organization

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

WHO Reference/ *Référence OMS*

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

TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

CONDITIONS GENERALES

Les conditions générales énoncées ci-après s'appliquent au présent Accord sur l'appui de l'OMS aux recherches ou autres services techniques. Cet appui vise à aider une institution à entreprendre pour le compte de l'OMS, des investigations portant sur un problème particulier ou des travaux convenus entre l'institution et l'OMS.

1. INSTITUTION ET CHERCHEUR PRINCIPAL

1.1 L'Institution et le Chercheur principal (ou l'Administrateur technique responsable), lequel doit être employé par l'Institution, sont conjointement responsables de l'ensemble des aspects techniques et administratifs des travaux visés par le présent Accord.

1.2 L'Institution est tenue d'aviser immédiatement l'OMS lorsqu'elle apprend que le Chercheur principal va cesser, ou a cessé, d'être employé par elle, ou bien qu'il ne continue pas à exercer les fonctions visées par le présent Accord. En pareil cas, l'OMS peut:

a. soit annuler le présent Accord;

b. soit accepter de poursuivre le projet sous la conduite d'un nouveau Chercheur principal proposé par l'Institution et approuvé par l'OMS.

2. DISPOSITIONS FINANCIERES

2.1 Des versements seront faits au(x) compte(s) bancaire(s) de l'Institution comme il est stipulé dans le présent Accord et conformément au calendrier qui y figure. Si, après communication du rapport financier final mentionné plus loin au paragraphe 4.3, il apparaît que l'Institution détient un solde non utilisé, ce solde reste payable à l'OMS. En cas d'annulation du présent Accord, quelles qu'en soient les circonstances, l'Institution restituera à l'OMS les sommes non encore engagées. Les sommes fournies en vertu du présent Accord ne pourront être dépensées que conformément aux dispositions dudit Accord.

2.2 Les fonds versés à l'Institution en vertu du présent Accord ne peuvent être utilisés pour verser des émoluments quelconques à un fonctionnaire de l'OMS, couvrir ses frais de voyage ou lui rembourser toute autre dépense.

2.3 Sauf dispositions contraires du présent Accord, ces fonds ne peuvent être utilisés pour couvrir:

a. les dépenses administratives et les frais généraux normaux de l'Institution;

b. le coût de l'entretien, de la réparation, de l'exploitation ou de l'assurance de matériels ou d'appareils existants qui appartiennent à l'Institution;

c. le coût de la construction de nouveaux bâtiments, ou de la transformation ou de la modification de bâtiments et locaux existants;

d. le versement d'un complément de traitement au Chercheur principal.

3. MATERIEL ET FOURNITURES

3.1 Sauf convention contraire, et sous réserve des dispositions de l'alinéa 3.2 ci-après, tout matériel obtenu en vertu du présent Accord sera la propriété de l'Institution. L'Institution et le Chercheur principal seront conjointement responsables du bon état de conservation et d'entretien de tout matériel acquis en application du présent Accord.

3.2 Nonobstant les dispositions de l'alinéa 3.1 ci-dessus et si l'OMS en fait la demande, l'Institution transférera à celle-ci, lors de la résiliation ou de l'expiration du présent Accord les droits de propriété afférents à tout matériel acquis au titre dudit Accord. L'Institution expédiera alors ce matériel vers toute destination que lui aura indiquée l'OMS, les frais d'expédition étant à la charge de cette dernière.

4. RAPPORTS

L'Institution soumettra à l'OMS des rapports techniques et financiers concernant ses travaux, chaque fois qu'il y a lieu et au moins une fois par an, selon les modalités suivantes.

4.1 Les rapports techniques seront établis par le Chercheur principal, envoyés sous couvert du responsable de l'Institution ou de son représentant l'un et l' autre dûment autorisés, et contresignés par eux. Chaque rapport annuel résumera les résultats du projet et en exposera les conclusions positives ou négatives de façon assez détaillée pour permettre d'apprécier la valeur des travaux.

4.2 Les rapports financiers devront être envoyés, après avoir été visés conjointement par le Chef des Services financiers de l'Institution et par le Chercheur principal qui utiliseront à cette fin la formule WHO 782. Les rapports devront indiquer l'utilisation des fonds provenant de l'OMS au regard des prévisions de dépenses initiales dont étaient convenues l'Institution et l'OMS.

4.3 Tous les rapports financiers et techniques sont soumis par l'OMS à une vérification comprenant l'examen de toutes pièces justificatives ainsi que des écritures comptables correspondantes dans les livres de l'Institution. En vue de faciliter l' établissement et la vérification de ces rapports, l'Institution veillera à la tenue de comptes et de registres exacts et systématiques pour tout ce qui concerne le projet. Les rapports techniques et financiers finaux devront être présentés dans les 90 jours suivant l'expiration du présent Accord.

5. RELATIONS ENTRE LES PARTIES ET LEURS RESPONSABILITES

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

6. UTILISATION DES RESULTATS, EXPLOITATION DES DROITS, ET PUBLICATION

6.1 Les résultats du projet financé en vertu du présent Accord pourront être librement utilisés ou divulgués par l'une ou l'autre partie. Toutefois, à défaut de l'assentiment de l'autre partie, les résultats ne pourront être utilisés à des fins commerciales et, s'ils sont susceptibles d'être protégés par des droits de propriété, ils conserveront leur caractère strictement confidentiel. L'Institution communiquera à l'OMS les résultats des recherches, sous forme de savoir-faire et autres

intellectuelle, y compris les droits qui s'attachent au savoir-faire, découlant du projet, devra permettre, dans toute la mesure du possible, d'atteindre les objectifs suivants énoncés par ordre de priorité:

a. mise à la disposition de tous les produits de l' activité créatrice;

b. leur mise à la disposition du secteur de la santé publique, notamment dans les pays en développement à des conditions préférentielles;

c. octroi à chaque partie d'avantages additionnels, y compris sous formes de redevances, compte tenu de la valeur relative de ses contributions financières, intellectuelles et autres.

6.3 Les droits mentionnés plus haut au paragraphe 6.2 seront la propriété de l'Institution, ou du Chercheur principal si l'Institution et l'OMS en conviennent ainsi. Dans la mesure où l'Institution n'entend pas les exercer, les droits seront promptement transmis à l'OMS, si celle-ci le demande. Chaque partie coopérera pleinement avec l'autre pour lui permettre d'exercer effectivement ses droits. La partie détentrice des droits pourra déposer des demandes de propriété industrielle et devra alors remettre à l' autre partie copie de ces dépôts et des autres documents relatifs au brevet. Tous les droits autres que celui de déposer des demandes s'exercent aux termes d'un accord qui sera négocié de bonne foi entre l'Institution et l'OMS.

6.4 Dans aucune de ses publications concernant les résultats du projet, l'Institution ou le Chercheur principal n'attribuera à l'OMS la responsabilité de la direction des travaux. Sauf instructions contraires de l'OMS, toutes les publications comporteront une note indiquant que les recherches qui sont à l'origine des résultats ont reçu un appui financier de l'OMS. A moins qu'un autre chiffre n'ait été stipulé, deux exemplaires ou tirés à part de ces publications seront envoyés à l'OMS et, sauf autorisation expresse, les fonds de l'OMS ne pourront être utilisés pour couvrir les coûts de publication.

7. RECHERCHES IMPLIQUANT L'ETUDE DE SUJETS HUMAINS.

7.1 Aspects déontologiques

Il incombe à l'Institution et au Chercheur principal de s'assurer qu'au cours des travaux financés totalement ou en partie par l'OMS et impliquant l'étude de sujets humains, les droits et la santé de ces derniers soient protégés conformément au code de déontologie ou à la législation du pays, ou, à défaut, à la Déclaration d'Helsinki et aux amendements qui pourraient lui être ultérieurement apportés. Les fonds ne peuvent être utilisés pour financer des recherches que si les conditions suivantes sont remplies:

a. les droits et le bien-être des sujets impliqués sont suffisamment protégés;

b. le consentement libre et éclairé des intéressés a été obtenu;

c. des experts indépendants désignés par l'Institution ont pesé les risques et les avantages potentiels et ont jugé qu'ils s'équilibraient de manière acceptable; et

d. il 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

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

105

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.

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

वी.ए.बी.एक्स./PABX : 26588 [illegible], 26589707, 26589336, 26589745,
26589773, 26589911
फैक्स/FAX : 011-26582662, 011-26589791, 011-26589257

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

भारतीय आयुर्विज्ञान अनुसंधान परिषद्

INDIAN COUNCIL OF MEDICAL RESEARCH

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

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

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

Dear Dr. Kodkany,

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

Placed below are the minutes :

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

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

Approved .

Thanking you,

Yours sincerely,

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

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

FDP Research Subaward Agreement
Amendment (Number 1)

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

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

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

Subaward Period of Performance: Start Date	End Date	Amount Funded This Action	Subaward No
Dec 9, 2017	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	
Name: Timothy Schalley	Date: 2/13/19	Name: Dr. N S Jahantashetti	Date: Feb 9, 2019
Title: Director, Office of Research Administration		Title: Principal, J N Medical College, Belagavi, India	

Dr. V.A.Kothiwale
Registrar
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Attachment 1

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.

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

FDP Cost Reimbursement Research Subaward Agreement

Pass-through Entity (PTE): Thomas Jefferson University	Subrecipient: Jawaharlal Nehru Medical College, KLE
PTE Principal Investigator (PI): Richard Derman, M.D.	Subrecipient Principal Investigator (PI): Dr. Shivaprasad S. Goudar

PTE Federal Award No: 1R21TW010609-01	FAIN: R21TW010609		Federal Awarding Agency: NIH
Federal Award Issue Date: Dec 11, 2017	Total Amount of Federal Award to PTE $ $ 199,846.00	CFDA No: 93.989	CFDA Title: International Research and Research Training

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

Subaward Period of Performance: Start: Dec 9, 2017 End: Nov 30, 2018	Amount Funded This Action: $ ~~$ 46,910.00~~ $ 55,188 (DS)	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 Schalley	Name: Dr N S Mahantashetti
Date: 1/19/18	Date: Jan 13, 2018
Title: Director, Office of Research Administration	Title: Principal, J N Medical College, Belagavi

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

World Health Organization

COVERING LETTER
LETTRE D'ACCOMPAGNEMENT

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

WHO Reference/ *Référence OMS*

WHO Reference	2018/791908-0
Purchase Order	201940772
Unit Reference	

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

TECHNICAL SERVICES AGREEMENT (TSA)

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

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

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

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

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

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

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

World Health Organization

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

WHO Reference/ *Référence OMS*

WHO Reference	2018/791908-0
Purchase Order	201940772
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 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*

Dr. V.A.Kothiwale
Registrar
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World Health Organization

Global Procurement and Logistics
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WHO Reference/ *Référence OMS*

WHO Reference 2018/791908-0
Purchase Order 201940772
Unit Reference

TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

annexes et ceux de l'Accord, les dispositions de l'Accord prévaudront dans tous les cas

General
The parties accept the "General Conditions" overleaf, which constitute an integral part of this Agreement. The institution certifies the correctness of the banking instructions provided on Page 1.
All necessary arrangements to comply with national regulations relating to this project and relevant to the Institution's responsibilities shall have been under-taken by the Institution; failure to do so will nullify this Agreement. The responsibility of the World Health Organization is limited only to the financial support as specified in this Agreement.

Généralités
Les parties acceptent les "Conditions générales" reproduites au verso, lesquelles font partie intégrante du présent accord. L'Institution certifie l'exactitude des instructions bancaires indiquées à la page 1.
Toutes les dispositions relevant des responsabilités de l'Institution et nécessaires à la mise en conformité de ce Projet avec la réglementation nationale, devront avoir été prises par l'Institution, faute de quoi l'accord sera nul. La responsabilité de l'Organisation Mondiale de la Santé se limite au soutien financier spécifié dans le présent accord

ON BEHALF OF WHO/ *POUR L'OMS*

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

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

Responsible Divisional Director
Directeur de division responsable

Ian ASKEW
Director
HQ/RHR - Reproductive Health and Research

Authorized Signatory
Signataire autorisé

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

Fauziah Binti Ahmad
National Professional Officer (Procurement)
HQ/GSC Global Service Centre
02-MAR-2018

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.*

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

World Health Organization

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and Logistics
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WHO Reference/ *Référence OMS*

WHO Reference	2018/791908-0
Purchase Order	201940772
Unit Reference	

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.

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

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gcc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Reference 2018/791908-0
Purchase Order 201940772
Unit Reference

TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

CONDITIONS GENERALES

Les conditions générales énoncées ci-après s'appliquent au présent Accord sur l'appui de l'OMS aux recherches ou autres services techniques. Cet appui vise à aider une institution à entreprendre pour le compte de l'OMS, des investigations portant sur un problème particulier ou des travaux convenus entre l'Institution et l'OMS.

1. INSTITUTION ET CHERCHEUR PRINCIPAL

1.1 L'Institution et le Chercheur principal (ou l'Administrateur technique responsable), lequel doit être employé par l'Institution, sont conjointement responsables de l'ensemble des aspects techniques et administratifs des travaux visés par le présent Accord.

1.2 L'Institution est tenue d'aviser immédiatement l'OMS lorsqu'elle apprend que le Chercheur principal va cesser, ou a cessé, d'être employé par elle, ou bien qu'il ne continue pas à exercer les fonctions visées par le présent Accord. En pareil cas, l'OMS peut:

a. soit annuler le présent Accord;

b. soit accepter de poursuivre le projet sous la conduite d'un nouveau Chercheur principal proposé par l'Institution et approuvé par l'OMS.

2. DISPOSITIONS FINANCIERES

2.1 Des versements seront faits au(x) compte(s) bancaire(s) de l'Institution comme il est stipulé dans le présent Accord et conformément au calendrier qui y figure. Si, après communication du rapport financier final mentionné plus loin au paragraphe 4.3, il apparaît que l'Institution détient un solde non utilisé, ce solde reste payable à l'OMS. En cas d'annulation du présent Accord, quelles qu'en soient les circonstances, l'Institution restituera à l'OMS les sommes non encore engagées. Les sommes fournies en vertu du présent Accord ne pourront être dépensées que conformément aux dispositions dudit Accord.

2.2 Les fonds versés à l'Institution en vertu du présent Accord ne peuvent être utilisés pour verser des émoluments quelconques à un fonctionnaire de l'OMS, couvrir ses frais de voyage ou lui rembourser toute autre dépense.

2.3 Sauf dispositions contraires du présent Accord, ces fonds ne peuvent être utilisés pour couvrir:

a. les dépenses administratives et les frais généraux normaux de l'Institution;

b. le coût de l'entretien, de la réparation, de l'exploitation ou de l'assurance de matériels ou d'appareils existants qui appartiennent à l'Institution;

c. le coût de la construction de nouveaux bâtiments, ou de la transformation ou de la modification de bâtiments et locaux existants;

d. le versement d'un complément de traitement au Chercheur principal.

3. MATERIEL ET FOURNITURES

3.1 Sauf convention contraire, et sous réserve des dispositions de l'alinéa 3.2 ci-après, tout matériel obtenu en vertu du présent Accord sera la propriété de l'Institution. L'Institution et le Chercheur principal seront conjointement responsables du bon état de conservation et d'entretien de tout matériel acquis en application du présent Accord.

3.2 Nonobstant les dispositions de l'alinéa 3.1 ci-dessus et si l'OMS en fait la demande, l'Institution transférera à celle-ci, lors de la résiliation ou de l'expiration du présent Accord les droits de propriété afférents à tout matériel acquis au titre dudit Accord. L'Institution expédiera alors ce matériel vers toute destination que lui aura indiquée l'OMS, les frais d'expédition étant à la charge de cette dernière.

4. RAPPORTS

L'Institution soumettra à l'OMS des rapports techniques et financiers concernant ses travaux, chaque fois qu'il y a lieu et au moins une fois par an, selon les modalités suivantes.

4.1 Les rapports techniques seront établis par le Chercheur principal, envoyés sous couvert du responsable de l'Institution ou de son représentant l'un et l' autre dûment autorisés, et contresignés par eux. Chaque rapport annuel résumera les résultats du projet et en exposera les conclusions positives ou négatives de façon assez détaillée pour permettre d'apprécier la valeur des travaux.

4.2 Les rapports financiers devront être envoyés, après avoir été visés conjointement par le Chef des Services financiers de l'Institution et par le Chercheur principal qui utiliseront à cette fin la formule WHO 782. Les rapports devront indiquer l'utilisation des fonds provenant de l'OMS au regard des prévisions de dépenses initiales dont étaient convenues l'Institution et l'OMS.

4.3 Tous les rapports financiers et techniques sont soumis par l'OMS à une vérification comprenant l'examen de toutes pièces justificatives ainsi que des écritures comptables correspondantes dans les livres de l'Institution. En vue de faciliter l' établissement et la vérification de ces rapports, l'Institution veillera à la tenue de comptes et de registres exacts et systématiques pour tout ce qui concerne le projet. Les rapports techniques et financiers finaux devront être présentés dans les 90 jours suivant l'expiration du présent Accord.

5. RELATIONS ENTRE LES PARTIES ET LEURS RESPONSABILITES

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

6. UTILISATION DES RESULTATS, EXPLOITATION DES DROITS, ET PUBLICATION

6.1 Les résultats du projet financé en vertu du présent Accord pourront être librement utilisés ou divulgués par l'une ou l'autre partie. Toutefois, à défaut de l'assentiment de l'autre partie, les résultats ne pourront être utilisés à des fins commerciales et, s'ils sont susceptibles d'être protégés par des droits de propriété, ils conserveront leur caractère strictement confidentiel. L'Institution communiquera à l'OMS les résultats des recherches, sous forme de savoir-faire et autres intellectuelle, y compris les droits qui s'attachent au savoir-faire, découlant du projet, devra permettre, dans toute la mesure du possible, d'atteindre les objectifs suivants énoncés par ordre de priorité:

a. mise à la disposition de tous les produits de l' activité créatrice;

b. leur mise à la disposition du secteur de la santé publique, notamment dans les pays en développement à des conditions préférentielles;

c. octroi à chaque partie d'avantages additionnels, y compris sous formes de redevances, compte tenu de la valeur relative de ses contributions financières, intellectuelles et autres.

6.3 Les droits mentionnés plus haut au paragraphe 6.2 seront la propriété de l'Institution, ou du Chercheur principal si l'Institution et l'OMS en conviennent ainsi. Dans la mesure où l'Institution n'entend pas les exercer, les droits seront promptement transmis à l'OMS, si celle-ci le demande. Chaque partie coopérera pleinement avec l'autre pour lui permettre d'exercer effectivement ses droits. La partie détentrice des droits pourra déposer des demandes de propriété industrielle et devra alors remettre à l' autre partie copie de ces dépôts et des autres documents relatifs au brevet. Tous les droits autres que celui de déposer des demandes s'exercent aux termes d'un accord qui sera négocié de bonne foi entre l'Institution et l'OMS.

6.4 Dans aucune de ses publications concernant les résultats du projet, l'Institution ou le Chercheur principal n'attribuera à l'OMS la responsabilité de la direction des travaux. Sauf instructions contraires de l'OMS, toutes les publications comporteront une note indiquant que les recherches qui sont à l'origine des résultats ont reçu un appui financier de l'OMS. A moins qu'un autre chiffre n'ait été stipulé, deux exemplaires ou tirés à part de ces publications seront envoyés à l'OMS et, sauf autorisation expresse, les fonds de l'OMS ne pourront être utilisés pour couvrir les coûts de publication.

7. RECHERCHES IMPLIQUANT L'ETUDE DE SUJETS HUMAINS.

7.1 Aspects déontologiques

Il incombe à l'Institution et au Chercheur principal de s'assurer qu'au cours des travaux financés totalement ou en partie par l'OMS et impliquant l'étude de sujets humains, les droits et la santé de ces derniers soient protégés conformément au code de déontologie ou à la législation du pays, ou, à défaut, à la Déclaration d'Helsinki et aux amendements qui pourraient lui être ultérieurement apportés. Les fonds ne peuvent être utilisés pour financer des recherches que si les conditions suivantes sont remplies.

a. les droits et le bien-être des sujets impliqués sont suffisamment protégés;

b. le consentement libre et éclairé des intéressés a été obtenu;

c. des experts indépendants désignés par l'Institution ont pesé les risques et les avantages potentiels et ont jugé qu'ils s'équilibraient de manière acceptable; et

d. il ait satisfait à toute exigence particulière de la réglementation nationale.

7.2 Dispositions réglementaires

Il incombe à l'Institution et au Chercheur principal de respecter la réglementation nationale relative aux recherches impliquant l'étude de sujets humains.

7.3 Protection des sujets d'expérience

Sans préjudice des obligations qui lui incombent aux termes des lois en vigueur, l'Institution prendra des mesures appropriées en vue d'éliminer ou d'atténuer les conséquences des expériences pour les sujets ou leur famille en cas de décès, de traumatisme ou de maladie résultant de la conduite des recherches mentionnées au paragraphe 7.1. Ces mesures comprendront, dans la mesure du possible, un traitement médical et un dédommagement financier. L'Institution et le Chercheur principal s'engagent à protéger le caractère confidentiel des informations qui pourraient permettre d'identifier les sujets impliqués dans les études effectuées en vertu du présent Accord.

8. RECHERCHES IMPLIQUANT L'UTILISATION D'ANIMAUX DE LABORATOIRE

L'Institution s'engage à veiller à ce que les animaux vertebrés 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

Dr. V.A Kothiwale
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115

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WHO Reference/ *Référence OMS*

WHO Reference	2018/791908-0
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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.

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

World Health Organization

COVERING LETTER
LETTRE D'ACCOMPAGNEMENT

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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

9-1-2019

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

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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

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

118

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 responsabilites 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.

Oluferni Tanwo 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'execution du projet.

Signature : .....
DR.Shivaprasad Goudar 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 * BELAGAVI * JNMC MEDICAL COLLEGE

* 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.*

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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 from 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/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

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120

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

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

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

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

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

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.

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121

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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 allouées 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 ses 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 récapitulera les résultats du projet et en exposera les conclusions positives ou négatives de façon assez détaillée pour permettre d'apprécier la valeur des travaux.

4.2 Les rapports financiers devront être envoyés, après avoir été visés conjointement par le Chef des Services financiers de l'Institution et par le Chercheur principal, les rapports devront indiquer l'utilisation des fonds provenant de l'OMS au regard des prévisions de dépenses initiales dont avaient convenu l'Institution et l'OMS.

4.3 L'OMS peut demander qu'un examen ou un audit de type financier et opérationnel du projet et des activités y afférentes soit effectué par l'OMS et/ou par des parties autorisées par l'OMS, et l'Institution s'engage à faciliter cet examen ou cet audit. Cet examen ou cet audit peut être effectué à tout moment pendant la mise en œuvre du projet ou liée au présent Accord ou dans les cinq ans suivant son achèvement. L'Institution permettra à l'OMS et/ou aux parties autorisées par celle-ci sans restriction:

(a) de consulter ses livres, archives et systèmes (y compris l'ensemble des

(a) les droits et le bien-être des sujets impliqués sont protégés comme il convient;

(b) le consentement libre et éclairé des intéressés a été obtenu;

(c) un groupe d'experts indépendants désignés par l'Institution ont pesé les risques et les avantages potentiels et ont jugé qu'ils s'équilibraient de manière acceptable; et

(d) toute exigence particulière de la réglementation nationale a été satisfaite.

8.2 Dispositions réglementaires

Il incombe à l'Institution et au Chercheur principal de respecter la réglementation nationale relative aux recherches impliquant l'étude de sujets humains.

8.3 Protection des sujets d'expérience

Sans préjudice des obligations qui lui incombent aux termes des lois en vigueur, l'Institution prendra des dispositions appropriées en vue d'éliminer ou d'atténuer les conséquences des expériences pour les sujets ou leur famille en cas de décès, de traumatisme ou de maladie résultant de la conduite des recherches mentionnées au paragraphe 8.1. Ces dispositions comprendront dans la mesure du possible un traitement médical et un dédommagement financier. L'Institution et le Chercheur principal s'engagent à protéger le caractère confidentiel des informations qui pourraient permettre d'identifier les sujets impliqués dans les études effectuées en vertu du présent Accord.

9. RECHERCHES IMPLIQUANT L'UTILISATION D'ANIMAUX DE LABORATOIRE

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

10. SECURITE DES RECHERCHES

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

11. RESPECT DES POLITIQUES DE L'OMS

En signant le présent Accord, l'Institution et le Chercheur principal reconnaissent avoir lu les politiques de l'OMS (telles que définies ci-après) et, par les présentes, acceptent ces politiques et conviennent de s'y conformer. En lien avec ce qui précède, l'Institution et le Chercheur principal prendront les mesures appropriées afin de prévenir et répondre à toute violation des normes de conduite, telles que décrites dans les politiques de l'OMS, par les employés de l'Institution ou toute autre personne que l'Institution et/ou le Chercheur principal aura engagée en vue de fournir un quelconque service au titre du présent Accord. Sans limiter la portée de ce qui précède, l'Institution et le Chercheur principal signaleront immédiatement à l'OMS, conformément aux dispositions des politiques de l'OMS applicables, toute violation réelle ou présumée dont ils ont connaissance concernant toute politique de l'OMS. Aux fins du présent Accord, l'expression « politiques de l'OMS » désigne, collectivement:

(a) le Code d'éthique et de déontologie de l'OMS;

(b) la Politique de l'OMS relative à la prévention et à la lutte contre l'exploitation et les abus sexuels;

(c) le Code de conduite pour une recherche responsable;

(d) la Politique de l'OMS sur le signalement des actes répréhensibles et la protection contre les représailles; et

(e) le Code de conduite des fournisseurs des Nations Unies, y compris leurs modifications éventuelles et qui sont publiquement accessibles sur le site internet de l'OMS aux liens suivants: http://www.who.int/about/finances-accountability/procurement/en/ (pour ce qui est du Code de conduite des fournisseurs des Nations Unies) et http://www.who.int/about/ethics/en/ (pour ce qui est des autres politiques de l'OMS).

12. TOLERANCE ZERO POUR L'EXPLOITATION ET LES ABUS SEXUELS

L'OMS applique la tolérance zéro en matière d'exploitation et d'abus sexuels. À cet égard, et sans limiter la portée de toute autre disposition du présent Accord, l'Institution garantit:

(a) qu'elle prendra toutes les mesures raisonnables et appropriées pour prévenir tout acte d'exploitation ou d'abus sexuels tels que décrits dans la Politique de l'OMS relative à la prévention et à la lutte contre l'exploitation et les abus sexuels, par l'un quelconque de ses employés et toute autre personne engagée par elle en vue de fournir un quelconque service au titre du présent Accord; et

(b) qu'elle signalera immédiatement à l'OMS et donnera suite à toute violation réelle ou présumée de cette Politique dont elle a connaissance, conformément aux dispositions de la Politique; et

- le Chercheur principal garantit:

(a) qu'il n'adoptera aucun comportement qui relèverait de l'exploitation ou l'abus sexuels tels que décrits dans la Politique de l'OMS relative à la prévention et à la lutte contre l'exploitation et les abus sexuels; et

(b) qu'il signalera immédiatement à l'OMS toute violation réelle ou présumée de la Politique dont il a connaissance, conformément aux dispositions de la Politique.

13. DECLARATION RELATIVE A L'INDUSTRIE DU TABAC/DE L'ARMEMENT

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

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

122

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	2019/928926-0
Purchase Order	202319732
Unit Reference	A65913

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

5. RELATIONS ENTRE LES PARTIES ET LEURS RESPONSABILITES

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

6. UTILISATION DES RESULTATS, EXPLOITATION DES DROITS

6.1 Les résultats du projet financé en vertu du présent Accord pourront être librement utilisés ou divulgués par l'une ou l'autre partie. Toutefois à défaut de 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 la 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'exerceront 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 se fera conformément à la politique de l'OMS en matière de libre accès, qui peut être consultée à l'adresse suivante : http://www.who.int/about/policy/fr/
7.3 Dans aucune de ses publications concernant les résultats du projet, l'Institution ou le Chercheur principal n'attribuera à l'OMS la responsabilité de la direction des travaux. Sauf instructions contraires de l'OMS, toutes les publications comporteront une note indiquant que les recherches qui sont à l'origine des résultats ont reçu un appui financier de l'OMS. A moins qu'un autre chiffre n'ait été stipulé, deux exemplaires ou tirages de chaque publication seront envoyés à l'OMS. Seul 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 utiliserait 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.

9/7/2019

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

123

World Health Organization

COVERING LETTER
LETTRE D'ACCOMPAGNEMENT

Global Procurement and Logistics
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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

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

World Health Organization

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TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

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

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

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

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 |
Unit 5	2017/716530 | Contractual - Statement of Work |

12/5/2017
Research Co-Ordinator
J.N.M.C. Belgaum & Christ
Head, Rese...
J.N. Medical College, BELAGAVI

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.*

J.N. MEDICAL COLLEGE BELAGAVI
Dr. V.A. Pothiwale Principal/Registrar
JNMC, BELAGAVI
12/5/2017

KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
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WHO Reference/ *Référence OMS*

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

TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

General

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

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

Généralités

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

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

ON BEHALF OF WHO/ *POUR L'OMS*

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

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

Responsible Divisional Director
Directeur de division responsable

Flavia BUSTREO
Assi 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 Cherchour principal - ayant pleins pouvoirs pour passer un contrat au nom de l'institution.*

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

126

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MALAYSIA
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TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

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.

22/5/2017
Research Co-Ordinator
JNMC ... Children's
... Technical Services Agreement
J.N. Medical College, BELAGAVI.

J.N. MEDICAL COLLEGE BELAGAVI

12/5/2017
PDr. V. A. Kothiwale
JNMC, BELAGAVI.
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

World Health Organization

TECHNICAL SERVICES AGREEMENT

ACCORD DE SERVICES TECHNIQUES

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WHO Reference/ *Référence OMS*	
WHO Reference	2017/716530-0
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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

1. INSTITUTION ET CHERCHEUR PRINCIPAL

1.1 L'Institution et le Chercheur principal (ou l'Administrateur technique responsable), lequel doit être employé par l'Institution, sont conjointement responsables de l'ensemble des aspects techniques et administratifs des travaux visés par le présent Accord.

1.2 L'Institution est tenue d'aviser immédiatement l'OMS lorsqu'elle apprend que le Chercheur principal va cesser, ou a cessé, d'être employé par elle, ou bien qu'il ne continue pas à exercer les fonctions visées par le présent Accord. En pareil cas, l'OMS peut.

a. soit annuler le présent Accord;

b. soit accepter de poursuivre le projet sous la conduite d'un nouveau Chercheur principal proposé par l'Institution et approuvé par l'OMS.

2. DISPOSITIONS FINANCIERES

2.1 Des versements seront faits au(x) compte(s) bancaire(s) de l'Institution comme il est stipulé dans le présent Accord et conformément au calendrier qui y figure. Si, après communication du rapport financier final mentionné plus loin au paragraphe 4.3, il apparaît que l'Institution détient un solde non utilisé, ce solde reste payable à l'OMS. En cas d'annulation du présent Accord, quelles qu'en soient les circonstances, l'Institution restituera à l'OMS les sommes non encore engagées. Les sommes fournies en vertu du présent Accord ne pourront être dépensées que conformément aux dispositions dudit Accord.

2.2 Les fonds versés à l'Institution en vertu du présent Accord ne peuvent être utilisés pour verser des émoluments quelconques à un fonctionnaire de l'OMS, couvrir ses frais de voyage ou lui rembourser toute autre dépense

2.3 Sauf dispositions contraires du présent Accord, ces fonds ne peuvent être utilisés pour couvrir

a. les dépenses administratives et les frais généraux normaux de l'Institution,

b. le coût de l'entretien, de la réparation, de l'exploitation ou de l'assurance de matériels ou d'appareils existants qui appartiennent à l'Institution;

c. le coût de la construction de nouveaux bâtiments, ou de la transformation ou de la modification de bâtiments et locaux existants;

d. le versement d'un complément de traitement au Chercheur principal

3. MATERIEL ET FOURNITURES

3.1 Sauf convention contraire, et sous réserve des dispositions de l'alinéa 3.2 ci-après, tout matériel obtenu en vertu du présent Accord sera la propriété de l'Institution. L'Institution et le Chercheur principal seront conjointement responsables du bon état de conservation et d'entretien de tout matériel acquis en application du présent Accord.

3.2 Nonobstant les dispositions de l'alinéa 3.1 ci-dessus et si l'OMS en fait la demande, l'Institution transférera à celle-ci, lors de la résiliation ou de l'expiration du présent Accord les droits de propriété afférents à tout matériel acquis au titre dudit Accord. L'Institution expédiera alors ce matériel vers toute destination que lui aura indiquée l'OMS, les frais d'expédition étant à la charge de cette dernière

4. RAPPORTS

L'Institution soumettra à l'OMS des rapports techniques et financiers concernant ses travaux, chaque fois qu'il y a lieu et au moins une fois par an, selon les modalités suivantes.

4.1 Les rapports techniques seront établis par le Chercheur principal, envoyés sous couvert du responsable de l'Institution ou de son représentant l'un et l'autre dûment autorisés, et contresignés par eux. Chaque rapport annuel résumera les résultats du projet et en exposera les conclusions positives ou négatives de façon assez détaillée pour permettre d'apprécier la valeur des travaux.

4.2 Les rapports financiers devront être envoyés, après avoir été visés conjointement par le Chef des Services financiers de l'Institution et par le Chercheur principal qui utiliseront à cette fin la formule WHO 782. Les rapports devront indiquer l'utilisation des fonds provenant de l'OMS au regard des prévisions de dépenses initiales dont étaient convenues l'Institution et l'OMS.

4.3 Tous les rapports financiers et techniques sont soumis par l'OMS à une vérification comprenant l'examen de toutes pièces justificatives ainsi que des écritures comptables correspondantes dans les livres de l'Institution. En vue de faciliter l' établissement et la vérification de ces rapports, l'Institution veillera à la tenue de comptes et de registres exacts et systématiques pour tout ce qui concerne le projet. Les rapports techniques et financiers finaux devront être présentés dans les 90 jours suivant l'expiration du présent Accord.

5. RELATIONS ENTRE LES PARTIES ET LEURS RESPONSABILITES

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

6. UTILISATION DES RESULTATS, EXPLOITATION DES DROITS, ET PUBLICATION

6.1 Les résultats du projet financé en vertu du présent Accord pourront être librement utilisés ou divulgués par l'une ou l'autre partie. Toutefois, à défaut de l'assentiment de l'autre partie, les résultats ne pourront être utilisés à des fins commerciales et, s'ils sont susceptibles d'être protégés par des droits de propriété, ils conserveront leur caractère strictement confidentiel. L'Institution communiquera à l'OMS les résultats des recherches, sous forme de savoir-faire et autres.

intellectuelle, y compris les droits qui s'attachent au savoir-faire, découlant du projet, devra permettre, dans toute la mesure du possible, d'atteindre les objectifs suivants énoncés par ordre de priorité:

a. mise à la disposition de tous les produits de l' activité créatrice;

b. leur mise à la disposition du secteur de la santé publique, notamment dans les pays en développement à des conditions préférentielles;

c. octroi à chaque partie d'avantages additionnels, y compris sous formes de redevances, compte tenu de la valeur relative de ses contributions financières, intellectuelles et autres.

6.3 Les droits mentionnés plus haut au paragraphe 6.2 seront la propriété de l'Institution, ou du Chercheur principal si l'Institution et l'OMS en conviennent ainsi. Dans la mesure où l'Institution n'entend pas les exercer, les droits seront promptement transmis à l'OMS, si celle-ci le demande. Chaque partie coopérera pleinement avec l'autre pour lui permettre d'exercer effectivement ses droits. La partie détentrice des droits pourra déposer des demandes de propriété industrielle et devra alors remettre à l' autre partie copie de ces dépôts et des autres documents relatifs au brevet. Tous les droits autres que celui de déposer des demandes s'exercent aux termes d'un accord qui sera négocié de bonne foi entre l'Institution et l'OMS

6.4 Dans aucune de ses publications concernant les résultats du projet, l'Institution ou le Chercheur principal n'attribuera à l'OMS la responsabilité de la direction des travaux. Sauf instructions contraires de l'OMS, toutes les publications comporteront une note indiquant que les recherches qui sont à l'origine des résultats ont reçu un appui financier de l'OMS. A moins qu'un autre chiffre n'ait été stipulé, deux exemplaires ou tirés à part de ces publications seront envoyés à l'OMS et, sauf autorisation expresse, les fonds de l'OMS ne pourront être utilisés pour couvrir les coûts de publication.

7. RECHERCHES IMPLIQUANT L'ETUDE DE SUJETS HUMAINS.

7.1 Aspects déontologiques

Il incombe à l'Institution et au Chercheur principal de s'assurer qu'au cours des travaux financés totalement ou en partie par l'OMS et impliquant l'étude de sujets humains, les droits et la santé de ces derniers soient protégés conformément au code de déontologie ou à la législation du pays, ou, à défaut, à la Déclaration d'Helsinki et aux amendements qui pourraient lui être ultérieurement apportés. Les fonds ne peuvent être utilisés pour financer des recherches que si les conditions suivantes sont remplies

a. les droits et le bien-être des sujets impliqués sont suffisamment protégés;

b. le consentement libre et éclairé des intéressés a été obtenu,

c. des experts indépendants désignés par l'Institution ont pesé les risques et les avantages potentiels et ont jugé qu'ils s'équilibraient de manière acceptable; et

d. il ait satisfait à toute exigence particulière de la réglementation nationale.

7.2 Dispositions réglementaires

Il incombe à l'Institution et au Chercheur principal de respecter la réglementation nationale relative aux recherches impliquant l'étude de sujets humains.

7.3 Protection des sujets d'expérience

Sans préjudice des obligations qui lui incombent aux termes des lois en vigueur, l'Institution prendra des mesures appropriées en vue d'éliminer ou d'atténuer les conséquences des expériences pour les sujets ou leur famille en cas de décès, de traumatisme ou de maladie résultant de la conduite des recherches mentionnées au paragraphe 7.1. Ces mesures comprendront, dans la mesure du possible, un traitement médical et un dédommagement financier. L'Institution et le Chercheur principal s'engagent à protéger le caractère confidentiel des informations qui pourraient permettre d'identifier les sujets impliqués dans les études effectuées en vertu du présent Accord.

8. RECHERCHES IMPLIQUANT L'UTILISATION D'ANIMAUX DE LABORATOIRE

L'Institution s'engage à veiller à ce que les animaux vertébrés vivants qu'il sera nécessaire d'utiliser comme animaux de laboratoire pour des recherches entreprises en vertu du présent Accord soient traités conformément aux principes universellement reconnus qui veulent que l'on épargne à ces animaux toute souffrance inutile.

9. SECURITE DES RECHERCHES

Il incombe à l'Institution d'arrêter et d'appliquer des politiques et pratiques préservant et garantissant la sécurité de ses employés et du public ainsi que celle de l' environnement pendant les recherches soutenues par l'OMS. Si les travaux impliquent l'utilisation de substances biologiques dangereuses, l'Institution établira et appliquera un plan de sécurité approprié,

10. PUBLICITE

L'Institution et le Chercheur principal ne pourront faire mention, dans un quelconque écrit ou déclaration à caractère publicitaire ou promotionnel diffusé à des fins commerciales, ou en vue d'un avantage financier, du lien existant entre l'OMS et le projet ou les produits ou procédés en découlant.

11. REGLEMENT DES LITIGES

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

12. PRIVILÈGES ET IMMUNITÉS

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

Co-Ordinator
...en's
J.N. Medical College, BELAGAVI.

Dr. V.A. Kothiwale
Principal
Registrar, BELAGAVI
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2/5/2017

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WHO Reference/ *Référence OMS*

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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

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

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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130

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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Belagavi-590 010,Karnataka

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

Dr. V.A. Kothiwale
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(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Belagavi-590 010, Karnataka

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 Insutution 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.

Dr. V.A.Kothiwale
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(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

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

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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Belagavi-590 010,Karnataka

135

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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Belagavi-590 010,Karnataka

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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Belagavi-590 010, Karnataka

137

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INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

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 Stamp Duty Paid
Jayan

.....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 the Certificate and as available on the website renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

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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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Belagavi-590 010,Karnataka

139

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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Belagavi-590 010,Karnataka

140

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.

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

141

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 on 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.

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

142

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: 15/10/16

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: 21/10/2016

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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Belagavi-590 010,Karnataka

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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Belagavi-590 010,Karnataka

144

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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Belagavi-590 010,Karnataka

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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146

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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Belagavi-590 010,Karnataka

148

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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149

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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Belagavi-590 010,Karnataka

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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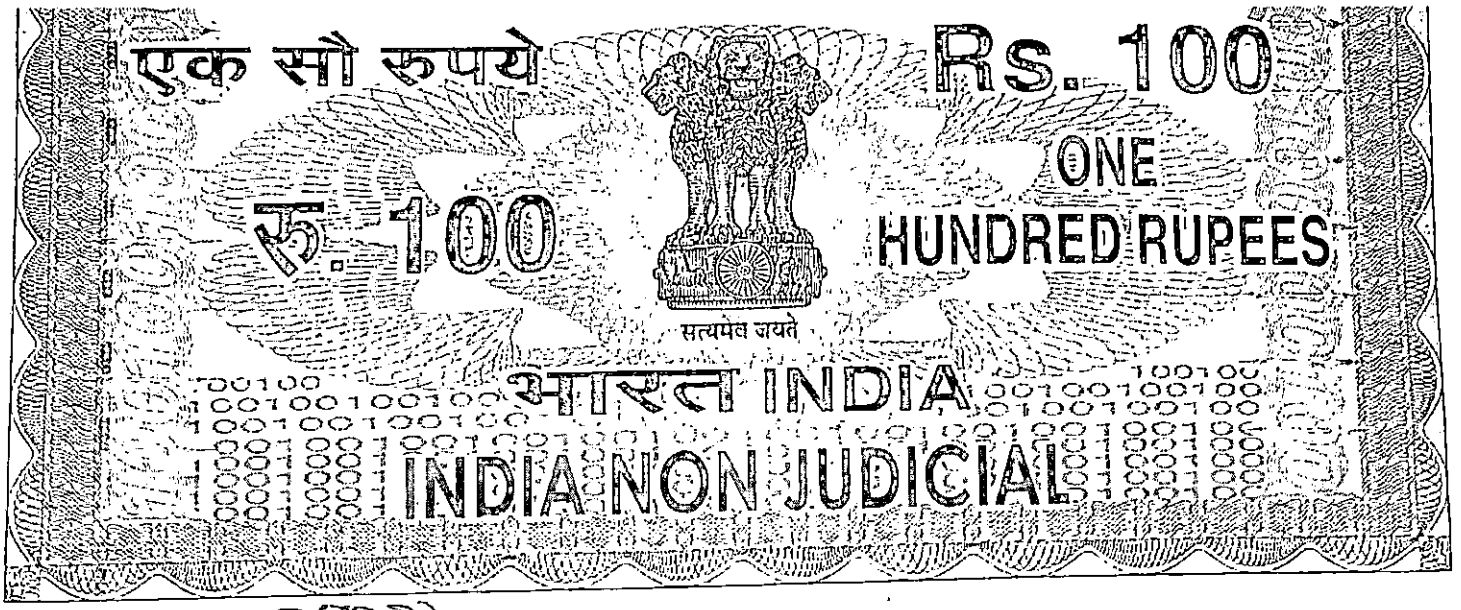

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12 JAN 2017

શૈલેષકુમાર વાસુદેવભાઈ ત્રિવેદી

લા. નં.:- એસ. બી.- ૬૩/૧૯૯૬

અમદાવાદ-સીટી સીવીલ કોર્ટના રાણાંદી

લેનાર ની સહીઃ

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

Confidential

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153

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, investo 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 Honade**

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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 compromis... 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.

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

Study prior to termination. Within ninety (90) days ... any termination, the Institution and the Principal Investigator shall provide to the Sponsor 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

Confidential

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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/ [illegible]

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

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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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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.

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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

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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

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

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 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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171

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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174

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: 15/10/16

ACKNOWLEDGED AND AGREED BY KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre :

By:

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:

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, 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.

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 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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177

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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178

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. eDiaries and Tablet Return

Section 1: 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.

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.

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182

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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184

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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PACE

THE ADVANTAGE OF FOCUS

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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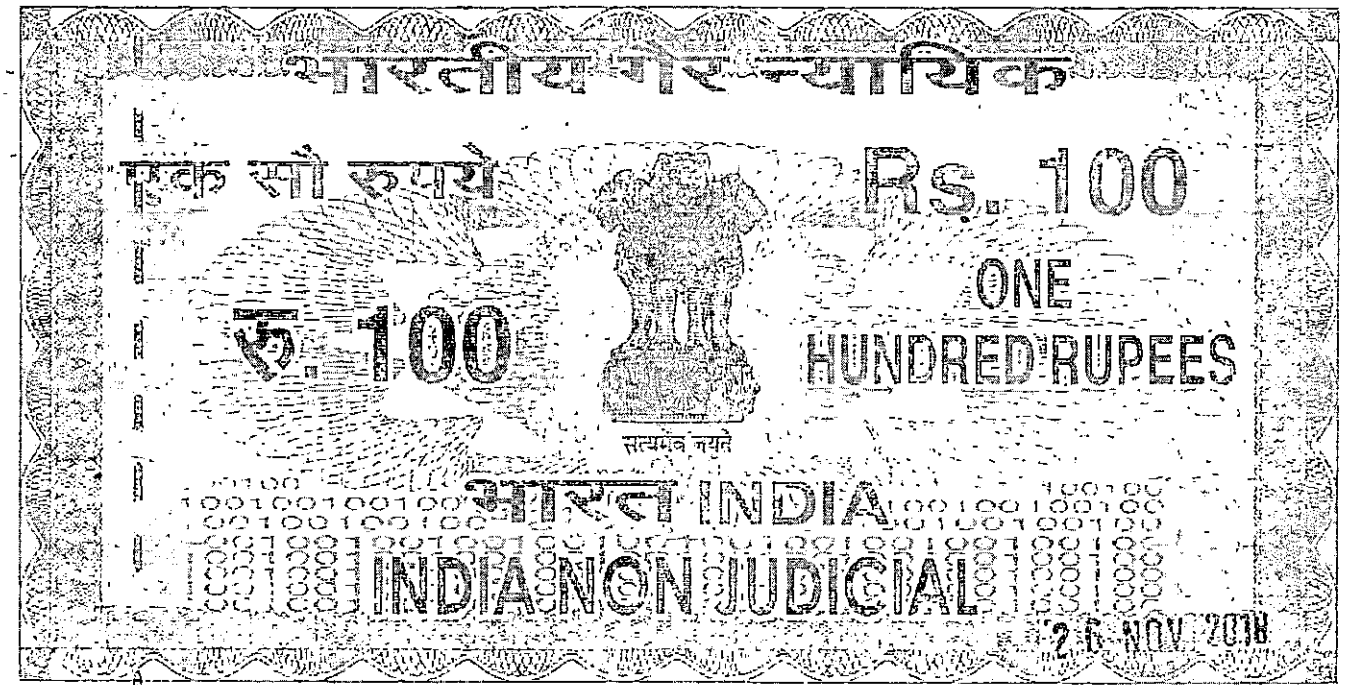

प्रतिज्ञापत्र/प्रतिज्ञापत्रा व्यतिरिक्त	
दस्ताचा प्रकार/अनुच्छेद क्रि	AGREEMENT
दस्त नोंदणी करणार आहेत का?	
नोंदणी करणार असल्यास दुय्यम निबंधक कार्यालयाचे नांव	
मिळकतीचे वर्णन	
मोबदला रक्कम	
मुद्रांक विक्रीत घेणाऱ्याचे नांव	
दस्तऐवज करून देणाऱ्याचे नांव	
दिवाणीमुल्यांकन त्याचे नांव व पत्ता	
मुद्रांक शुल्क रक्कम	26 NOV 2018
मुद्रांक बिक्री नोंदवही अनु. क्रमांक/दिनांक	54404
मुद्रांक विक्रीत घेणाऱ्याची सही	

ठाणे
19 NOV 2018

CLINICAL STUDY AGREEMENT

This clinical study agreement (together with Schedules and Appendices, the "**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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188

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

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Belagavi-590 010,Karnataka

189

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 financial

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190

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.

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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

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192

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

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193

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

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194

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.

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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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196

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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Belagavi-590 010,Karnataka

197

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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Belagavi-590 010,Karnataka

198

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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Belagavi-590 010,Karnataka

199

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	Dr. M. V. JALI MD, FRCP (London) Medical Director & Chief Eye Chief Consultant - Diabetology KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi.	Dr. Jayaprakash Appajigol
Name (print or type)	**Name (print or type)**	**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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SCHEDULE A

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FINAL DOCUMENT
Reviewed by: RA
PAGE

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202

MEDPACE
THE ADVANTAGE OF FOCUS

SCHEDULE A

ENTASIS THERAPEUTICS

PROTOCOL ID: CS2514-2017-0004

DR. JAYAPRAKASH APPAJIGOL

SITE: 356-005

SCHEDULE A VERSION: VERSION #2

COUNTRY: INDIA

CONFIDENTIAL

FINAL DOCUMENT
Reviewed by: SKS
PACE

Dr. Jayaprakash Appajigol | 356-005

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Belagavi-590 010,Karnataka

203

SCHEDULE A

A1 STUDY BUDGET

Sponsor, either directly or through its designee, shall make payment to the payee specified in the Payee Information Table ("Payee") under this Agreement from funds escrowed by Sponsor for services provided according to the payment schedule below. The budget contained in Schedule A is inclusive of all applicable taxes, overhead, and patient stipend or travel reimbursement, as applicable. **The amounts listed below are inclusive of 18% GST.** Payments are based on electronic case report forms ("eCRFs"), laboratory data, IVRS data or other specific data source. All amounts shown herein are calculated in INR.

A1.1 Fee for Each Evaluable Subject (inclusive of 18% GST) — INR 601,370.48

An "evaluable subject" is one who has been enrolled (randomized to treatment) and in whom all the applicable terms and conditions of the Protocol and this Agreement have been satisfied. Randomization occurs at Visit 2.

A1.2 Total Subject Budget (Estimated) (inclusive of 18% GST) — INR 1,202,740.96

The total subject budget is based on 2 subjects expected to be randomized at site.

A2 SET UP FEE &VISIT PAYMENTS

A2.1 Set up fee

2.1.1. Administrative Fee (inclusive of 18% GST) — INR 41,300

Payment will be made within forty-five (45) days of:

- Sponsor declaring Institution to be ready for Study Initiation (ie., regulatory package complete and approved to receive Study Drug);
- IRB/EC approval; and
- Sponsor's or its designee's receipt of the fully executed Agreement.

A2.2 Ongoing Payments

Payments for Study subject visits, as set forth in Table below, will be paid on a quarterly basis for the actual number of Study subjects for whom eCRFs have been completed less ten percent (10%) of each quarterly payment, which will be withheld until and paid with the final payment. Quarterly payments will be made within forty-five (45) days after the end of each quarter. The quarterly schedule may be offset from the calendar quarter.

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Belagavi-590 010,Karnataka

204

Table 1 - Fees for Completed Clinical Visits for Randomized Subjects

VISIT	Visit Payments	Institute Overheads (25%)	GST Amount (18%)	TOTAL FEE
Visit 1 / -48 hour to D1	INR 29,736.00	INR 7,434.00	INR 6,690.60	INR 43,860.60
Visit 2 / Day 1*	INR 39,051.20	INR 9,762.80	INR 8,786.52	INR 57,600.52
Visit 3 / Day 2	INR 35,851.20	INR 8,962.80	INR 8,066.52	INR 52,880.52
Visit 4 / Day 3	INR 36,639.20	INR 9,159.80	INR 8,243.82	INR 54,042.82
Visit 5 / Day 4*	INR 37,201.60	INR 9,300.40	INR 8,370.36	INR 54,872.36
Visit 6 / Day 5	INR 41,319.20	INR 10,329.80	INR 9,296.82	INR 60,945.82
Visit 7 / Day 6	INR 35,851.20	INR 8,962.80	INR 8,066.52	INR 52,880.52
Visit 8 / Day 7	INR 38,168.80	INR 9,542.20	INR 8,587.98	INR 56,298.98
Visit 9 / Day 8	INR 35,851.20	INR 8,962.80	INR 8,066.52	INR 52,880.52
Visit 16 / EOT	INR 40,383.20	INR 10,095.80	INR 9,086.22	INR 59,565.22
Visit 17 / EOT + 7	INR 18,828.00	INR 4,707.00	INR 4,236.30	INR 27,771.30
Visit 18 / EOT + 14	INR 18,828.00	INR 4,707.00	INR 4,236.30	INR 27,771.30
TOTAL PER PATIENT	**INR 407,708.80**	**INR 101,927.20**	**INR 91,734.48**	**INR 601,370.48**
Total number of patients (Minimum)	2	2	2	2
TOTAL FOR ALL PATIENTS	**INR 815,417.60**	**INR 203,854.40**	**INR 183,468.96**	**INR 1,202,740.96**
Days 9-14 (per day)	INR 35,851.20	INR 8,962.80	INR 8,066.52	INR 52,880.52
LFU (Day 28, on-site)	INR 18,828.00	INR 4,707.00	INR 4,236.30	INR 27,771.30
LFU (Day 28, telephone)	INR 6,020.00	INR 1,505.00	INR 1,354.50	INR 8,879.50
Early Termination	INR 19,683.20	INR 4,920.80	INR 4,428.72	INR 29,032.72

* Includes costs for single PK * It also includes the subject travel reimbursement of 1,000 INR per visit and is to be reimoursed to subjects on actuals
*Applicable visit fees include site's cost of all IV consumables.

A2.3 Screen Failures

Table 2 Screen Failures

VISIT OF FAILURE	SITE AMOUNT	25% OVERHEAD	18% GST AMOUNT	TOTAL COST
Rapid Test Screening Failure* - Negative result	INR 7,224.80	INR 1,806.20	INR 1,625.58	INR 10,656.58
Screening Visit - failure after Screening visit completed	INR 24,507.20	INR 6,126.80	INR 5,514.12	INR 36,148.12

Payment for screen failures will be made based on the corresponding visit(s) eCRF completed with the next scheduled payment owed to the Payee.

* Rapid screening of respiratory samples utilizing the BioFire FilmArray® Pneumonia Panel should be conducted for patients with a definite or probable diagnosis of HABP/VABP that also meet the protocol inclusion and exclusion criteria based on the clinical information available at that time.

A2.4 Final Payment

Final payment for all services performed under this Agreement will be paid to Payee by Sponsor either directly or through its designee after:

- Final resolution of all queries;
- Upon final acceptance of all eCRFs;
- The receipt and approval of any outstanding regulatory documents as required by Sponsor;
- The return of all unused Study Drug, Study supplies (including any equipment provided by Sponsor) and Confidential Information to Sponsor; and
- Upon completion of all other applicable conditions set forth in the Agreement.

A2.5 Unscheduled Visit (inclusive of 18% GST) — INR 12,678

Payable with final payment. Unscheduled Visit must be entered into EDC prior to database lock and visit must occur after randomization. Unscheduled Visit will not be payable if it occurs on the same date as another visit.

A3.4 Archiving Fee (inclusive of 18% GST) — INR 76,700

One-time fee, payable with final payment for a period of 25 years.

A3 INVOICEABLE ITEMS

Payment will be made within forty-five (45) days of receipt of invoice and supporting documentation if applicable and requested.

A3.1 Additional Procedures (inclusive of 18% GST)

Payment will be made for procedures listed below if required by the protocol and not considered as standard of care.

Table 3 – Unlisted Procedures

FEES	COST
X-ray	INR 708
MRI Scan	INR 6,490
CT Scan	INR 9,440
Intense PK	INR 4,909 per Day 1 & Day 4
ICU Hospitalization Fee	INR 5,900 per Day
Non-ICU Hospitalization Fee	INR 4,130 per Day

A3.2 Additional Study-necessitated Fees

Payee will be reimbursed at actual cost for any other unforeseen but reasonable procedures or costs necessitated by the Study or Protocol (and any amendments thereto) and pre-approved by Sponsor or its designee.

A3.3 Nominal equipment

Institution may be provided during the course of the Study small items of equipment necessitated by the Study or Protocol and pre-approved by Sponsor or its designee.

A4 SPONSOR RIGHTS

Sponsor reserves the right to suspend payments due to Payee, if Principal Investigator and/or Institution do not complete data entry, query resolutions, and electronic signatures on eCRFs and/or provide regulatory documents to Sponsor or its designee within timelines defined by the project team. Payments will resume once the missing or incomplete information is resolved.

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

206

A5 SPONSOR INVOICING

All payment inquiries and invoices submitted shall include the Protocol number and Principal Investigator name and be sent to the following Sponsor's designee:

Email: siteinvoices@medpace.com
Phone: 513-579-9911

Medpace Clinical Research, LLC
Attn: Clinical Operations Site Payments
5375 Medpace Way
Cincinnati, Ohio 45227

All invoices must be submitted to Sponsor's designee within ninety (90) days of occurrence or up to thirty (30) days after receipt of the final payment.

A6 PAYEE INFORMATION

All payments made by Sponsor, either directly or through its designee, as set forth herein shall be payable solely to Payee at the address set forth below. Any such payments which are due to any other party performing services in connection with the Study shall be a matter solely between Payee and such party.

Table 4 - For sites receiving payment by foreign wire transfer

PAYEE INFORMATION	
Beneficiary Name	GDD experts (India) Pvt Ltd.
Payee Mailing Address	GDD Experts India Pvt. Ltd Ground Floor, Gulmohar Complex, Opposite Hislop College, Civil Lines, Nagpur-440001, Maharashtra, India
Contact Name	Dr. Vinod Gyanchandani
Email Address	vgyanchandani@gddexperts.com
Bank	AXIS BANK LTD
Account №	910020034162231
BIC Code/Swift Code	AXISINBB046
IFSC Code (India)	UTIB0000048
GST ID#**	27AADCG0363Q1ZA
PAN No.	AADCG0363Q

**Requested for Medpace Accounting tracking purposes only

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SCHEDULE B

EQUIPMENT USE, HANDLING, OWNERSHIP & DISPOSITION

Sponsor or its designee may provide Institution with certain equipment to be used solely in connection with performance of the Study, including but not limited to the items listed in Table 1 below (the "**Equipment**"). Institution, Investigator and SMO will additionally comply with the terms set forth in this Schedule B in connection with all Equipment entrusted to them.

Table 1:

Item:	**Quantity:**	**Estimated Value (INR):**
Infusion pump	3	566,247 (188,749/ piece)
Computer	1	139,918
Printer	1	34,979
BioFire Film Array Device Software	1	1,539,090
BioFire pouches (kit of 6 pouches)	Up to 5 kit	409,255 (81,851 / kit)
BioFire Film Array Device Software	1	175,000

A-1: Facilities; Use; Restrictions.

Adequate Facilities and Access. Institution, Investigator and SMO will ensure that: (i) all Equipment is diligently kept in a safe and secure location compliant with the Requirements (defined below) and industry standard practices; and (ii) Sponsor and Sponsor's designees have sufficient access to such location(s) as reasonably necessary for installing, auditing, providing training for, maintaining, reviewing and/or repairing all Equipment. Institution, Investigator and SMO will inspect all Equipment at the time of delivery and at reasonable intervals throughout the Study and will immediately, upon becoming aware, notify Sponsor or its designee of any shortage or error in delivery, loss of, damage to, defects in, expiration of, malfunctioning of or other similar issues related to the Equipment (each a "**Defect**"). Institution, Investigator and SMO will not use any Equipment containing any Defect unless Sponsor or Sponsor's designee consents to such use in writing, in advance. Further, Institution, Investigator and SMO will not attempt to repair or otherwise correct any Defect without Sponsor's or its designee's prior written consent and, in any event, will comply with Sponsor's and its designees' written instructions regarding repairing or otherwise addressing any Defect, including without limitation, reasonably assisting Sponsor and Sponsor's designees with exercising any warranty claim.

A-2: Use and Handling of Equipment; Publicity.

Unless Sponsor or its designee provides prior, written consent, Institution, Investigator and SMO will not:

- use Equipment for any purpose other than performance of the Study;
- permit any third-party access to or use of the Equipment or non-public information pertaining to Equipment, except, for authorized Study Personnel as reasonably necessary to perform the Study;
- use or handle the Equipment in a manner that is inconsistent with the Requirements. For purposes of this Schedule B, "**Requirements**" means collectively (i) applicable law; (ii) the Protocol; (iii) written

CONFIDENTIAL

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208

instructions by or behalf of the Equipment manufacturer, Sponsor or their respective designees, including without limitation, all applicable user's manuals, instructions for use, product labels, package inserts, and similar; and (iv) applicable license terms and restrictions:

- will not modify, copy, reverse engineer, disassemble or otherwise alter the Equipment in any way.
- will not install any components or software.

Upon Sponsor or its designee's request, Institution, Investigator and SMO will, and will ensure relevant Study Personnel will complete any training offered by or on behalf of Sponsor regarding use or handling of Equipment. Institution, Investigator and SMO agree that each will not name or otherwise refer to Equipment or any Equipment manufacturer in any advertising, promotional material or public announcement without first obtaining the Equipment Manufacturer's consent. Further, upon Sponsor's request, Institution and/or Investigator and/or SMO will remove any references to Equipment and/or the Equipment manufacturer in any publication of the Study results made pursuant to this Agreement.

A-3: Ownership; Responsibility.

Unless expressly agreed otherwise by Sponsor in writing, Equipment remains at all times the property of Sponsor or a third party. Equipment must, at Sponsor's direction and expense, be returned to Sponsor or its designee within five (5) days of (i) Sponsor or its designee's request; or (ii) expiration or the earlier termination of this Agreement. Institution and/or Investigator and/or SMO agree to return the Equipment in substantially the same condition as when received by Institution and/or Investigator and/or SMO. Institution and SMO are responsible to cover (a) any loss or destruction to Equipment while in Institution's, Investigator's and SMO's care, which exceeds ordinary wear and tear and/or lacks a reasonable causal relationship to proper performance of the Study; and (b) any damages resulting from Institution's, Investigator's, SMO's or Study Personnel's (1) negligence; or (2) use or handling of Equipment in breach of this Agreement. Sponsor has no liability for damages of any sort, including but not limited to personal injury or property damage, resulting from the use of Equipment by Institution and/or Investigator and/or SMO and/or Study Personnel.

209

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COLGATE-PALMOLIVE (INDIA) LIMITED
Colgate Research Ce[illegible], Main Street, Hiranandani Gardens, Powai, Mumbai 400076
[illegible]

11th Aug'15

Dr. Vaibhav Kumar
PG. Dept. of Public Health Dentistry
KLE VK Institute of Dental Sciences,
Neharu Nagar, Belgaum- 590010

Re: Sponsorship of Research Grant for MDS Dissertation

Dear Dr. Vaibhav Kumar,

This is with regards to your request for sponsorship of Research grant for MDS Dissertation for topic "ORAL HEALTH STATUS AND TREATMENT NEEDS AMONG 3-5 YEAR OLD CHILDREN ATTENDING ANGANWADI CENTERS OF BELGAUM CITY : A CROSS-SECTIONAL STUDY".
We are pleased to inform you that we would sponsor the captioned dissertation-cum-research study being carried out by you, the sponsorship amount being Rs. 10,000/- subject to following terms and conditions.

1. Colgate-Palmolive (I) Ltd being sole sponsors of this research project, no collaboration should be entered into with any other organisation for this purpose.

2. A brief report of the project should be sent to us from time to time and on completion of the same, following documents should be mailed to us on seema_amin@colpal.com

3. Grants would be given on Submission of scan copies of following documents.

a) PDF copy of the final Thesis/ Dissertation submitted to the University.
b) Acceptance Letter from University.
c) Dean's Letter for successfully completion of thesis.
d) Candidate Form (encl.)

4. The company should be given due acknowledgement in your project report.

Dr. V.A.Kothiwale
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KLE/BMK/IRC/150/18

INSTITUTIONAL ETHICS COMMITTEE
KAHER's Shri B. M. Kankanawadi Ayurveda Mahavidyalaya &
KLE Ayurveda Hospital, Shahapur, Belagavi

COMMUNICATION OF DECISION OF THE INSTITUTIONAL ETHICS COMMITTEE (IEC)

Protocol No: BMK/15/BRT/01

Protocol Title: Evaluation of clinical efficacy and safety of Alert capsule in the management of Generalized Anxiety Disorder

Principal Investigators/Co-investigators: Dr. Basavaraj Tubaki

Name & Address of Institution:
KAHER's Shri B. M. Kankanawadi Ayurveda Mahavidyalaya & KLE Ayurveda Hospital, Shahapur, Belagavi

☐ New Review ☐ Revised Review ☑ Expedited Review

Date of Review (DD/MM/YY): 20.03.2018

Date of previous review, if revised application: 18.02.2016

Name of the Reviewers who attended the meeting:

Dr. SupriyaBhalerao, Dr. RajashreeKamat, Dr. PradeepShinde, Mr.Sudheer Kulkarni, Mrs. Arati S Balikai, Mrs. Sarita S. Shirodkar, Dr. Basavaraj R Tubaki,

Decision of the the Ethics Committee:

Recommended	☑	**Recommended with suggestions**	☐
Revision	☐	**Rejected**	☐

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Suggestions/ Clarifications / Reasons/ Remarks:
Recommended for a period of :OneYear

Please note *

- Inform EC immediately in case of any Adverse Events and Serious Adverse Events
- Inform EC in case of any change of study procedure, site and investigator
- This permission is only for period mentioned above
- Annual report to be submitted to EC
- The study has to be conducted as per approved protocol. Any amendments in the Protocol/ICF/CRF has to be approved from IEC before implementation
- Members of EC have right to monitor the trial with prior intimation
- The status of the study (Completed/Ongoing/Terminated) should be reported annually
- It is mandatory to obtain renewal of approval and apply for the same at the end of 11 months
- The renewal of approval is subjected to submission of annual report. If the above application is not received within specified period then the permission to renew the project may lapse

Dr. Basavaraj R Tubaki
(Member Secretary)

Bhalerao

Dr. Supriya Bhalerao
(Chairperson)

Dr. V.A.Kothiwale
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212

RESEARCH PROJECT

EFFICACY AND SAFETY OF ALERT CAPSULE IN THE MANAGEMENT OF GENERALIZED ANXIETY DISORDER- AN OPEN LABEL CLINICAL STUDY

ABSTRACT

Generalized anxiety disorder (GAD) is characterized by excessive, uncontrolled and often irrational worry, that is, apprehensive expectation about events or activities. In India, around 6-10% population is suffering from GAD. Anxiolytic drugs are extremely tempting, and prescribed to millions of individuals suffering from anxiety and stress. But some of them (like Benzodiazepines, Buspirone) are known to produce side effects like hypotension, nausea, memory loss, sexual dysfunction, headache etc. Thus, it needs to search for safe and effective solution. The present study is to be initiated for evaluating clinical efficacy and safety of Alert Capsule in the management of Generalized Anxiety Disorder (GAD). Disease specific inclusion and exclusion criteria have been selected and shall be employed for the enrolment of patients. For the assessment of efficacy appropriate subjective parameters like Generalized Anxiety Disorder 7 (GAD-7) scale, Hamilton Anxiety Rating Scale (HAM-A), Hamilton Depression Rating Scale (HAM-D), WHO Quality of life BREF, Pittsburg sleep quality index, Clinical global Impression will be used. On another hand, bio-chemical parameter like serum cortisol level will be analysed as anxiety marker other investigations like liver Function test, Renal Function test, Complete blood profile like Hb, ESR, RBC, PCV, MCV, MCH, MCHC, WBC, WBC Differential, total platelet count, MPV and blood clotting time will be evaluated. Urine & Stool routine examination will also be carried out. Total study period in a patient will be of 60 days. Treatment with test drug will be provided for 1 month and followed by 1 month period of placebo interventional observation period. Follow-up visit is to be scheduled at every 2 weeks of interval with 4 follow up. All the laboratory investigations will be carried out at base line and 30th day. However evaluation with all the clinical assessment scales will be carried out at all the visits. Appropriate statistics tools shall be applied to find out statistical significance of undergoing therapy.

Prepared by

Vasu Research Centre [VRC]

(A Division of VASU Health Care Pvt. Ltd.)

896/A, G.I.D.C., Makarpura, Vadodara- 390010

Year- 2015

INTRODUCTION:

Generalized anxiety disorder (GAD) is characterized by excessive, uncontrolled and often irrational worry, that is, apprehensive expectation about events or activities.[1] This excessive worry often interferes with daily functioning, as individuals with GAD typically anticipate disaster, and are overly concerned about everyday matters such as health issues, money, death, family problems, friendship problems, interpersonal relationship problems, or work difficulties.[2,3]

Generalized anxiety disorder affects about 3.1% American adults age 18 years and older (about 18%) in year 2010, causing them to be filled with fearfulness and uncertainty. The average age of onset is 31 years old.[4] In India, around 6-10% population is suffering from GAD.[5]

Anxiolytic drugs are extremely tempting, and prescribed to millions of individuals suffering from anxiety and stress. But some of them (like Benzodiazepines, Buspirone) are known to produce side effects like hypotension, nausea, memory loss, sexual dysfunction, headache etc.[6] Thus, it needs to search for safe and effective solution.

In Ayurveda, various medicinal plants are recommended for management of anxiety. Thinking in the same line, Vasu Healthcare has formulated polyherbal capsule known as Alert Capsule in soft gelatine form. It contains *Celastrus paniculatus* (Jyotishmati) Seed oil,[7-11] and Cow Ghee,[12,13] processed with *Acorus calamus* (Vaj) Rhizome,[14] *Convolvulus pluricaulis* (Shankhapushpi) Whole plant,[15-19] *Nardostachys jatamansi* (Jatamansi) Rhizome,[20-21] and *Eclipta alba* (Bhringraj) Whole plant.[22] Ingredients of Alert capsule are well reported in Ayurvedic texts and scientific research publications for Anti-anxiety activity. Alert capsule at therapeutic dose levels has shown good anti-fatigue activity in experimental rats.[23]

AIM & OBJECTIVE:

***Primary Objective*:**

To assess the clinical efficacy of Alert Capsule in the management of Generalized Anxiety Disorder (GAD)

***Secondary Objective*:**

To assess the safety of Alert Capsule

MATERIALS AND METHODS:

Study type	: Interventional, open labelled
Purpose	: Treatment
Timing	: Prospective
End point	: Efficacy and safety (Completion of treatment and follow-up period)
No. of Group	: 1 group
Subjects	: 60 patients

Selection of patients for clinical study:

For the purpose of this study, established cases of generalized anxiety disorder who are fulfilling the inclusion criteria and willing to give their consent to participate in the clinical trial, will be selected irrespective of their sex, caste, religion, habitat from OPD & IPD of respective institute.

Patient undergoing conventional treatment if matches inclusion criteria can be included after wash out period of 15 days.

Pre-treatment Observation:

All selected patients following registration will be informed regarding the objectives of clinical trial and their consent will be taken before initiating study. After preliminary registration diagnostic medical history will be taken according to Ayurveda and modern clinical methods. Detailed proforma will be prepared to assess the status of the patient.

INCLUSION CRITERIA:

(1) Patients (Male & Female) between the age group of 18 and 60 years and willing to give consent to participate in the study.
(2) Patients having Generalized Anxiety Disorder 7 (GAD-7) score ≥ 10
(3) Patients having Hamilton Anxiety Rating Score (HAM-A) ≥ 11
(4) Patients suffering from psycho- physiological insomnia especially due to anxiety.

EXCLUSION CRITERIA:

(1) Patients below 18 years and above 60 years
(2) Patients with Hamilton Depression Rating Scale score >13
(3) Patients suffering from any serious liver, kidney and cardiac diseases.
(4) Patients having history of any genetic disorders
(5) Patients on hypnotic medicine or other drugs which known to cause drowsiness.
(6) Lactating & pregnant women
(7) Patients on any Psychotropic or Nuerotrophic drugs 4 weeks prior to the study

DRUG UNDER TRIAL: ALERT CAPSULE

Composition: Each soft gelatine capsule contains

Sr. No.	Ingredients	Part Used	Quantity
1.	*Celastrus paniculatus (Jyotishmati) oil*	Seed	75 %
2.	*Cow Ghee*	---	25 %
Processed with (Sidhdha with)			
3.	*Acorus calamus (Vaj)*	Rhizome	---
4.	*Convolvulus pluricaulis* (Shankhapushpi)	Whole plant	---
5.	*Nardostachys jatamansi* (Jatamansi)	Rhizome	---
6.	*Eclipta alba* (Bhringraj)	Whole plant	---

TEST DRUG, DOSE AND DURATION:

Test Drug: Alert Capsule
Dose: 1 capsules twice a day, after meal
Vehicle: Normal drinking water
Route of administration: Oral
Duration: 1 month

DO'S & DONT'S:

All the subjects during the course of clinical trial shall be advised to take healthy diet.

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215

Smoking and sedentary life shall be discouraged in the patients.

DURATION OF STUDY: 60 days. 30 days of active intervention followed by 30days of follow up observation with placebo intervention.

STUDY PERIOD: 24 Months

FOLLOW UP:

Follow up study will be carried out for 1 (One) month after completion of the treatment at interval of 2 weeks. Placebo will be provided during follow-up period.

ADR (Adverse drug reaction):- Any adverse drug reaction is to be duly attended and treated.

Rescue medicine / treatment: In case of any emergency, patients will be terminated from the study and transferred for appropriate emergency treatment.

CRITERIA FOR THE ASSESSMENT:

Assessment of therapeutic efficacy & safety will be done on the basis of subjective as well as objective parameters.

Subjective parameters:

1. Generalized Anxiety Disorder 7 (GAD-7)[24]
2. Hamilton Anxiety Rating Scale (HAM-A)[25]
3. Hamilton Depression Rating Scale (HAM-D)[26,27]
4. Pittsburg Sleep Quality Index [28]
5. WHO quality of life BREF (Ref) [29, 30]
6. Clinical Global Impression Scale [31,32]

Objective parameters:

1. Serum cortisol level
2. CBC: Hb, ESR, RBC, PCV, MCV, MCH, MCHC, WBC, WBC Differential, total platelet count, MPV and blood clotting time.
3. Liver function test: SGOT & SGPT
4. Renal function test: Blood urea nitrogen, S. creatinine & Creatinine clearance rate
5. Urine examination
6. Stool examination

PRIMARY AND SECONDARY OUTCOME MEASURES

Primary: Primary outcomes will be effect of drug on subjective and objective parameters

Secondary: Assessment of drug safety and patient's compliance

STATISTICAL ANALYSIS:

The Wilcoxon signed rank method will be used to check the significance of the subjective criteria and paired "t" test will be used for objective criteria in a single group.

Values will be expressed in Mean ± SD. The obtained results will be interpreted as follow,

$P > 0.05$	: Insignificant	$P \leq 0.01$	: Highly significant
$P \leq 0.05$	: Significant	$P \leq 0.001$	: Very highly significant

POLICY REGARDING HANDLING OF IMPERFECT DATA

1. In case of complete failure of the treatment, all data will be submitted to sponsor company. Company is to take decision on it.
2. In case of intolerance to the drug, trial will be terminated and informed to the sponsor with detail justification.
3. In case of patients lost in follow-up, try to counsel such patients who really willing to complete the treatment. Selection of the patients is the responsibility of principal investigator.
4. In case of lost data, principal investigator and his / her team will be considered responsible.
5. In case of withdrawal from therapy due to any reason, additional 10 patients will be enrolled to avoid interference in data due to dropout / withdrawal.

FINANCIAL IMPLICATION:

Clinical examinations will be carried out at Pathology and biochemistry laboratories available in hospital. Detail financial break-up will be provided by institutes.

FREQUENCY OF ASSESSMENT PARAMETERS:

Sr. No.	Investigation	B.T.	After 15 days	After 30 days	After 45 days	After 60 days	Frequency of test / patients	No. of Patient
1	Subjective parameters	Y	Y	Y	Y	Y	5	60+5
2	Serum cortisol level	Y	---	Y	---	---	2	60+5
3	CBC	Y	---	Y	---	---	2	60+5
4	Urine examination	Y	---	Y	---	---	2	60+5
5	Stool examination	Y	---	Y	---	---	2	60+5
6	Liver function test	Y	---	Y	---	---	2	60+5
7	Renal function test	Y	---	Y	---	---	2	60+5

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Flow Chart

Content	Screening (Before treatment)	Treatment		Follow-up	
		Visit 1 (After 15 days)	Visit 2 End of the study (After 30 days)	Visit 3 (At 2 weeks after completion of treatment)	Visit 4 (At 4 weeks after completion of treatment)
Informed consent	√				
Inclusion / Exclusion criteria	√				
Medical history	√				
Subjective parameters	√	√	√	√	√
Serum cortisol level	√	√	√		
Liver function test	√		√		
Renal function test	√		√		
CBC	√		√		
Urine examination	√		√		
Stool examination	√		√		
Product dispensing	√	√	√ (Placebo)	√ (Placebo)	
Adverse event		√	√		
Follow-up				√	√
Data compilation					√
Report preparation					√

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220

ANNEXURE – 1

Generalized Anxiety Disorder 7-item (GAD-7)

(Ref.: Spitzer RL, Kroenke K, Williams JBW, Lowe B. A brief measure for assessing generalized anxiety disorder. Arch Inern Med. 2006;166:1092-1097.)

The Generalized Anxiety Disorder 7-item (GAD-7) is the most widely used psychological instrument for measuring the severity level of disorder. Each item is rated on a 4-point scale, as mentioned below

0 = Not at all; 1 = Several days; 2= Over half days; 3 = Nearly everyday

Kindly mention appropriate score

Sr. No.	In the last 2 weeks, how often have you been bothered by the following problems?	Score		
		Before treatment	After 15 days of treatment	After 30 days of treatment
1	Feeling nervous, anxious, or on edge			
2	Not being able to stop or control worrying			
3	Worrying too much about different things			
4	Trouble relaxing			
5	Being so restless that it's hard to sit still			
6	Becoming easily annoyed or irritable			
7	Feeling afraid as if something awful might happen			
	Total Score			

Total score & interpretation:

Total score	Your GAD level
0	Nil
1-5	Mild severity
6-10	Moderate severity
11-15	Severe
16-21	Very severe

221

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ANNEXURE - 2

Hamilton Anxiety Rating Scale (HAM-A)

(Ref: Hamilton M. The assessment of anxiety states by rating. Br J Med Psychol 1959; 32:50–55.)

The Hamilton Anxiety Rating Scale (HAM-A) is a rating scale developed to quantify the severity of anxiety symptomatology, often used in psychotropic drug evaluation. It consists of 14 items, each defined by a series of symptoms. Each item is rated on a 5-point scale, as mentioned below

0 = Not present; 1 =Mild; 2= Moderate; 3 =Severe; 4= Very severe

Kindly mention appropriate score

Sr. No.	Condition	Before treatment	After 15 days of treatment	After 30 days of treatment
1	**Anxious mood:** Worries, anticipation of the worst, fearful anticipation, irritability			
2	**Tension:** Feelings of tension, fatigability, startle response, moved to tears easily, trembling, feelings of restlessness, inability to relax			
3	**Fears:** Of dark, of strangers, of being left alone, of animals, of traffic, of crowds			
4	**Insomnia:** Difficulty in falling asleep, broken sleep, unsatisfying sleep and fatigue on waking, dreams, nightmares, night terrors			
5	**Intellectual:** Difficulty in concentration, poor memory			
6	**Depressed mood:** Loss of interest, lack of pleasure in hobbies, depression, early waking, diurnal swing			
7	**Somatic (muscular):** Pains and aches, twitching, stiffness, myoclonic jerks, grinding of teeth, unsteady voice, increased muscular tone			
8	**Somatic (sensory):** Tinnitus, blurring of vision, hot and cold flushes, feelings of weakness, pricking sensation			
9	**Cardiovascular symptoms:** Tachycardia, palpitations, pain in chest, throbbing of vessels, fainting feelings, missing beat			
10	**Respiratory symptoms:** Pressure or constriction in chest, choking feelings, sighing, dyspnea			
11	**Gastrointestinal symptoms:** Difficulty in swallowing, wind abdominal pain, burning sensations, abdominal fullness, nausea, vomiting, borborygmi, looseness of bowels, loss of weight, constipation			

12	**Genitourinary symptoms**: Frequency of micturition, urgency of micturition, amenorrhea, menorrhagia, development of frigidity, premature ejaculation, loss of libido, impotence			
13	**Autonomic symptoms**: Dry mouth, flushing, pallor, tendency to sweat, giddiness, tension headache, raising of hair			
14	**Behavior at interview**: Fidgeting, restlessness or pacing, tremor of hands, furrowed brow, strained face etc			
	TOTAL SCORE			

Total score & interpretation:

A total score range of 0–56, where

Total score	**Your anxiety level**
0 to 10	Nil
11 to 17	Mild severity
18 to 25	Moderate severity
26 to 30	Severe
31 & Above	Very severe

ANNEXURE - 3

Hamilton Depression Rating Scale (HAM-D)

(Hamilton M. A Rating Scale for Depression. J Neurol Neurosurg Psychiatry 23:56-62, 1960)
(Hamilton M. Development of Rating scale for Primary Depressive illness. Br. J Soc Clin Psychol 6: 278-296, 1967)

The Hamilton Depression Rating Scale (HAM-D) is a rating scale developed to quantify the severity of Depression symptomatology, often used in psychotropic drug evaluation. It consists of 17 items, each defined by a series of symptoms. Each item is rated on a 5-point scale, as mentioned below

0 = Not present; 1 =Mild; 2= Moderate; 3 =Severe; 4= Very severe

Kindly mention appropriate score

Sr. No.	Condition	Before treatment	After 15 days of treatment	After 30 days of treatment
1	Depressed mood This item covers both the verbal and the non-verbal communication of sadness, depression, despondency, helplessness and hopelessness.			
2	Self-depreciation and guilt feelings This item covers the lowered self-esteem with guilt feelings.			
3	Suicidal impulses			
4	Initial insomnia			
5	Middle insomnia			
6	Delayed insomnia = Premature awakening			
7	**Work and interests** This item includes both work carried out and motivation. Note, however, that the assessment of tiredness and fatigue in their physical manifestations is included in item 13 (general somatic symptoms) and in item 23 (tiredness and pain)			
8	**Retardation (general)**			
9	**Agitation**			
10	**Anxiety (psychic)** This item includes tenseness, irritability, worry, insecurity, fear and apprehension approaching overpowering dread. It may often be difficult to distinguish between the patient's experience of anxiety ("psychic" or "central" anxiety phenomena) and the physiological ("peripheral") anxiety manifestations which can be observed, e.g., hand tremor and sweating. Most important is the patient's report on worry, insecurity, uncertainty, experiences of dreadfulness, i.e. the psychic ("central") anxiety.			

11	**Anxiety (somatic)** This item includes physiological concomitants of anxiety: All feeling states should be rated under item 10 and not here.			
12	**12. Gastro-Intestinal** Symptoms may stem from the entire gastro-intestinal tract. Dry mouth, loss of appetite, and constipation are more common than abdominal cramps and pains. Must be distinguished from gastro-intestinal anxiety symptoms ("butterflies in the stomach" or loose bowel movements) and also from nihilistic ideas (no bowel movements for weeks or months; the intestines have withered away) which should be rated under 15 (Hypochondriasis).			
13	**General Somatic** Central are feelings of fatigue and exhaustion, loss of energy. But also diffuse muscular achings and pains in neck, back or limbs, e.g. muscular headache.			
14	**Sexual interests** This subject is often difficult to approach, especially with elderly patients. In males try to ask questions concerning sexual preoccupation and drive, in females responsiveness (both to engage in sexual activity and to obtain satisfaction in intercourse).			
15	Hypochondriasis Preoccupation with bodily symptoms or functions (in the absence of somatic disease)			
16	Loss of insight This item has, of course, only meaning if the observer is convinced that the patient at the interview still is in a depressive state.			
17	Weight loss Try to get objective information; if such is not available be conservative in estimation.			
	TOTAL SCORE			

ANNEXURE - 4

Pittsburg Sleep Quality Index

[Buysse DJ, Reynolds CF, Monk TH, Berman SR, DJ Kupfer (1989) The Pittsburgh Sleep Quality Index: A New Instrument for Psychiatric Practice and Research, **Psychiatry Research, 28**: 193-213].

Instructions:

The following questions relate to your usual sleep habits during the past month ONLY. Your answers
should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

1. During the past month, when have you usually gone to bed at night?

USUAL BED TIME_____

2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night?

NUMBER OF MINUTES_____

3. During the past month, when have you usually gotten up in the morning?

USUAL GETTING UP TIME_____

4. During the past month, how many hours of *actual sleep* did you get at night? (This may be different than the number of hours you spend in bed.)

HOURS OF SLEEP PER NIGHT_____

For each of the remaining questions, check the one best response. Please answer ***all*** questions.

5. During the past month, how often have you had trouble sleeping because you.....

(a) cannot get to sleep within 30 minutes
Not during the Less than Once or Three or more
past month_____ once a week_____ twice a week_____ times a week_____

(b) Wake up in the middle of the night or early morning
Not during the Less than Once or Three or more
past month_____ once a week_____ twice a week_____ times a week_____

(c) Have to get up to use the bathroom.
Not during the Less than Once or Three or more
past month_____ once a week_____ twice a week_____ times a week_____

(d) Cannot breathe comfortably.
Not during the Less than Once or Three or more
past month_____ once a week_____ twice a week_____ times a week_____

(e) Cough or snore loudly.
Not during the Less than Once or Three or more
past month_____ once a week_____ twice a week_____ times a week_____

(f) Feel too cold.
Not during the Less than Once or Three or more
past month_____ once a week_____ twice a week_____ times a week_____

(g) Feel too hot.
Not during the Less than Once or Three or more
Past month_____ once a week_____ twice a week_____ times a week_____

(h) Had bad dreams.
Not during the Less than Once or Three or more
Past month_____ once a week_____ twice a week_____ times a week_____

(i) Have pain.
Not during the Less than Once or Three or more
Past month_____ once a week_____ twice a week_____ times a week_____

(j) Other reason(s), please describe_____
_____

How often during the past month have you had trouble sleeping because of this?
Not during the Less than Once or Three or more
Past month_____ once a week_____ twice a week_____ times a week_____

6. During the past month, how would you rate your sleep quality overall?

Very good _____
Fairly good _____
Fairly bad _____
Very bad _____

7. During the past month, how often have you taken medicine (Prescribed or "over the counter") to help you sleep?

Not during the Less than Once or Three or more
Past month_____ once a week_____ twice a week_____ times a week_____

8. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

Not during the Less than Once or Three or more
Past month_____ once a week_____ twice a week_____ times a week_____

9. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

No problem at all _____
Only a very slight problem _____
Somewhat of a problem _____
A very big problem _____

10. Do you have a bed partner or share a room?

No bed partner or do not share a room _____
Partner/ flatmate in other room _____
Partner in same room, but not same bed _____
Partner in same bed _____

11. If you have a bed partner or share a room, ask him/her how often in the past month you have had.....

(a) Loud snoring.
Not during the Less than Once or Three or more
Past month_____ once a week_____ twice a week_____ times a week_____

(b) Long pauses between breaths while asleep.
Not during the Less than Once or Three or more
Past month_____ once a week_____ twice a week_____ times a week_____

(c) Legs twitching or jerking while you sleep.
Not during the Less than Once or Three or more
Past month_____ once a week_____ twice a week_____ times a week_____

(d) Episodes of disorientation or confusion during sleep.
Not during the Less than Once or Three or more
Past month_____ once a week_____ twice a week_____ times a week_____

(e) **Other restlessness while you sleep: please describe**_____
_____
Not during the Less than Once or Three or more
Past month_____ once a week_____ twice a week_____ times a week_____

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ANNEXURE - 5

WHO quality of life BREF

(Skevington SM, Lotfy M, O'Connell KA. The World Health Organization's WHOQOL-BREF quality of life assessment: Psychometric properties and results of the international field trial. A report from the WHOQOL group. Qual Life Res 2004;13:299–310)

(Development of the World Health Organization WHOQOLBREF quality of life assessment. The WHOQOL Group. Psychol Med 1998;28:551–558.)

The following questions ask how you feel about your quality of life, health, or other areas of your life. I will read out each question to you, along with the response options. **Please choose the answer that appears most appropriate.** If you are unsure about which response to give to a question, the first response you think of is often the best one.

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life **in the last four weeks.**

		Very Poor	Poor	Neither Poor	Good	Very Good
1.	How would you rate your quality of life?					

		Very Dissatisfied	Dissatisfied	Neither Satisfied nor Dissatisfied	Satisfied	Very Satisfied
2.	How satisfied are you with your health?					

The following questions ask about how much you have experienced certain things in the last four weeks.

		Not at all	A Little	A moderate amount	Very Much	An extreme Amount
3.	To what extent do you feel that physical pain prevents you from doing what you need to do?					
4.	How much do you need any medical treatment to function in your daily life?					
5.	How much do you enjoy life?					
6.	To what extent do you feel your life to be meaningful?					

		Not at all	A Little	A moderate amount	Very Much	Extremely
7.	How well are you able to concentrate?					

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8.	How safe do you feel in your daily life?					
9.	How healthy is your physical environment?					

The following questions ask about how completely you experience or were able to do certain things in the last four weeks.

		Not at all	A Little	Moderately	Mostly	Completely
10.	Do you have enough energy for everyday life?					
11.	Are you able to accept your bodily appearance?					
12.	Have you enough money to meet your needs?					
13.	How available to you is the information that you need in your day-to-day life?					
14.	To what extent do you have the opportunity for leisure activities?					

		Poor	Very Poor	Neither Poor nor good	Good	Very Good
15.	How well are you able to get around?					

		Very Satisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very Satisfied
16.	How satisfied are you with your sleep?					
17.	How satisfied are you with your ability to perform your daily living activities?					
18.	How satisfied are you with your capacity for work?					
19.	How satisfied are you with yourself?					
20.	How satisfied are you with your personal relationships?					
21.	How satisfied are you with your sex life?					
22.	How satisfied are you with the support you get from your friends?					

23.	How satisfied are you with the conditions of your living place?					
24.	How satisfied are you with your access to health services?					
25.	How satisfied are you with your transport?					

The following question refers to how often you have felt or experienced certain things in the last four weeks.

		Never	Seldom	Quite often	Very often	Always
26.	How often do you have negative feelings such as blue mood, despair, anxiety, depression?					

ANNEXURE - 6

Clinical Global Impression Scale

(Guy W. Patient assessment in clinical trials. Prog Neuropsychopharmacol Biol Psychiatry 1982;6:601–606)
(GuyW. ECDEU Assessment Manual for Psychopharmacology– Revised (DHEW Publ. No. ADM 76-338). Rockville, MD: U.S. Department of Health, Education, and Welfare, Public Health Service, Alcohol, Drug Abuse, and Mental Health Administration, NIMH Psychopharmacology Research Branch, Division of Extramural Research Programs, 1976: 218–222.)

Severity of illness-Considering your total clinical experiences with this particular population, how mentally ill is the patient at this time?

1.Normal, not at all ill.
2.Border line mentally ill.
3.Mildly ill.
4.Moderately ill.
5.Markedly ill.
6.Severely ill.
7.Among the most extremely ill patients

Global Improvement-Rate total improvement whether or not in your judgment it is due entirely to drug treatment. Compared to his condition at admission to the project, how much has he changed?

1.Very much improved.
2.Much improved.
3.Minimally improved.
4.No Change
5.Minimally worse.
6.Much worse
7.Very much worse.

Efficacy Index- Rate this item on the basis of drug effect only. Select the terms that best describe the degrees of therapeutic effect and side effects and make a mark in the box where the two items intersect.

Therapeutic Effect	Side effects			
	None	Do not Significantly interfere with Patient's functioning	Significantly interfere with Patient's functioning	Outweigh Therapeutic effect
4.Marked-Vast improvement complete or nearly complete remission of all symptoms	4.00	2.00	1.33	1.00
3.Moderate-Decided improvement. Partial remission of symptoms	3.00	1.5	1.00	0.75
2.Minimal-Slight improvement which doesn't alter status of care of patient	2.00	1.00	0.67	0.50
1.Unchanged or Worse	1.00	0.55	0.33	0.25

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INSTITUTIONAL ETHICS COMMITTEE
KLE University's Shri B. M. Kankanawadi Ayurved Mahavidyalaya &
KLE Ayurved Hospital, Shahapur, Belgaum

COMMUNICATION OF DECISION OF THE INSTITUTIONAL ETHICS COMMITTEE (IEC)

Protocol No: BMK/15/BRT/01

Protocol Title: "EFFICACY AND SAFETY OF ALERT CAPSULE IN THE MANAGEMENT OF GENERALIZED ANXIETY DISORDER-AN OPEN LABEL CLINICAL STUDY"
Principal Investigators/Co-investigators: Dr.B.R.Tubaki, Dr Sukumar Nandigowdar
Name & Address of Institution: KLE University's Shri B. M. Kankanawadi Ayurved Mahavidyalaya &KLE Ayurved Hospital, Shahapur, Belgaum
☐ New Review ☑ Revised Review ☐ Expedited Review
Date of Review (DD/MM/YY): 18.02.2016 **Date of previous review, if revised application:** **Name of the Reviewers who attended the meeting:** Dr Supriya Bhalerao, Dr Harsha Hegde, Dr.S.K.Hiremath, Dr. P.Shinde, Dr.Sameer N Naik, Dr. Rajashree Kamat, Dr.B.S.Hebballi, Mrs Sarita Shirodkar, Mrs. Arati S. Balikai, Mr. Sudheer kulkarni
Decision of the the Ethics Committee: **Recommended** ☑ **Recommended with suggestions** ☐ **Revision** ☐ **Rejected** ☐

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Suggestions/ Clarifications / Reasons/ Remarks: Following are the suggestions/clarifications of the EC- NIL
Recommended for a period of : One Year

Please note *

- Inform EC immediately in case of any Adverse Events and Serious Adverse Events
- Inform EC in case of any change of study procedure, site and investigator
- This permission is only for period mentioned above
- Annual report to be submitted to EC
- The study has to be conducted as per approved protocol. Any amendments in the Protocol/ICF/CRF has to be approved from IEC before implementation
- Members of EC have right to monitor the trial with prior intimation
- The status of the study (Completed/Ongoing/Terminated) should be reported annually
- It is mandatory to obtain renewal of approval and apply for the same at the end of 11 months
- The renewal of approval is subjected to submission of annual report. If the above application is not received within specified period then the permission to renew the project may lapse

Dr. Basavaraj R Tubaki
(Member Secretary)

Dr Supriya Bhalerao
(Chairperson)

Dr. V.A.Kothiwale
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17 JUN 2015

VASU RESEARCH CENTRE

MEMORANDUM OF UNDERSTANDING

Dr. V.A.Kothiwale
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234

WHEREAS

AND WHEREAS

THEREFORE

NOW, THEREFORE

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17 JUN 2015

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AYUBES DIABETES CLINICAL STUDY
(TIMER - MIA)

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
705, 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
K.L.E.U'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., I.C. COLONY, Borivali (W), Borivali Branch
Authorised Signatory
MUMBAI-400 103.
D-5/SSP(V)/C.R.1009/96/ 05/2008-211

Page 1 of 8

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238

PRINCIPAL
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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 / poly drug 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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239

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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240

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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241

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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242

MOU-DIABETES CLINICAL STUDY
(TIMER DIAB)

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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243

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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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244

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 Giridhar

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
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KLES
AYURVED HOSPITAL

Ethics Committee for Research on Human Subjects
KLE University's Shri B. M. Kankanawadi Ayurved Mahavidyalaya &
KLE Ayurved Hospital, Shahapur, Belagavi

COMMUNICATION OF DECISION OF THE ETHICS COMMITTEE (EC)

Protocol No: BMKH/KM/01/ AYUBES/DM/WELX/2017

Protocol Title: "A Clinical Evaluation of Efficacy and Safety of AYUBES CAPSULE as an Add-on therapy to Oral Hypoglycemic Agent (OHA) in Type 2 Diabetic Patients - A randomized, multi-center, double blind, placebo controlled study"
Principal Investigators/Co-investigators: Dr. Kirankumar Mutnali, Dr Sukumar Nandigoudar, Dr Dnyanesh N Morakar, Dr Giridhar Vedantam
Name & Address of Institution: KLE University's Shri B. M. Kankanawadi Ayurved Mahavidyalaya &KLE Ayurved Hospital, Shahapur, Belagavi
[√] New Review [ ] Revised Review [ ] Expedited Review
Date of Review (DD/MM/YY): **Date of previous review, if revised application:** **Name of the Reviewers who attended the meeting:** Dr. Supriya Bhalerao, Dr. Rajashree Kamat, Dr. Pradeep Shinde, Mr. Sudheer Kulkarni, Mrs. Arati S Balikai, Mrs. Sarita S. Shirodkar, Dr. Basavaraj R Tubaki, Dr Giridhar Vedantam,
Decision of the the Ethics Committee: Recommended [ ] Recommended with suggestions [ ] Revision [ ] Rejected [ ]

Dr. V.A.Kothiwale
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246

Suggestions/ Clarifications / Reasons/ Remarks:

- Following are the suggestions/clarifications of the EC

- NIL

Recommended for a period of : One Year

Please note *

- Inform EC immediately in case of any Adverse Events and Serious Adverse Events
- Inform EC in case of any change of study procedure, site and investigator
- This permission is only for period mentioned above
- Annual report to be submitted to EC
- The study has to be conducted as per approved protocol. Any amendments in the Protocol/ICF/CRF has to be approved from IEC before implementation
- Members of EC have right to monitor the trial with prior intimation
- The status of the study (Completed/Ongoing/Terminated) should be reported annually
- It is mandatory to obtain renewal of approval and apply for the same at the end of 11 months
- The renewal of approval is subjected to submission of annual report. If the above application is not received within specified period then the permission to renew the project may lapse

Dr. Basavaraj R Tubaki
(Member Secretary)

Dr. Supriya Bhalerao
(Chairperson)

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
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Certificate No.	:	IN-DL52945729502204P
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Account Reference	:	IMPACC (IV)/ dl957503/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL95750306393239347782P
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
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Stamp Duty Paid By	:	M B LIFE SCIENCES PVT LTD
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For MB Lifesciences Pvt. Ltd.,

Jitender Kumar

Director.

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

Dr. V.A.Kothiwale
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248

Statutory Alert:

1. The authenticity of this Stamp Certificate should be verified at [illegible] details on this Certificate and as available on the website renders it invalid.
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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.

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K.L.E. University's
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Ayurved Mahavidyalaya
Shahapur-BELAGAVI-03

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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.

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Shri B. M. Kankanwadi
Ayurved Mahavidyalaya
Shahapur-BELAGAVI-03

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

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

(1) Dr. Pradeep L.G.

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

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Ethics Committee for Research on Human Subjects
KLE University's Shri B. M. KankanawadiAyurvedMahavidyalaya&
KLE Ayurved Hospital, Shahapur, Belagavi

COMMUNICATION OF DECISION OF THE ETHICS COMMITTEE (EC)

Protocol No: BMK/17/PLG/01

Protocol Title: Evaluation of analgesic and anti-inflammatory activities of CONTRAPAIN – LEPA& OIL topical application in Musculoskeletal Disorders – CLINICAL STUDY
Principal Investigators/Co-investigators: Dr. Pradeep L Gramapurohit Dr.VedantamGiridhar
Name & Address of Institution: KLE University's Shri B. M. KankanawadiAyurvedMahavidyalaya&KLE Ayurved Hospital, Shahapur, Belagavi
[√] New Review [ ] Revised Review [ ] Expedited Review
Date of Review (DD/MM/YY):25/03/2017 **Date of previous review, if revised application:** **Name of the Reviewers who attended the meeting:** Dr. SupriyaBhalerao, Dr. RajashreeKamat, Dr. Pradeep Shinde, Mr.Sudheer Kulkarni, Mrs. Arati S Balikai, Mrs. Sarita S. Shirodkar, Dr. Basavaraj R Tubaki.
Decision of the the Ethics Committee: **Recommended** [ ] **Recommended with suggestions** [√] **Revision** [ ] **Rejected** [ ]

Dr. V.A.Kothiwale
Registrar
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(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010;Karnataka

Suggestions/ Clarifications / Reasons/ Remarks:

Following are the suggestions/clarifications of the EC

1. Replace the word 'subjects' with 'patients'
2. Replace the twice '0' Day with '-7' Day
3. More assessment of joint pain viz. inflammation, joint pain can be added
4. CRP can be used as efficacy parameter

Recommended for a period of : One Year

Please note *

- Inform EC immediately in case of any Adverse Events and Serious Adverse Events
- Inform EC in case of any change of study procedure, site and investigator
- This permission is only for period mentioned above
- Annual report to be submitted to EC
- The study has to be conducted as per approved protocol. Any amendments in the Protocol/ICF/CRF has to be approved from IEC before implementation
- Members of EC have right to monitor the trial with prior intimation
- The status of the study (Completed/Ongoing/Terminated) should be reported annually
- It is mandatory to obtain renewal of approval and apply for the same at the end of 11 months
- The renewal of approval is subjected to submission of annual report. If the above application is not received within specified period then the permission to renew the project may lapse

Dr. Basavaraj R Tubaki
(Member Secretary)

Dr.SupriyaBhalerao
(Chairperson)

Dr. V.A.Kothiwale
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 National Capital Territory of Delhi

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सत्यमेव जयते

Certificate No	:	IN-DL52946211730541P
Certificate Issued Date	:	28-Feb-2017 02:13 PM
Account Reference	:	IMPACC (IV)/ dl961503/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL96150306394255287213P
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 Lifescience Pvt. Ltd.

Director

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

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

MEMORANDUM OF UNDERSTANDING

The memorandum understanding ...

BETWEEN

M/s. M.B.Life Sciences Pvt. Ltd., New Delhi, a company incorporated under the Indian Companies act, having its Registered Office at5478, DeshBandhu Gupta Road, Karol Bagh, New Delhi ..., through its authorized signatory Mr. Jitender ...

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

AND

KLE University'sShri B M KankanwadiAyurvedaMahavidyalaya ... Medical Research ... 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 ... include its heirs, successors and assignees of the Second Part

WHERE AS the company is engaged ... research and development ... Ayurveda Drugs

AND WHERE AS the institute ... established good research facilities ... clinical studies in the field of Ayurveda and Ayurvedic Drugs

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

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

1. That the Institute has agreed to conduct a clinical assessment of the ... VATSYAYAN PLUSPower Capsule, development by the company
2. That the company has agreed to provide to the Institute detail ingredients ... investigation required in the clinical trial, brief details of the product ... certificate of analysis of used raw materials and ingredient pharmacology of used raw ...
3. That the company has also agreed ... patients and ... requirement ... of the project
4. That the clinical study would require certain amount of expenses ... herewith in the ... proposal ... amount of project ... Rs ... Hundred Only ...

For MB Lifesciences Pvt. Ltd.
Jitender ...

Dr. V.A.Kothiwale
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(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

PRINCIPAL
K.L.E. University's
... B. M. Kankanwadi

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

KLE | BMK | MRC | 448 | 18

KLES
AYURVED HOSPITAL

INSTITUTIONAL ETHICS COMMITTEE
KAHER's Shri B. M. Kankanawadi Ayurveda Mahavidyalaya &
KLE Ayurveda Hospital, Shahapur, Belagavi

COMMUNICATION OF DECISION OF THE INSTITUTIONAL ETHICS COMMITTEE (IEC)

Protocol No: BMK/17/SN/01

Protocol Title: Evaluation of Vatsyayan plus (capsule) in the management of Male Impotency – Double Blind Placebo control clinical study

Principal Investigators/Co-investigators: Dr. Sukumar Nandigoudar

Name & Address of Institution:

KAHER's Shri B. M. Kankanawadi Ayurveda Mahavidyalaya & KLE Ayurveda Hospital, Shahapur, Belagavi

☐ New Review ☐ Revised Review ☑ Expedited Review

Date of Review (DD/MM/YY): 20.03.2018

Date of previous review, if revised application: 25.03.2017

Name of the Reviewers who attended the meeting:

Dr. SupriyaBhalerao, Dr. RajashreeKamat, Dr. PradeepShinde, Mr.Sudheer Kulkarni, Mrs. Arati S Balikai, Mrs. Sarita S. Shirodkar, Dr. Basavaraj R Tubaki,

Decision of the the Ethics Committee:

Recommended	☑	**Recommended with suggestions**	☐
Revision	☐	**Rejected**	☐

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257

Suggestions/ Clarifications / Reasons/ Remarks:
Recommended for a period of :One Year

Please note *

- Inform EC immediately in case of any Adverse Events and Serious Adverse Events
- Inform EC in case of any change of study procedure, site and investigator
- This permission is only for period mentioned above
- Annual report to be submitted to EC
- The study has to be conducted as per approved protocol. Any amendments in the Protocol/ICF/CRF has to be approved from IEC before implementation
- Members of EC have right to monitor the trial with prior intimation
- The status of the study (Completed/Ongoing/Terminated) should be reported annually
- It is mandatory to obtain renewal of approval and apply for the same at the end of 11 months
- The renewal of approval is subjected to submission of annual report. If the above application is not received within specified period then the permission to renew the project may lapse

Dr. Basavaraj R Tubaki
(Member Secretary)

Dr. Supriya Bhalerao
(Chairperson)

Dr. V.A.Kothiwale
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MEMORANDUM OF UNDERSTANDING

BETWEEN

RASAYU CANCER CLINIC, B-1, AMRUT KUMBHA, LAKSHMI PARK SOCIETY, NAVIPETH PUNE

AND

KLE UNIVERSITY'S
SHRI B.M. KANKANAWADI AYURVEDA MAHAVIDYALAYA
SHAHAPUR, BELAGAVI, KARNATAKA.

For

Establishment of Cancer OPD at KLE Ayurveda Hospital And Research Activities

MEMORANDUM OF UNDERSTANDING

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

This Memorandum of Understanding ("**MoU**") dated this 11th day of July 2017

by and between:

KLEU's Shri B M Kankanawadi Ayurveda Mahavidyalaya & KLE Ayurveda hospital, Belagavi is a leading institute in offering super speciality quality health care in field of Ayurveda in India., having its office at Nathpai circle, Shahapur, Belagavi (here in after referred to as '**KLE Ayurveda hospital'**) which expression shall unless it be repugnant to the context or meaning there of shall be deemed to mean and include its successors and permitted assigns) of the **One Part**

AND

Rasayu cancer clinic having its place of business at B-1 Amrut kumbha,Lakshmipark society, Navipeth Pune .(here in after referred to as '**RCC**' which expression shall unless it be repugnant to the context or meaning thereof shall be deemed to mean and include its successors and permitted assigns) of the **Other Part**

KLE Ayurveda hospital and RCC shall be individually here in after referred to as '**Party**' and collectively as '**Parties**'.

Where as

A. 'KLE Ayurveda hospital' is a Teaching Ayurveda hospital providing vide range of super-specialty healthcare facilities to Patients.

B. 'RCC' is engaged in specialised Ayurveda based cancer therapies to cancer patients and cancer survivors. These facilities include but are not limited to offering Ayurveda consultation, preparing Ayurveda medicines and dietary supplements for these patients, Panchakarma therapies, offering diet, yoga and psychology consultation.

C. The parties are interested in exploring possible opportunities of establishing a mutually cooperative and beneficial relationship, including the carrying out of Projects relevant to their respective capabilities in India.

D. KLE Ayurveda hospital and RCC, confirm and understand that this MOU is not intended to provide and set out any contractual terms binding or otherwise

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governing the terms and conditions or the manner of conduct of any Projects and that may necessarily require the Parties to:

- share relevant information on a confidential basis with the aim and objective of identifying their requirements, needs and capabilities;
- establish a working relationship between themselves (which is targeted to the parties' specific needs);
- establish Projects which may be of mutual benefits and interest;
- Determine the details of Projects, their scope and purview, Project work plan, funding of the Project, their rights, duties and obligations in relation to the Project and its outcome.

For the purposes of each Project, the Parties shall enter into separate Agreements.

For the purposes of this MOU, "**Project**" shall mean a collaboration relating to Establishing specialty cancer OPD for development of Standard Treatment Protocol's in Cancer Management through specialized Ayurveda consultation and therapies for cancer patient at the premise of KLE Ayurveda hospital, Shahapur, Belagavi.

1. SCOPE OF THE MOU

1.1 The Parties will co-operate to:

(a) Establish facilities for offering specialized Ayurveda consultation to cancer patients which includes offering Ayurveda, yoga, diet and psychological consultation; preparing personalized medicines and dietary supplements for cancer Patients.

(b) Conduct cancer awareness drives, campaigns and lectures for common public and patients.

(c) Conducting various oncology based training programs for Medical students and professionals.

(d) Conduct an annual review of current and future Projects approximately one (1) week prior to the anniversary of the execution of this MOU.

1.2 Subject to the terms and conditions of any Collaboration Agreement agreed to and executed, each Party will have the right, in any field related to the Project or otherwise, to:

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(a) conduct business or research independently, whether or not with third parties;

(b) continue existing commitments, or make new ones;

(c) Exploit or otherwise take advantage of its intellectual property.

2. COLLABORATION AGREEMENT

2.1 The Parties acknowledge and confirm their intention to negotiate and settle the terms and conditions of a Collaboration Agreement in respect of each Project.

2.2 The parties agree that the ownership of the intellectual property rights arising out collaboration will be jointly shared between RCC & KLE. Publications, Authorship rights of involved Doctors/Consultants will be protected. Freedom for conducting individual OPD and Research & Developing new protocols on their own.

2.3 Each Collaboration Agreement will include provisions relating amongst other things to:

(a) A Project plan pursuant to which the Project will be carried out which will include information pertaining to technical objectives, statement of work, deliverables, schedule, decision gates, resource requirements and costs;

(b) Funding arrangements for the Project;

(c) Holding by the Parties of periodic Project review meetings to assess the management and the progress of the Project and the status of any expenditure;

(d) Exploitation of Intellectual property and rights arising from the same including their protection, enforcement and commercialization.

(e) Commercial arrangements between the KLE Ayurveda hospital and RCC.

2.4 The Parties agree, acknowledge and confirm that for any agreement to be binding on them, it must be in writing and shall be executed by a duly authorized representative of each of the KLE Ayurveda hospital and RCC.

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2.5 KLE Ayurveda hospital will provide basic infrastructure/facilities required for offering patient care which include consultation, treatment procedure, inpatient hospitalisation, investigations, dispensing medicines and dietary supplements and collecting treatment charges. KLE will establish speciality Cancer OPD for Ayurveda management. KLE will provide OPD facility in it to RCC for their expert consultancy as per mutual understanding and permit to prescribe the proprietary/ Research formulations of RCC and protect the confidentiality of RCC.

2.6 KLE Ayurveda hospital will make necessary arrangements for offering medical care and consultation by qualified Ayurveda physician trained in RCC Treatment protocol, to patients approaching for treatment in the collaborative RCC and KLE cancer OPD. Consultant from KLEU in Speciality Cancer OPD will have freedom to plan for different protocols and medications based on the clinical case otherwise RCC standard protocol will be used.

2.7 KLE Ayurveda hospital will make necessary arrangements to avail expert medical opinion or to refer the patient to appropriate medical facilities in case of any emergencies.

2.8 KLE Ayurveda hospital will make arrangements to procure medicines manufactured by Ayurved Rasayani, as required for the collaborative RCC and KLE cancer OPD.

2.9 RCC will offer appropriate training in Ayurveda oncology to doctors deputed by KLE Ayurveda hospital. The number of doctors at a given point of time will not exceed two (2).

2.9 RCC will periodically depute a trained qualified Ayurveda physician so as to provide direct consultation to patients approaching the collaborative RCC and KLE cancer OPD. This doctor will visit KLE Ayurveda hospital at least once in a month. The travel expenses for this visit will be totally beared by RCC.

2.10 KLE Ayurveda hospital will be conducting regular awareness activities about the collaborative RCC and KLE cancer OPD. These activities includes Awareness programs, lectures, pamphlets, banners, newspaper articles and Radio broadcast. KLE Ayurveda hospital will bear all the expenses of such activities.

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2.11 If required for the betterment of patient, RCC will make necessary arrangement to provide online/skype consultation to these patients in Belgaum.

2.12 The responsibility for providing best possible treatment for patient and ensuring his wellbeing lies entirely with the treating physician.

3. REPRESENTATIVE

3.1 For the term and purposes of this MOU, each party shall appoint a designated representative ("the **Representative**").

3.2 The Representative of the appointing Party will be responsible for:

a) managing, overseeing or coordinating that Party's relationship with the other Party;

b) identifying any commercial issues that arise between the Parties and refer them to the **Competent Authority** within the Representative's organization;

c) discussing any issues arising out of this MOU or a Collaboration Agreement with the Representative of the other party; and

d) Co-coordinating the exchange of information between the Parties.

3.3 The Representatives designated at the time of signing this MOU by the parties are:

(a) for KLE Ayurveda hospital:

Name: Dr B S Prasad.

Designation: Medical Director

Email: kleayurvedahospital@gmail.com

Mob. 9448569289.

(b) for RCC

Name: Dr. Avinash Kadam

Designation: Administrator.

Email: avinashk@rbpl.co.in

Mob. 9970259583

4. CONFIDENTIAL INFORMATION

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4.1 **Definition:** As used herein **Confidential Information**" shall mean and include all information and data which has been provided/disclosed/shared by RCC to KLE Ayurveda hospital prior and post the execution of this MOU and/or the Collaboration Agreement either written or oral or in any other form or manner of communication or which has been acquired or will be acquired by either Party such as designs, drawings, specifications, technical information, documents and know-how, designs, manufacturing processes, ideas, data, financial information and other technologies, whether patentable, copyrightable or susceptible to any other form of protection. The terms and existence of this MOU, the fact that Confidential Information has been shared and/or made available, that discussions or negotiations pertaining to the technology are taking place between the Parties shall also be considered Confidential Information for the purposes of this MOU.

4.2 **Purpose:** The Parties shall use the Confidential Information strictly and solely for the purposes the Confidential Information is provided under this MOU and none other.

4.3 **Ownership:** The Parties hereby understand, acknowledge, and confirm that the Confidential Information is a valuable trade secret owned by each Party and which retains all right, title, and interest in and unto the same. Neither Party shall have any right, title and interest in the Confidential Information of the other Party. By virtue of either Party disclosing the Confidential Information, no license to such Confidential information or any Intellectual Property rights owned by that Party is or are granted to the other Party. Neither Party shall directly or indirectly, through its directors, employees or agents, at any point of time, do any acts, things or deeds that may prejudicially affect the proprietary right, title and interests of either Party in and unto the Confidential Information.

4.4 **No Warranties:** At no point of time shall either Party be responsible for any loss or damages which may be suffered by the Party receiving the Confidential Information or for that matter by its customers or any third parties on account of or arising from the use of the Confidential Information. Neither Party makes any representations or warranties of any kind, whether expressed or implied as to the accuracy or completeness of the Confidential Information.

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4.5 **Use of Confidential Information:** Each Party may use the Confidential Information for the purposes stated in Clause 4.2 above only. Each Party recognizes that this MOU imposes an affirmative duty on the other Party to hold such information in confidence and to protect it from dissemination to and use by any and all unauthorized parties. In the absence of any prior written consent neither Party shall copy, reproduce or disclose the Confidential Information to any third party in any manner whatsoever.

4.6 **Further Responsibility**: The Parties agree and undertake to use the same degree of care to protect the confidentiality of the Confidential Information as it would exercise to protect its own trade secrets and information but in no case less than a reasonable degree of care. Each Party may grant access to the Confidential Information to its directors, officers, employees, advisors and consultants ("**related parties**") who have a clear need to know, for purposes of this MOU and shall advise such related parties of the existence and terms of this MOU and of its obligations of confidentiality herein. MoU shall lead to standard clinical protocols in management of cancer which will be asset of both the institutions. Each organisation will have the right to continue or utilize the products, protocols developed during the collaboration even after termination of MoU.

4.7 **Return of Confidential Information**Promptly following the request of either Party the receiving Party will return to the disclosing Party or certify in writing to the disclosing Party as to the destruction of (without retaining any copy in any form or manner) all Confidential Information including copies and extracts thereof as may have been or will be furnished as by the disclosing Party to the receiving Party. But the Hospital records/ data and pharmacy data will be archived to oblige hospital/ pharmacy regulations.

4.8 **Remedies:** The Parties acknowledge, understand and confirm that the disclosing Party is the proprietor of the Confidential Information and that any unauthorized disclosure, misappropriation or unauthorized use of such Confidential Information by the receiving Party in any manner whatsoever will cause serious irreparable loss and harm to disclosing Party. The receiving Party expressly agrees that the disclosing Party shall be entitled to seek injunctive and other

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equitable relief against it to prevent the breach or further breaches of any of its confidentiality obligations under this MOU and which it will not dispute by challenging the jurisdiction of the competent Courts where injunctive or equitable relief is being sought at by the disclosing Party.

5. TERMINATION AND AMENDMENT

The term of this MOU is a period of one (1) year from the date of execution. The MOU will be automatically renewed for a further period of one (1) year unless one Party notifies the other Party in writing 30 days in advance that they do not wish to renew the MOU at the completion of the annual review of current and future projects.

5.1 his MOU may be terminated by mutual consent of the parties. Either party may terminate this MOU upon one (1) month written notice to the other.

5.2 A Collaboration Agreement made pursuant to clause 2 of this MOU shall survive termination or expiration of this MOU.

5.3 This MOU may be amended only by an agreement in writing between the Parties and not otherwise.

6. GENERAL

6.1 KLE Ayurveda hospital and RCC agree that each of them is free to undertake R&D and business projects on their own or in conjunction with third party, and that the Parties will co-operate only in circumstances where each of them agrees if co-operation is for their mutual benefit and each is satisfied that the specific provisions covering their co-operation are appropriate and will not adversely or prejudicially affect their interests.

6.2 With the exception of Clause 4 herein, this MOU is not binding and the Parties do not intend that it or any part of it be binding. It serves only as a record of the understanding between the Parties' intentions pending possible execution of a Collaboration Agreement as contemplated by Clause 2 herein.

6.3 Nothing in this MOU will oblige or cast any obligation upon either Party to enter into a Collaboration Agreement with the other Party or to conduct any Project.

7. This MOU constitutes the entire understanding between the Parties regarding the subject matters contained herein. Any prior agreements,

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commitments or negotiations concerning the subject matters herein are superseded.

8. The headings contained herein are for the purposes of convenience only and are not intended to define or limit the contents of the provisions contained therein.

9. If one or more provisions of this MOU are held to be illegal or unenforceable,
such provisions will be limited or excluded to the minimum extent required so that this MOU will otherwise remain enforceable in accordance with the remaining terms.

10. The rights of the Parties hereto shall not be prejudiced or restricted by any
indulgence or forbearance extended to the other party and no waiver by the parties hereto of any breach of the other party of any of the terms hereunder shall operate as a waiver in respect of any subsequent breach. No variation of this MOU shall be effective unless it is in writing and duly signed by both parties.

11. **FORCE MAJEURE:** Neither party shall be liable for any delay in or failure of discharging respective obligations under this MOU caused by occurrence beyond the control of KLE Ayurveda hospital or RCC as the case may be, including but not limited to fires, floods, explosions, power shortage, failure/breakdown of UPS/DG set/computer, acts of GOD, hostility, acts of public enemy wars, insurrections, riots, strikes, lockouts, sabotage. Either parties shall promptly but not later than 10 days of the commencement there of notify the other in writing of such contingency and prove that such is beyond the control and affects the implementation of this MOU adversely and materially. If such contingency continues beyond 30 days both the parties, agree to discuss and agree upon an equitable solution.

12. **ARBITRATION:** For any interpretation of clauses in this MOU or in case of any dispute during implementation, such matter will be jointly discussed by representative of KLE Ayurveda hospital and RCC. In case of disagreement, the matter would be referred to the International Centre for Alternative Dispute Resolution (ICADR, an autonoMoUs organization

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working under the aegis of the Ministry of Law and Justice, Govt. of India) New Delhi-110 070. ICADR decision would be binding on both parties.

IN WITNESS, WHERE OF, the parties have executed this MOU as of the date first above written

SIGNED AND DELIVERED BY	**SIGNED AND DELIVERED BY**
Registrar KLE University	**RCC**
through its Authorized Signatory	**through its Authorized Signatory**
Signature	**Signature** Yogesh Bendale
Name of person signing MOU	**Dr Yogesh Bendale**
Designation	**Chairman and MD (RBPL)**
in the presence, of	in the presence, of Dr. Anand Patil
in the presence, of Sivadhas (Dr. Vedantam Grivadhas)	in the presence, of Dr. Neha Mali

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INSTITUTIONAL ETHICS COMMITTEE
KLE University's Shri B. M. KankanawadiAyurvedMahavidyalaya&
KLE Ayurveda Hospital, Shahapur, Belgaum

COMMUNICATION OF DECISION OF THE INSTITUTIONAL ETHICS COMMITTEE (IEC)

Protocol No: BMK/17/BSP /01

Protocol Title: "A prospective, open labelled, pilot, group study to evaluate efficacy, safety and bio availability of oral Arsenic Trioxide prepared by Ayurvedic method (Somal) in patients of solid tumours "
Principal Investigators/Co-investigators: Dr. B. S Prasad. Dr Santosh Patil
Name & Address of Institution: KLE University's Shri B. M. KankanawadiAyurveda Mahavidyalaya&KLE Ayurveda Hospital, Shahapur, Belgaum
☐ New Review ☑ Revised Review ☐ Expedited Review
Date of Review (DD/MM/YY): 5.4.2018 **Date of previous review, if revised application: 21.07.2017** **Name of the Reviewers who attended the meeting:** Dr. SupriyaBhalerao, Dr. RajashreeKamat, Dr. Pradeep Shinde, Dr Aziz Arbar, Mrs. Arati S Balikai, Mrs. Sarita S. Shirodkar, Dr. Basavaraj R Tubaki,
Decision of the the Ethics Committee: **Recommended** ☐ **Recommended with suggestions** ☑ **Revision** ☐ **Rejected** ☐

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Suggestions/ Clarifications / Reasons, Remarks,

1 Minor revisions to the protocol have been approved by IEC

Recommended for a period of :One Year

Please note :

- Inform EC immediately in case of any Severe Events and Serious Adverse Events
  Inform EC in case of any change of study procedure site and investigator
- This permission is only for period mentioned above
- Annual report to be submitted to EC
- The study has to be conducted as per approved protocol. Any amendments in the Protocol/ICF/ CRF has to be approved from IEC before implementation
- Members of EC have right to monitor the trial with prior intimation
  The status of the study (Completed/Ongoing/Terminated) should be reported annually
- It is mandatory to obtain renewal of approval and apply for the same at the end of 11 months
  The renewal of approval is subjected to submission of trial report. If the above application is not received within specified period then the permission to renew the project may lapse

Dr. Basavaraj R Tubaki
(Member Secretary)

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(Chairperson)

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American Association of Government College of Pharmacy (Bengaluru) Alumni, New York, USA

H. N. Shivakumar, Ph.D. – Award Recipient
November 10 (Thursday) 2016

Dr. Shivakumar, Professor and Head of the Department of Pharmaceutics, KLE University's College of Pharmacy, Rajajinagar, Bengaluru, Karnataka, India, is the recipient of the **2016 Excellence in Academic Research - The Teacher Difference Award** of the Sri Subbaraya Setty Teacher and Research Students Award in Pharmaceutical Sciences.

Accomplishments of Dr. Shivakumar

Dr. Shivakumar obtained his B. Pharm and Pharm degrees from Bengaluru University in 1991 and 1993 respectively. He received his PhD in 2006 from Rajiv Gandhi University of Health Sciences, Karnataka. From 2008 to 2009, he was a postdoctoral research associate in Professor S. N. Murthy Research Group which specializes in non-invasive drug delivery, in the Department of Pharmaceutics, University of Mississippi, United States.

Shivakumar began his academic career as a lecturer at P.E. S. College of Pharmacy, Bengaluru, in 1993. After two years, he moved to industry serving as a production executive at Bengaluru Pharmaceutical and Research Labs. In 1996, he returned to academia and was a lecturer at K.LE.S's College of Pharmacy. He rose through the ranks and was promoted to Professor in 2006. He again returned to industry as a Manager in Kemwell Pvt Ltd, Bengaluru, where his responsibilities included the implementation of Quality by Design in pharmaceutical development. After two years in the industry, he returned as Professor and Head to KLE University's College of Pharmacy. Shivakumar has numerous funded grants. He is the Principal Investigator for the project entitled "Transdermal Iron Replenishment Therapy" funded by Biotechnology Industry Research Assistance Council. A second project entitled, "Non-invasive electrical device for Transcutaneous Iron replenishment" has been recommended for funding of Rs. 48 Lakhs. His project entitled "Effect of Gamma Sterilization on the Properties of Microneedle Array Transdermal Patch System" has been approved for funding by Board of Research in Nuclear Sciences, Department of Atomic Energy, Govt of India. He also has successfully completed numerous projects. One representative example is the project entitled, "Development of fast-dissolving tablets for neurological disorders" under Research Project Scheme supported by AICTE, New Delhi. In addition, there were numerous industrially supported projects.

Shivakumar also has many consulting responsibilities. He is the cofounder of Institute for Drug Delivery and Biomedical Research. The goal of this non-profit research organization is to conduct interdisciplinary and advanced research on innovative drug delivery and novel treatment methods. The research areas focused have a bench to bedside approach and are intended to improve the quality of

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life of patients suffering from chronic disorders. The Institute aims to discover affordable health care solutions to address unmet medical needs and develop platform technologies that would transform the health of large section of the society. The Institute has established active collaborations with renowned academic institutions, industries and research organizations. He is actively involved in training industrial scientists in several areas, including Formulation Development, Design of Experiments, Establish Design Space, Process/Product Optimization and Implementation of the principles of Quality by Design in Pharmaceutical Development.

Professor Shivakumar is actively involved in mentoring students and preparing the next generation of pharmaceutical scientists. He has guided the M. Pharm dissertation research of 38 students and 3 are currently in progress. In addition, he has supervised the research work of one and mentoring three Ph.D. scholars. Shivakumar is nationally and internationally recognized for his scholarship. He has authored four book chapters, 35 publications and 5 review articles. He also has 45 conference presentations to his credit. In the interest of time, I will briefly summarize some representative research accomplishments.

Transdermal replenishment of iron is a novel, potential approach of iron replenishment. A soluble microneedle array was developed, incorporated with ferric pyrophosphate and tested. If successful, this will be a novel avenue to treat iron deficiency anemia. Currently, the products are being tested at the Veterinary science department of the University of Sydney, Australia in anemic pig model. Dr. Shivakumar worked in the area of delivery of drugs into the nail apparatus. He demonstrated the permselectivity of nail plate under an applied electric field. The concept was demonstrated in a paper published in 'Journal of Dermatological Sciences'. The technology was licensed to an industry partner. The technology was demonstrated to be safe and effective in a phase I clinical investigation. Dr. Shivakumar also works in the area of chronic pain management. In a publication in 'Journal of Controlled Research', he and his coauthors have demonstrated the feasibility of delivery of Ziconotide to cerebrospinal fluid following intranasal administration. The results suggest that intranasal administration could be a potential noninvasive and patient compliant treatment modality of delivering ziconotide to CSF to treat chronic pain.

In summary, based on the outstanding contributions to numerous areas of pharmaceutical sciences through his innovative research, student mentoring and service to the scientific and to the broader community, he has earned the Sri Subbaraya Setty Teacher and Research Students Award for the year 2016. Dr. Shivakumar is a rising star, and we believe that he has many years of outstanding scientific and scholarly productivity. On behalf of the Award Management Coordination Committee of the STARS-AAGCPA, I congratulate **Dr. Shivakumar** on his grandeur success. Please step forward and receive the most distinguished award of our association from the Chief Guest, Professor Dr. Goyal, Vice Chancellor of Delhi Pharmaceutical Sciences & Research University, Delhi.

Dr. K. P. Ravindra
President

Dr. G. Jagadeesh
Scientific Convener

Award Management coordination Committee, STARS
AAGCPA, New York, USA
10 November 2016

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AMERICAN ASSOCIATION OF GOVERNMENT COLLEGE OF PHARMACY (BENGALURU) ALUMNI

New York, USA

Sri Subbaraya Setty Teacher And Research Students (STARS)
Award in Pharmaceutical Sciences

Presents

2016 Excellence in Academic Research - The Teacher Difference Award

to:

Dr. H.N. Shivakumar

Professor and Head, Department of Pharmaceutics, KLE University's College of Pharmacy, Rajajinagar, Bengaluru, Karnataka, India

For his noteworthy research contribution in: transdermal iron replenishment therapy, development of fast-dissolving tablets for neurological disorders, innovative drug delivery and novel treatment methods to improve the quality of life of patients suffering from chronic disorders, noninvasive chronic pain management. Furthermore, for training industrial scientists in pharmaceutical development; and for inspiring, guiding, and furthering the research of aspiring graduate and doctoral students.

Dr. K. P. Ravindra
President

AAGCPA, New York
10 November 2016

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Spectrum Solutions

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29.08.2017

RECEIPT

Received the the cheque No:238393 dated 29/08/2017 for Rs 40,000/- from Dr.H.N. Shivakumar (KLE Universitys College of Pharmacy) against the PO No: KLEU/COPBLR/2017-18 Dated 29.08.2017 (For Flame photometer) as Advance Amount.

Thanks and Regards

Authorized Signatory

Dr. V.A.Kothiwale
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