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2016-2017

SWAMI VIVEKANAND SUBHARTI UNIVERSITY

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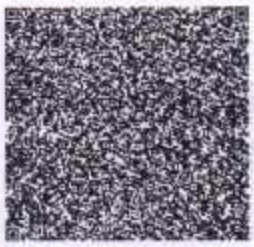
Certificate No.	:	**IN-DL209682538349890**
Certificate Issued Date	:	27-Feb-2016 04:50 PM
Account Reference	:	IMPACC (IV)/ dl740303/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL74030340639453967333O
Purchased by	:	SUN PHARMACEUTICAL INDUSTRIES LTD
Description of Document	:	Article 5 General Agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	SUN PHARMACEUTICAL INDUSTRIES LTD
Second Party	:	Not Applicable
Stamp Duty Paid By	:	SUN PHARMACEUTICAL INDUSTRIES LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)



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CLINICAL STUDY AGREEMENT

This clinical study agreement ("**Agreement**") is executed as of this the **11th day of April 2016** by and between:

Sun Pharmaceutical Industries Ltd, **(CIN L24230GJ1993PLC019050)** a company incorporated under the Companies Act, 1956 and having its registered office at SPARC, Tandalja, Vadodara - 390020, Corporate office at Sun House, 201 B/1, Western Express Highway, Goregaon (E), Mumbai - 400063, Maharashtra India, (hereinafter referred as the "SPONSOR", which expression unless contrary to the context or its meaning thereof shall include its successors and permitted assigns) of the First Part

AND

Principal investigator Dr. Ajay Punj, Associate Professor, Department of Pediatrics, Subharti Medical College and Hospital Meerut, UP, India (hereinafter referred as the "**Investigator**")

AND

Principal Dr. A.K Asthana on behalf of Subharti Medical College and Hospital an institute registered under the law of India having its registered office at Meerut, UP, India, which expression shall, where the context so permits include his successors in office and permitted assigns (hereinafter referred to as the "**Institution**")

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

WHEREAS:

A. The Institution is a health care and research organization engaged in the diagnosis, treatment and prevention of disease and clinical research for the improvement of healthcare, and has the facilities and personnel necessary to conduct the clinical trial;

B. Sponsor is a pharmaceutical company involved, inter alia, in the research, development and manufacture of medicines for use in humans and has developed a fixed dose combination of Arterolane Maleate 37.5 mg and Piperaquine Phosphate (PQP) 187.5 mg dispersible tablets which will be used for treatment of pediatric patients with acute uncomplicated *Plasmodium vivax* malaria. Sponsor represents that it has applied for the necessary permissions and licenses required under the provisions of relevant Acts and Rules which are required for use of the same on subjects/healthy human volunteers etc.

C. Sponsor desires Institution to study the safety and/or efficacy of Fixed Dose Combination of Arterolane Maleate 37.5 mg and Piperaquine Phosphate (PQP) 187.5 mg Dispersible tablets as per Good Clinical Practices ("GCP") and protocol with the title, "A Phase III, Open Label, Randomized, Multicenter, Parallel Group Trial to Assess the Efficacy and Safety of Fixed Dose Combination of Arterolane Maleate 37.5 mg and Piperaquine Phosphate (PQP) 187.5 mg Dispersible tablets in Comparison with Chloroquine Phosphate in Pediatric Patients with Acute Uncomplicated *Plasmodium vivax* Malaria and Institution is willing to perform a clinical study of the Investigational Product (IP).

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

1. **SCOPE**

1.1 The Study is of mutual interest and benefit to Sponsor and Institution, and will further the Institution's instructional and research objectives in a manner consistent with the terms and conditions of this Agreement.

1.2 The Institution shall exercise its best efforts to carry out the research ("**Study**") set forth in the Protocol "A Phase III, Open Label, Randomized, Multicenter, Parallel Group Trial to Assess

the Efficacy and Safety of Fixed Dose Combination of Arterolane Maleate 37.5 mg and Piperaquine Phosphate (PQP) 187.5 mg Dispersible tablets in Comparison with Chloroquine Phosphate in Pediatric Patients with Acute Uncomplicated *Plasmodium vivax* Malaria" Version 1.2 dated 1 September 2015 which has been provided prior to signing of this Agreement. In the event of any inconsistency between this Agreement and the Protocol, the terms of this Agreement shall govern. Changes in the Protocol may be made only through prior written agreement between the Sponsor and the Institution. The Study shall be conducted under the direction of Investigator in accordance with this Agreement, subject to review and prior approval by the institution's ethical committee.

2. CONDUCT OF THE CLINICAL TRIAL

2.1 The Investigator and the Institution shall conduct the Study in accordance with the Protocol. The Sponsor is responsible for obtaining and maintaining all applicable regulatory approvals for the Study in India. The Sponsor, Investigator and Institution shall perform the Clinical Study in accordance with all applicable laws, government regulations and guidelines including but not limited to the Drugs & Cosmetics Act 1940 and Rules 1945 : Schedule-Y (as amended from time to time), The Indian Council of Medical Research (ICMR) guidelines, Good Clinical Practices (GCP) and the standards conforming to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

2.2 It is explicitely agreed and acknowledged by the Parties that the Protocol for clinical trial/Study be reviewed and approved by the Institution's Ethical Committee ("EC") before the commencement of the Study. The Investigator shall obtain and deliver a copy of such approval to the Sponsor. The approval must indicate the date of issuance and bear the name and signature of the Chairperson or Secretary of the EC.

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

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

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

applicable subject privacy and informed consent laws and in compliance with all applicable laws and regulations.

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

3. OBLIGATIONS, REPRESENTATIONS &WARRANTIES OF THE PARTIES

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

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

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

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

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

In addition, Investigator shall make efforts to enrol (randomize) a maximum of 25 subjects within the agreed time period. The parties estimate that the whole study will take approximately approx. 2 to 3 months (from the first visit of the first subject to the last visit of the last subject)

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

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

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

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

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

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

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

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

3.9 The Investigator undertakes to document all Adverse Events (AE) on adverse event page of Case Report Form (CRF). The Investigator shall report all Serious Adverse Events (SAEs) to DCGI, Sponsor's safety physician /CRO and the EC within 24 hours of their occurrence. The Investigator shall report SAE after due analysis to DCGI, Sponsor's safety physician, the EC, head of institution and expert committee in cases of death within 10 calendar days of its occurrence. Subsequent follow-up information shall be reported to all stakeholders as mentioned above. Sponsor's safety physician shall ensure reporting of all SAE after due analysis to DCGI, Ethics committee, Head of the institution (trial site), and additionally to expert committee (in cases of death) within 10 calendar days of SAE occurrence. Subsequent follow-up information shall be reported to all stakeholders as mentioned above. Sponsor's safety physician shall ensure reporting of all serious adverse events to other applicable licensing authority, as appropriate. Sponsor's safety physician or CRO (as the case may be) shall send safety letters narrating SAEs to all other participating Investigator(s). As much information as possible shall be supplied by Investigator at the time of the initial report with at least the following information using SAE Report Form.

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

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

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

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

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

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

If Subject has a medical emergency, illness or injury that was caused by the research drug or study procedures, Sponsor will provide subject medical management as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.

In case of Study related injury or death, to the maximum extent permissible under applicable laws and DCGI regulation, Sponsor will provide complete medical care along with compensation for the injury or death. In case of any SAEs (death and other than death) EC will evaluate and give its opinion regarding compensation to DCGI. Subject will get an additional compensation from Sponsor if recommended by DCGI. Subject or his/her nominee(s) has the right to contact the Sponsor or his representative, for the purpose of making claim in the case of trial related injury or death.

3.11 Investigator warrants and represents that:

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

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

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

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

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

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

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

4. FINANCIAL ARRANGEMENTS

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

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

Payee Name: SUBHARATI K. K. B. CHARITABLE TRUST
PAN: AADTS2638D

- Investigators coordinator grant to be paid by cheques payable and sent to the :

Payee Name : GAURAV MITTAL
PAN : BYGPM4137D

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

4.4 The Institution shall raise invoice on the Sponsor and separately specify Service Tax payable, if applicable on the services rendered and shall also show other necessary details such as Service Tax registration no. etc. so as to enable Sponsor to claim credit for the same as per law. The Sponsor shall verify the invoice and make the payment within 15 days from the receipt of the invoice submitted by Institution. However, if, upon verification by Sponsor, the invoice is found to be incorrect or inappropriate, the same shall be returned by Sponsor to the Institution for correction and revision. No other costs, payments and expenses would be borne by Sponsor unless specifically mentioned in this agreement or mutually agreed in writing in advance. Notwithstanding the foregoing, any payment under this Agreement is subject to deduction of applicable Tax-deduction-at-source (TDS). Sponsor shall deduct the amount and pay balance amount to the Institution.

5. TERM AND TERMINATION

5.1 Unless otherwise terminated earlier, this Agreement shall commence upon Effective Date and will continue for a period of 5 years from the Effective Date or upon completion of the Clinical Study, whichever is earlier. **'Effective Date'** means the date when this Agreement becomes effective which shall be the date of last signature hereto by the Parties.

5.2 Any Party may terminate this Agreement with immediate effect, at any time, if another Party is in breach of any of the defaulting Party's obligations hereunder (including a material failure without just cause to meet a timeline) and fails to remedy such breach, where it is capable of remedy, within thirty (30) days of a written notice from the terminating Party specifying the breach and requiring its remedy. Notwithstanding to the above, the Investigator may terminate the Study, if the Investigator suspects an adverse drug reaction / adverse drug event related to the Study related procedure and of serious nature to take its cognizance, after informing Institution, EC and Sponsor in writing. It is explicitly agreed and acknowledged by the Investigator and Institution that in case of termination of study, no further payment shall be made by Sponsor to Principal Investigator, Institution or any other person under this agreement.

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

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

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

5.4.2 in case of failure of the Investigator and/ or Institution to provide access by Sponsor representatives /Clinical monitor all original medical records necessary to verify entries on study case report forms;

5.4.3 in case of an unauthorized replacement of Investigator;

5.4.4 if Sponsor determine that business or scientific considerations require termination of this Agreement (either full or in part);

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

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

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

6. INDEMNIFICATION

6.1 To the maximum extent permitted by applicable laws, the Institution agrees to defend, indemnify and hold harmless the Sponsor and its respective directors, officers, employees and agents (the "Indemnities") and those of its affiliates against all claims, actions, suits, proceedings, liability, losses, damages, charges, orders, fines and expenses, including assessable legal fees and disbursements made or brought by a third party against an Indemnity for harm:

6.1.1 Arising out of or relating to the negligence or willful misconduct or malpractices of the Institution, its employees and agents in performing their obligations under this Agreement;

6.1.2 Arising out of errors or omissions by Institution;

6.1.3 arising out of or relating to the failure of the Institution, its employees and agents to comply with the provisions of this Agreement, the Protocol, or any written instructions of Sponsor concerning the Clinical Study; or

6.1.4 Arising out of the violation of applicable Law related to the conduct of the Clinical Study by the Institution, its employees or agents.

6.2 The Investigator agrees to defend, indemnify and hold harmless the Sponsor and its respective directors, officers, employees and agents **(the "indemnities")** and those of its affiliates against all claims, actions, suits, proceedings, liability, losses, damages, charges, orders, fines and expenses, including assessable legal fees and disbursements made or brought by a third party against an indemnity for harm:

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

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

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

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

6.3 To the maximum extent permitted by applicable laws, SPONSOR agrees to indemnify and hereby indemnifies, defend and hold the Site, its Principal Investigator, Sub-Investigators and study team, directors, officers and the support staff, agents, the trustees of the Institution harmless from and against any proven liability, loss, damage, costs, expenses, claims, demands and suits (including reasonable attorney's fees and expenses) including arising from and resulting out of (i) the breach of any of Sponsor representations, warranties or covenants set forth in this Agreement or (ii) the performance of the Study or any of its results / outcome including, adverse drug experiences or an injury, death to/of a Study subject directly or indirectly caused by or attributed to the Study , (iii) any injury or claim arising due to any defect / malfunction of the IP used during the Study in accordance with the provisions of the Protocol and this Agreement.

6.4 Each Party shall use reasonable efforts to inform the other Parties promptly of any circumstances of which it is aware that are reasonably likely to give rise to a claim or proceeding and shall keep the other Parties reasonably informed of developments in relation to any claim or proceeding, even where a Party decides not to make a claim for indemnification under this Section 5. The Parties further agree that they have a right to retain their own counsel to conduct a full defense of any such claim or proceeding.

6.5 The Institution, Investigator and Sponsor shall each give to the others such help as may reasonably be required for the efficient conduct and prompt handling of any claim or proceeding concerning the Clinical Study.

6.6 No settlement or compromise of a claim or proceeding subject to indemnification under this Section 6 shall be binding on a Party without the prior written consent of the other affected Party(s). A Party shall not unreasonably withhold such consent of a settlement or compromise. Without limiting the generality of the preceding, no Party shall admit fault on behalf of an indemnity or enter into a non-monetary settlement that places future obligations on an indemnity without the written approval of the indemnity.

7. CONFIDENTIALITY.

"Confidential Information" means all information (including, without limitation, subject identity, Study Protocol(s), Investigator Brochure, informed consent form, subject diaries, case report forms, clinical data, other data, reports, specifications, computer programs or models and related documentation, know-how, trade secrets, or business or research plans) of Sponsor or Sponsor's Affiliates that are: (1) provided to Institution or Investigator in connection with this Agreement or a Study; (2) cumulative Study data, results, and reports from all sites conducting the Study.

7.1 Sponsor Confidential Information and all tangible expressions, in any media, of Sponsor Confidential Information are the sole property of Sponsor. Each party shall endeavor to identify tangible Confidential Information provided to the other party as "Confidential" given the understanding that failure to do so does not constitute a designation of non-confidentiality when the confidential nature is apparent from context and subject matter. Institution and Investigator agree to treat Sponsor's Confidential Information as it would its own proprietary and confidential information. Institution and Investigator will only accept information from Sponsor which is required for conduct of the Study and which must be maintained for Institution's records.

7.2 Investigator agrees for a period of five (05) years after the expiration or termination of the Study not to use and disclose Sponsor Confidential Information to any third party. Institution and Investigator agrees not to disclose Sponsor Confidential Information to third parties or use except as necessary to conduct a Study and under an agreement by the third party to be bound by the obligations of this Section. Institution and Investigator shall safeguard Sponsor Confidential Information with the same standard of care that is used with own Confidential Information, but in no event less than reasonable care. The parties understand and agree that information communicated to EC is "Confidential and Privileged".

7.3 The Parties agree to abide by applicable Law relating to the protection of Clinical Trial Subject Personal Information and where Confidential Information is also Personal Information, the obligations in this Section 7 shall remain in force for the period required under such law. The Party that received Personal Information hereunder shall only use or disclose the Personal Information as set out in the Clinical Trial Subject's consent form or as required by applicable Law. Each Party shall give prompt notice to the other Parties of any privacy or security breach it has experienced that affects Clinical Trial Subject Personal Information.

8. PUBLICATION

8.1 Institution and/or Investigator shall have the right to publish his own site patients' data generated during the Study. Upon receipt of written instruction from Sponsor, Institution and/or Investigator shall have the right to publish the results of the Study subject to the terms and conditions of this Section 8. Prior to submission for Publication purpose, the Institution and/or Investigator shall provide Sponsor thirty (30) days to review a Publication. If Sponsor requests in writing, the Institution and/or the Investigator shall withhold any publication or presentation an additional sixty (60) days solely to permit Sponsor to seek patent protection and to remove any Confidential Information from all publications. For the purpose of this Section, "Publication" means a paper, article, manuscript, report, poster, Internet posting, presentation slides, abstract, outline, video, instructional material, presentation (in the form of a written summary), or other disclosure of Study Results, in printed, electronic, oral or other form.

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

8.3 Any publication or disclosure by the Investigator contrary to the provisions of this section or without prior written consent of Sponsor shall be void-ab -initio. It is agreed and acknowledged by the Parties that in the event of any breach of this Section, Section (7) & (8), in addition to other legal remedies that may be available, Sponsor shall have the right to seek specific performance and other injunctive and equitable relief, in any court having jurisdiction over the Parties and the subject matter hereof.

9. INTELLECTUAL PROPERTY RIGHTS

9.1 All Intellectual Property Rights owned by or licensed to Sponsor prior to and after the date of this Agreement are and shall remain the exclusive property of Sponsor.

9.2 All Intellectual Property Rights owned by or licensed to the Institution or the Investigator prior to and after the date of this Agreement, other than any Intellectual Property Rights arising from the clinical Study, are and shall remain the exclusive property of the Institution or the Investigator, as applicable.

9.3 All Intellectual Property Rights (including Clinical trial data and clinical trial documentation) arising from and relating to the Clinical Study/trial, the Investigational drug or the Protocol (the "**Clinical Trial Intellectual Property**") shall be the exclusive property of Sponsor and for this purpose, the Institution and the Investigator hereby assign and transfer, and shall cause the trial site team members to assign and transfer, without additional consideration, to Sponsor (or its nominate designee), all their rights and title in and to the Clinical Trial Intellectual Property throughout the world on perpetual basis. The Institution and the Investigator shall execute and deliver, and shall cause the trial site team members to execute and deliver, all such documents and, at Sponsor's expense, do all such other acts as Sponsor may reasonably require in order to vest fully and effectively all Clinical Trial Intellectual Property in Sponsor or its nominate designee.

9.4 The Institution and the Investigator shall promptly disclose to Sponsor any Clinical Trial Intellectual Property generated pursuant to this Agreement and shall treat the Clinical Trial Intellectual Property as Confidential Information.

10. MISCELLANEOUS

10.1 All notices required to be given by one Party to the other shall be deemed to have been properly served when sent by a registered post or any other means of communication acceptable in law to the addresses mentioned in the first page of this Agreement or such appropriate addresses available in public domain.

10.2 No forbearance or tolerance on the part of the either Party of any breach of this Agreement by the other shall constitute waiver of the requirements of this Agreement.

10.3 Each Party acknowledges that it is entering into this Agreement solely on its own behalf, and will perform any and all of its obligations or work under this Agreement as an independent contractor. Nothing under this Agreement shall create any other relationship between the Parties including without limitation one of principal and agent, employer and employee, or partnership.

10.4 The Institution and Investigator will be responsible for payment to its employees, study team members and/or agents of all salaries, wages, benefits, workman compensations reimbursable travel, lodging, and other expenses to which the study team members or employees or agents may be entitled to receive for performing services. Institution will be solely responsible for withholding and paying all applicable taxes of whatsoever in nature, statutory contributions ,benefits, dues etc. that may be payable to its employees and/or agents.

10.5 This Agreement constitutes the entire Agreement between the Parties and supersedes all prior oral and written understandings between the Parties on the subject matter of this Agreement. Any Exhibit, Annexure or otherwise any documents, including but not limited amendment or modification made in reference with this Agreement shall be valid if the same is incorporated in writing on the terms that may be mutually agreed and signed by the authorized signatories of the respective parties.

10.6 The Parties hereby agree that any provision/s of this Agreement which is held to be invalid and unenforceable in law shall not by itself make this Agreement invalid nor effect the other provisions of this Agreement and the other terms shall remain fully enforceable and valid in law.

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

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

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

10.10 Neither Party to this Agreement shall be liable for breach of this Agreement to the extent caused by or arising from prohibition or restriction by law or regulation of any Government, fire, flood, storms, weather, strike, lock-out or other labour problems, accident, riots, acts of God, breakdown of communication facilities, breakdown of web host, breakdown of internet service provider or other events beyond that Party in breach. The Party affected by such circumstances shall promptly notify the other Parties in writing when such circumstances cause a delay or failure in performance and shall take whatever reasonable steps are necessary to relieve the effect of such cause as rapidly as reasonably possible. In the event of a delay lasting for four (4) weeks or more, the non-affected Parties shall have the right to terminate this Agreement in accordance the term of this Agreement.

10.11 The provisions of this Agreement which, by their terms, require performance after the termination or expiration of this Agreement, or have application to events that may occur after the termination or expiration of this Agreement, will survive the termination or expiration of this Agreement. All indemnity obligations and any applicable indemnification procedures will be deemed to survive the termination or expiration of this Agreement.

11. INTERPRETATION

11.1 Unless the context requires otherwise:

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

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

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

11.1.4. any phrase introduced by the expressions "**including**", "**include**" or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms;

11.1.5. reference to any law: shall be deemed to include any bye-laws, licenses, statutory instruments, rules, regulations, orders, notices, directions, consents or permissions made under that law; and shall be construed as referring to any law which replaces, re-enacts, amends or consolidates such law (with or without modification) at any time;

11.1.6. references to "**writing**" or "**written**" include any modes of reproducing words in a legible and non-transitory form but do not include writing on the screen of a visual display unit or other similar device;

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

11.2 The parties hereto have participated jointly in the negotiation and drafting of this Agreement and, in the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as jointly drafted by the parties hereto and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any provision of this Agreement.

IN WITNESS WHEREOF the parties have executed this Agreement after carefully reading the contents of this Agreement out of their free will and consent without any kind of force or coercion on them.

Signature page follows-

BY SPONSOR:

Sun Pharmaceutical Industries Ltd

Signature:

Name: Dr Rajinder K. Jalali 15 MAY 2016

Designation: Vice President & Head - MACR, Global Head Pharmacovigilance

(who by his signature hereto warrants his authority)

Date:

Place: Gurgaon

BY INVESTIGATOR:

Signature:

Name: Dr Ajay Punj

Designation: Associate Professor

(who by his signature hereto warrants his authority)

Date: 27/05/2016

Place: Meerut

BY INSTITUTION:

Signature:

Name: Dr. A K Asthana

Designation: Principal Subharti medical college

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

Date: 27/05/2016

Place: Meerut

Registrar
Swami Vivekanand
Subharti University
MEERUT

EXHIBIT-A

Dr. Ajay Punj
Associate Professor
Department of Pediatrics
Subharti Medical College and Hospital
NH-58 Subhartipuram, Meerut, UP
India

Phone: +91-9165627101

Dear Dr Punj,

Vide Clinical Trial Agreement dated 11th April 2016, this Agreement Letter summarizes certain important elements regarding your obligations in the execution of the Study Number R2013005 entitled "A Phase III, Open Label, Randomized, Multicenter, Parallel Group Trial to Assess the Efficacy and Safety of Fixed Dose Combination of Arterolane Maleate 37.5 mg and Piperaquine Phosphate (PQP) 187.5 mg Dispersible tablets in Comparison with Chloroquine Phosphate in Pediatric Patients with Acute Uncomplicated *Plasmodium Vivax* Malaria" Version 1.2 dated 1 September 2015. The Sponsor is furnishing the below mentioned funds payable upon receipt of appropriate documents from you.

These funds are partly meant for defraying the expenses for diagnostic or other procedures as per the study protocol, so that neither the subject, nor an insurance program or public assistance agency/ hospital is billed for the same. Part of the funds will not be used for such direct subject care but will be used as professional and clerical allowances for the activities as per the protocol and letter of agreement, including preparation of subject records, medication accountability records and other trial related documentation. The mutually agreeable break-up is given below:

You agree to observe all policies and procedures including financial, of the institution with which you are associated. You will notify Sun Pharmaceutical Industries Ltd in the event of any conflict between the terms of this agreement and any such policies and procedures so that we could attempt to reach an appropriate accommodation.

The payments mentioned above will be made in accordance with the mutually agreed schedule (stated below), and on a pro-rated basis of the number of patients completing the protocol. In the event that the study is terminated at your centre, the payments to be made will be the actual reasonable expenses already incurred or committed to at the time of termination, less payments already made. We will deduct tax at source for the payments according to the prevailing laws of the land, where applicable.

S. No.	Details	Grant (INR)	Unit	Total (INR)
1	Ethics Committee Fee	25, 000	1	25, 000
2	Investigator Coordinator Grant (per Completed patients)	9, 000	25	225,000
3	Administrative/Hospitalization charges (Completed patients)	1, 000	25	25, 000
4	Patient reimbursement	1, 500	25	37, 500
5	Institutional Overhead Charges (per Completed patients)	400	25	10, 000
6	Lab (On actuals for hematology, biochemistry, urinalysis, UPT, parasitology and ECG)	8, 440	25	211, 000
	Total			533,500

Installment	Details	Full/Part
1st	After enrolling 5 patients	20%
2nd	After enrolling 10 patients	20%
3rd	After enrolling 15 patients	20%
4th	After enrolling 25 patients	20%
Final	After data query resolution (after deducting the screen failure cost, if number of screen failures are less than 20% of enrolled pts)	20%
Total		100%

*Terms of payment: 15 days from receipt of bills/invoices

All invoices will be addressed to:

Dr. Rajinder Kumar Jalali
Vice President, MACR
SUN Pharmaceutical Industries Ltd
Sector 18, Gurgaon - 122015

We wish to evaluate 25 patients at your center. The financial terms will remain same in case there is less number of enrollments or you are requested to enroll more than 25 patients.

If the foregoing is acceptable to you, please sign and date three copies of this letter as confirmation of your acceptance. You are requested to send a duly signed financial agreement to the undersigned.

PAYMENT DETAILS

Annexure IA

Head	Cheque to be drawn in favor of	PAN
Laboratory Investigation charges	SUBHARATI K. K. B. CHARITABLE TRUST	AADTS2638D
Institutional Overhead Charges	SUBHARATI K. K. B. CHARITABLE TRUST	AADTS2638D
Investigator Coordinator Grant and Patient reimbursement	GAURAV MITTAL	BYGPM4137D

Reviewed by: Signature, Date Name: **Dr. Amit Nasa** Group Leader, MACR Sun Pharmaceuticals Industries Limited, Gurgaon	**Reviewed by:** Signature, Date Name: **Dr. Sanjay K. Sharma** Associate Director-Clinical Research Sun Pharmaceuticals Industries Limited, Gurgaon
SUN's Authorized Signatory Signature and Date: **Name: Dr. Rajinder K. Jalali** Vice President & Head - MACR, Global Head Pharmacovigilance Sun Pharmaceuticals Industries Limited Medical Affairs & Clinical Research Sarhaul, Sector-18, Gurgaon, Haryana Udyog Vihar Industrial Area Gurgaon, Haryana	**INVESTIGATOR** Signature and Date: 27/05/2016 **Name: Dr. Ajay Punj** Associate Professor Department of Pediatrics Subharti Medical College and Hospital Subhartipuram, NH- 58 Meerut, UP India
INSTITUTE **Name: A K Asthana** Principal/Dean Subharti Medical College and Hospital Subhartipuram,NH-58 Meerut, UP India Signature and Date 27/05/2016	Registrar Swami Vivekanand Subharti University MEERUT

Standard Chartered

Standard Chartered Bank

S – 32, Green Park Main Market,
New Delhi 110 016
IFSC 'SCBL0036026'

VALID FOR THREE MONTHS FROM THE DATE OF ISSUE

दिनांक Date 2 2 0 8 2 0 1 6

D D M M Y Y Y Y

A/c Payee Only

Pay SUBHARTI K K B CHARITABLE TRUST *****

को या उनके आदेश पर Or Order

NINE THOUSAND THREE HUNDRED NINETY-SIX and paise ZERO

रुपये Rupees

Only

अदा करें। ₹*********9,396.00*

खाता सं. A/c No. 527-0-501053-4

For SUN PHARMACEUTICAL INDUSTRIES LIMITED-SSC

Malaria

Dr. Ajay Garg

Authorised Signatories

Please sign above

PAYABLE AT PAR AT ALL THE BRANCHES OF STANDARD CHARTERED BANK IN INDIA

"903010" 110036015: 735095" 29

Please find enclosed cheque towards payments as per details below :

Registrar
Swami Vivekanand
Subharti University
MEERUT

SUN PHARMACEUTICAL INDUSTRIES LIMITED
Plot No. 89,90,91, Sector - 32 Gurgaon - 122001 INDIA
Tel: 124-5135000 Fax:

To,
SUBHARTI K K B CHARITABLE TRUST
Dr Ajay Punj Associate Professor
Department of Padiatrics Subhati Me
College and Hospital Meerut

Dispatch Mode

Document
3417032997
Date
22.08.2016
Your account with us
3600039410

Dear Sir/Madam,

Please find enclosed cheque towards payments as per details below :

PARTICULARS OF BILLS		PAYMENTS	DEDUCTIONS	
Bill No.	Bill Date	Amount	Tax	Gross Amt.
R2013005 RESEARCH GRANT/LABORATORY/INVEST/R2013005	16.08.2016	9396.00	1044.00	10440.00
Sum total		9396.00	1044.00	10440.00
Net Payable		**9396.00**		

Drawn On Standard Chartered Bank New Delhi - 110016
Account number 527-GREENPARK
Check number 903010

SUN PHARMACEUTICAL INDUSTRIES LIMITED

Accounts Manager

Dr. Rajesh Gupta
(PI PACK)
R&D-II

I2208 On 22.08.2016

REGISTERED OFFICE: Sun Pharma Advance Research Center (SPARC), TANDALJA VADODARA - 390020 India

Registrar
Swami Vivekanand
Subharti University
MEERUT

UTTAR PRADESH CM 266524

CLINICAL TRIAL AGGREEMENT

This contract (hereinafter "the Contract") is made as on the 22thof Jun 2015herein after "the Effective Date", by and among:

PROFESSOR /DOCTOR:

Principal Investigator Dr. Abhay S Dube,Professor, Department of Orthopaedics, Subharti Medical College & Hospital Subhartipuram NH-58 Meerut bypass (Delhi Haridwar Road) Pin Code-250005 Uttar Pradesh (INDIA)and CO-INVESTIGATORS Dr. Prem Prakash Khosla, Professor and Head, Department of Pharmacology, Dr. Hira Lal Bhalla, Associate Professor, Department of Pharmacology, Dr. Yashpal Monga, Professor and Head, Department of Surgery, Dr. Abhishek Gupta, Assistant Professor, Department of Medicine, Dr. Molly Madan, Professor and HOD, Department of Microbiology and Dr. Gaurav Mittal, Resident Department of Pharmacology from Subharti Medical College & Hospital, Meerut.

Here in after "the **INVESTIGATORS**"

AND

Principal Dr. A. K' Asthana on behalf of Subharti Medical College & Hospital, Subhartipuram, NH-58, Meerut bypass (Delhi Haridwar Road) Pin Code-250005 Uttar Pradesh (INDIA).

Hereinafter "the **INSTITUTION**" study site

AND

KPS CLINICAL SERVICES PVT. LTD., a company incorporated under the Companies Act, 1956 and having its corporate office at S-203/204, II[nd] Floor, Meridian View Plaza, Alpha Commercial Belt, Alpha 1, Greater Noida (NCR), Gautam Buddha Nagar 201 306, Uttar Pradesh, INDIA represented for the purposes hereof by Mr. Mukesh Kumar, CEO & Director – Clinical Operation . Hereinafter "the **CRO**"

The INVESTIGATORS, the INSTITUTION, and the CRO are hereinafter individually referred to as a "Party "or collectively referred to as the "Parties".

WITNESSETH:

WHEREAS, the CRO is to perform a clinical trial (hereinafter the Study) to evaluate its product [Arbekacin Sulphate] (hereafter the Investigational Product) in accordance with a protocol entitled **"A Multi-centric, Open label, Randomized, Comparative, Parallel-group, Active-Controlled Phase III Clinical Trial to Evaluate Safety and Efficacy of Arbekacin Sulphate injection versus Vancomycin injection in Patients diagnosed with MRSA infection"** Alkem/CT/Arbk/032012, Version No.: 02 and its amendments hereinafter collectively the Protocol,

AND WHEREAS, the INSTITUTION and the INVESTIGATORS having each reviewed the Protocol for the Study, the Clinical Brochure and sufficient information regarding the Investigational Product to evaluate their interest in participating in the Study, agreed to participate in the Study and assure that they have sufficient authority, competence and experience, along with the necessary infrastructure and technical means to perform the Study after the Institutional Ethical Committee has approved this project.

NOW, in consideration of the undertakings and commitments set forth herein, the Parties agree to enter into the Contract, which provisions shall apply in compliance with those of the Protocol.

ARTICLE 1. PROTOCOL

The Study shall be performed in strict compliance with the Protocol a copy of which has been provided and signed by the INVESTIGATORS, INSTITUTION and CRO, as such Protocol is submitted to the registered Institutional Ethic Committee (IEC/IRB) for favorable opinion/ approval and as the Protocol may be amended from time to time thereafter.

Any amendment to the Protocol shall be notified to the relevant IEC/IRB according to regulation & guidelines mentioned in section 3.1. All the terms of the Protocol and any further amendments to the Protocol are incorporated hereunder and are part of the Contract.

To the extent that there may be any inconsistency between this Contract and the Protocol, this Contract shall control, except with respect to medical or clinical matters for which the provisions of the Protocol shall take precedence.

ARTICLE 2.STUDY SITE.

The Study shall be performed at the INSTITUTION (hereafter the Study Site). The INVESTIGATORS and the INSTITUTION shall be responsible for obtaining any authorization from the representatives of the Study Site where the Study is performed.

For the avoidance of doubt, the sums paid under financial disclosure agreement with study sites of the Contract to the INSTITUTION involves compensation for the performance of the Study carried out at the Study Site.

The INVESTIGATORS hereby represents, warrants and covenants that they shall maintain all necessary authorizations from the Study Site representatives to perform the Study and that INSTITUTION shall take responsibility for the payment of any cost incurred by the Study Site in connection with the Study, the amount and terms of which shall be directly and exclusively handled by the INSTITUTION.

NOTARY GOVT. OF INDIA AKHILESH KUMAR Reg No 9527 Distt. Meerut

ARTICLE 3.COMPLIANCE

The Study shall be performed in accordance with (i) the Protocol (ii) all applicable Central, State and Local laws, rules and regulations in India including the Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research and the Indian GCP Guidelines, (iii) the Guideline for Good Clinical Practice of the International Conference on Harmonization (hereinafter the ICH–GCP), (iv) the principles laid down by the 18th World Medical Assembly (Helsinki, 1964) and all applicable amendments laid down by the World Medical Assemblies, and (v) the specific procedures provided by the CRO applicable for conducting the Study And that the Institutional Ethical Committee shall analyze the contents of this trial on behalf of the INSTITUTION.

3.2 The INVESTIGATORS, -and the INSTITUTION shall ensure that all procedures defined in the Protocol are complied with, so that all data coming from the Study Site are reliable and have been processed correctly (especially the randomization lists, and the blind character of the Study as the case may be) and will ensure that the content of the case Record Form (CRF) will accurately reflect source documents.

3.3 The INVESTIGATORS, -and the INSTITUTION shall submit CRF to the CRO which ensures the quality, validity and integrity of the data complied herein.

ARTICLE 4 .TERM.

This Contract is being entered into force from the effective date and shall expire upon receipt by the CRO of all data generated by the INVESTIGATORS and after completion of the close-out visit for the Study Site.

If the INVESTIGATORS withdraws from the Study before Close out visit, he should hand over all the responsibilities and relevant study related documents as per ICH-GCP and applicable regulatory requirements to the new INVESTIGATORS after taking prior approval from the IEC and Sponsor. In such case the INVESTIGATORS who withdrawn from the study will not be responsible for submitting any receipt to the CRO of all generated data.

If any study related procedure(s) cause harm/ Injury to the subject or leads to any serious adverse event, the INVESTIGATORS may stop the treatment as per his discretion and may switch over the subject to some other therapy for further care and management of the disease. The expenses of the same will be reimbursed to the INSTITUTION by the Sponsor (Alkem Laboratories) through the Insurance Company. In addition.

NOTARY AKHILESH KUMAR Advocate Reg. No. 3547 Distt. Meerut GOVT. OF INDIA

The Parties estimate that the whole Study will take approximately total study duration will be about seven (07) months including recruitment period] from the first visit of the first Subject to the last visit of the last Subject.

ARTICLE 5 .ITEMS SUPPLIED BY THE CRO

5.1 The CRO shall provide the INVESTIGATORS and/or the INSTITUTION with all necessary information, documents and materials, including but not limited to:

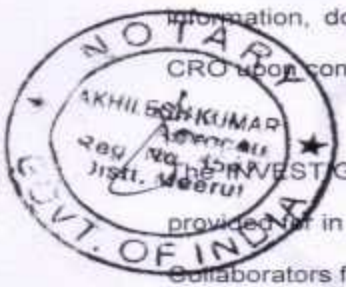
- the INVESTIGATORS's Brochure (IB)

- the Protocol,
- the Informed Consent Form
- the CRF
- Various Logs of study
- the Investigational Product manufactured in accordance with the applicable regulations and/or the Good Manufacturing Practice (GMP), suitably packaged and labeled and in sufficient quantity to conduct the Study.
- a digital video camera (for Audio-Video consenting process), however same needs not to be returned to CRO after completing study enrollment(s).INVESTIGATORS will not be held liable for any damage caused to the digital video camera. The cost to repair any damage caused to digital video camera will be borned by the CRO.

5.2 The INVESTIGATORS, the Collaborators and the INSTITUTION shall use the information, documents and Investigational Product provided by the CRO, solely for the purpose of the Study or to fulfill their own regulatory obligations, to the exclusion of any use for their own or for a third party's account.

For the purpose of the Contract, the term "Collaborator(s)" shall mean any person involved in the Study including but not limited to research associates, sub-INVESTIGATORS, biologists, assistants and nurses.

Unless otherwise instructed by the CRO or required by applicable laws and regulations, the information, documents and Investigational Product shall be returned or made available to the CRO upon completion of the Study.



The INVESTIGATORS shall bind the Collaborators with obligations at least as stringent as those provided for in the Contract. Therefore, the INVESTIGATORS shall be held liable should any of the Collaborators fail to comply with any of the obligations provided for in this Contract.

The Investigational Product will not be released until the CRO has received a copy of the written and dated approval/opinion of the IEC/IRB.

5.3 TheINVESTIGATORS / INSTITUTION or its designee shall ensure that an accurate record of the quantity of Investigational Product received and dispensed to each patient is maintained. The INVESTIGATORS/INSTITUTION shall ensure that the Investigational Product is stored and dispensed in accordance with the CRO/SPONSOR's specifications and applicable laws and regulations.

5.4 TheINVESTIGATORS/INSTITUTION agrees to take responsibility for the safeguarding of such materials and to notify CRO promptly in case of any loss damage, or failure of these materials.

5.5 Upon termination or completion of the Study, all unused Study Drug, compounds, drugs devices, case report forms, whether or not completed, and other related materials that were furnished to the INVESTIGATORS/INSTITUTION by CRO and/or SPONSOR shall be returned to the CRO and/or SPONSOR.

ARTICLE 6.SUBJECTS RECRUITMENT

6.1 The INVESTIGATORS has estimated that he/she can recruit a maximum of No of Twenty seven (27)Subjects (the "Subjects"), within [six (06) months recruitment period].This target of recruitment can be increased or decreased only upon discretion the CRO. In addition, CRO may establish a threshold number of Subjects and rate of accrual of Subjects (e.g., x Subjects per day/week/month) to allow for appropriate monitoring of the Study and will communicate this information to the INVESTIGATORS. The INVESTIGATORS undertakes to comply with these limitations and conditions for further recruitment at the Study Site as required by the CRO.

6.2A minimum of six (6) patients must be enrolled within within three (3) months of initiating the Study at the STUDY SITE. Subsequently, if less number of subjects is enrolled over a period of three (3) months, or if the INVESTIGATORS cannot begin the Study at the STUDY SITE, CRO may decide at its discretion to discontinue the Study at the STUDY SITE.

NOTARY AKHILESH KUMAR Advocate Reg. No. 4547 Distt. Meerut GOVT. OF INDIA

6.3 The CRO reserves the right to request the INVESTIGATORS to limit the recruitment of further Subjects or cease the recruitment, notably in case the recruitment target for the Study has been reached. In such case, the CRO shall inform the INVESTIGATORS to stop the recruitment of any Subject who has not yet signed informed consent. The INVESTIGATORS shall upon receipt of the written notice stop immediately further recruitment of Subjects. Payments shall only be made according to the number of Subjects recruited up to the date of receipt of the notice by indicating no further recruitment. The CRO will not take any responsibility and make any payment for the Subjects recruited after this date.

CONSENT OF THE SUBJECTS

7.1 Before any Subject's participation in the Study, the INVESTIGATORS shall fully inform any subject and/or, as the case may be, her/his legal representative, in language understandable to them, of all pertinent aspects of the Study in accordance with the requirements stipulated under Indian laws/regulations (Article 3.1).

7.2 The INVESTIGATORS shall ensure that all Subjects participating in the Study and/or their legal representative (i) have received a copy of the Subject information leaflet, and (ii) have expressed their prior consent by signing the informed consent form, in such format as approved by DCGI or Other Authority, without the undue influence or coercion of any person directly involved in the Study, and only after having been duly informed.

7.3 The INVESTIGATORS &/ INSTITUTION shall ensure that the entire Informed consent process is audiovisually recorded. The INVESTIGATORS&/ INSTITUTION should ensure that the confidentiality of the recorded files is appropriately maintained and will be achieved in form of CD andh ard copy for a period of atleast five (5) years or as per the latest regulatory requirements after submission of approved clinical study report to regulatory authorities &Ethics Committee.

ARTICLE 8.MONITORING OF THE STUDY.

8.1 The CRO shall appoint monitor(s), bound by a professional confidentiality obligation, who will work with the INVESTIGATORS and the INSTITUTION to ensure proper conduct of the Study (hereinafter the « Monitor(s) »). The INVESTIGATORS and the INSTITUTION agrees to fully cooperate with the CRO monitoring procedures and maintain all necessary patient information

8.2 The Monitor shall be entitled to visit the Study Site and be regularly informed about the performance of the Study and shall collect all the documents and information about the Study in accordance with the Protocol and the ICH-GCP. He/she shall have access to all records on the subjects and all information pertaining to the Study, as well as, copies thereof, if needed.

NOTARY AKHILESH KUMAR Advocate Reg. No. 6847 Distt. Meerut GOVT. OF INDIA

ARTICLE 9. DUTY OF INFORMATION

The INVESTIGATORS and/or the INSTITUTION shall immediately inform the CRO, Licensing Authority & Ethics Committee of any serious adverse event (SAE) or other events as defined in the Protocol or as per latest applicable regulatory requirements.

If during the study treatment of any subject the INVESTIGATORS are absent for more than seven calendar days, then INVESTIGATORS or the INSTITUTION will inform the CRO and Ethics Committee in writing and will delegate his/her responsibilities to the authorized INVESTIGATORS, INVESTIGATORS.

ARTICLE 10.FINANCIAL TERMS AND CONDITIONS

In consideration for the proper performance by the INVESTIGATORS and the INSTITUTION of their obligations under the Contract, CRO shall compensate the INSTITUTION in compliance with the payment terms defined in budget approval sheet.

ARTICLE 11.CONFIDENTIALITY AND RESTRICTED USE.

11.1 All information disclosed or provided by the CRO or produced during the Study, including but not limited to the Protocol, the INVESTIGATORS' brochure and CRF/e-CRF, the results obtained during the course of the Study, the financial terms of the contract signed with CRO (hereafter the « Confidential Disclosed Agreement(CDA) »), is confidential. The INVESTIGATORS and the INSTITUTION agree to keep confidential and not to disclose the Confidential Information to any third party without the prior written approval of the CRO. The INVESTIGATORS and the INSTITUTION shall use the Confidential Information solely for the purposes of the Study.

Furthermore, the Parties agree to adhere to the principles of personal data confidentiality in relation to the Subjects, the INVESTIGATORS, the INSTITUTION and the Collaborators involved in the Study. Each Collaborator shall be subject to these obligations of confidentiality and restricted use. The INVESTIGATORS shall inform the Collaborators of the confidential nature of the Study and will only provide them with the Confidential Information that is strictly necessary for the accomplishment of their acts.

The Confidential Information shall not include information that: (1) is at the time of disclosure, or thereafter becomes, publicly available through no fault of the INVESTIGATORS or the INSTITUTION; (2) is disclosed to the INVESTIGATORS or to the INSTITUTION by a third party entitled to disclose such information in a non-confidential manner; (3) is known to the INVESTIGATORS or to the INSTITUTION prior to disclosure under this Contract, as shown by the INVESTIGATORS's or the INSTITUTION's prior written records; (4) can be documented to have been independently developed by Study Site's personnel without reliance on Confidential

Information; or (5) is required by applicable law to be disclosed, provided that the INVESTIGATORS or the INSTITUTION give the CRO prompt notice of such fact so that it may obtain a protective order or other appropriate remedy concerning any such disclosure, cooperate fully with the CRO in connection with its efforts to obtain any such order or other remedy, and disclose, where disclosure is necessary, only the information legally required to be disclosed.

11.3 The obligations of confidentiality and restricted use contained herein are applicable during the term of the Contract and shall survive for 10 (ten) years from its date of termination or expiry whichever is later.

ARTICLE 12 .RECORD RETENTION

The INVESTIGATORS and the INSTITUTION through the Study Site shall retain and preserve one (1) set only of all original data(such as source notes, study logs, TMF, CRF, Labs investigation report, patients diaries etc. in secure area with control access to authorise study site personnel) generated in the course of the Study for 5 years or as per the latest regulatory requirements from the date of site close out visit.

The CRO must be informed in writing of any change of address or relocation of the Study files and of the INVESTIGATORS /the INSTITUTION during this period.

Following the Retention Period, as instructed by the CRO, the INVESTIGATORS and/or the INSTITUTION will either forward such records to the CRO at the CRO's expense, retain such records for a reasonable additional charge to be mutually agreed , or destroy the records, and send the CRO proof of such destruction. Subject files should be retained as per GCP requirements as defined in the Protocol and in compliance with local regulations.

NOTARY AKHILESH KUMAR Advocate Reg No. 9547 Distt. Meerut GOVT. OF INDIA

ARTICLE 13.DATA PROTECTION

13.1 The Subject data, the INVESTIGATORS's data, the INSTITUTION's data and Collaborators' data, which may be included in the CRO's databases, shall be treated by the Parties in compliance with all applicable laws and regulations.

13.2 The CRO also collects specific data regarding the INVESTIGATORS and the Collaborators which may be included in the CRO's databases, shall be treated by both Parties in compliance with all applicable laws and regulations.

13.3 When archiving or processing data pertaining to the INVESTIGATORS, the Collaborators, the INSTITUTION and/or the Subjects, and CRO shall take all appropriate measures to safeguard and prevent access to this data by unauthorized third party.

ARTICLE 14 .PUBLICATIONS AND COMMUNICATIONS

14.1 TheSponsor or their Designee undertakes not to hold any publication rights of the study in any part without consulting the INVESTIGATORS but the right to publication are with the Sponsor or their Designee only. The INVESTIGATORS understand that this is a multi-centric trial. Any publication arising out of this study may be made only after consulting with the INVESTIGATORS and their names may be included in it, the order of which shall be discussed later.

14.2 The INVESTIGATORS and the INSTITUTION shall not use the name(s) of the CRO and/or of its employees in advertising or promotional material or publication without the prior written consent of the CRO. The CRO shall not use the name(s) of the INVESTIGATORS, the INSTITUTION and/or the Collaborators in advertising or promotional material or publication without having received their prior written consent(s).

ARTICLE 15.PROPERTY RIGHTS

15.1 All information, documents, materials (hereinafter collectively "Information") and Investigational Product provided by the CRO are and shall remain the sole and exclusive property of the CRO.

The INVESTIGATORS and INSTITUTION shall not and shall cause the Collaborators not to mention any Information or the Investigational Product in any application for a patent or any other intellectual property rights whatsoever.

15.2 All the results, data, documents, discoveries and inventions which arise directly or indirectly from the Study in any form, shall be the immediate and exclusive property of the CRO or its designee except for the publication generated out of this study. For this purpose, the INVESTIGATORS, the Collaborators and the INSTITUTION presently assign to the CRO (or its designee) all intellectual property rights (including all patents, copyrights, databases and any application or right to apply for registration of any of those rights) which may arise directly or indirectly from the Study and all existing or future materials created in relation to the Study. The results of the study will be used by the CRO after getting the Clinical Study Report signed and approved by the INVESTIGATORS and the INSTITUTION.

15.3 The CRO may use all the results at its own discretion, without any limitation to its property right (territory, field, continuance...), and without any additional payment. The CRO shall be under no obligation to patent, develop, market or otherwise use the results of the Study, issued under this Contract.

ARTICLE 16.LIABILITY – INDEMNIFICATION - INSURANCE

16.1 The CRO on behalf of SPONSOR certifies it has subscribed a liability insurance policy to cover its liability as required by applicable law. The CRO will provide the INVESTIGATORS and/or the INSTITUTION with a certificate of insurance.

16.2 The insurance subscribed by the CRO does release neither the INVESTIGATORS nor the INSTITUTION from their obligation to maintain their own liability insurance policy.

16.3 The CRO agrees to indemnify, hold harmless and defend the INVESTIGATORS, the INSTITUTION, and the Collaborators ("Indemnities") from and against any and all claims and suits, including reasonable attorneys' fees incurred in the defence thereof, arising out of an injury to a Subject (including death) caused by the administration of the Investigational Product or the performance of any procedure required under the Protocol, except to the extent such claim or suit is attributable to:

(1)a failure to adhere to the terms of this Contract, the Protocol or any written instructions from the CRO regarding the administration of the Investigational Product or the performance of any required procedure;

(2) a failure to comply with any applicable laws, regulations and government requirements (including, without limitation, obtaining informed consents); or

(3)the negligence or willful malfeasance of the Indemnities.

NOTARY AKHILESH KUMAR Advocate Regd. No. 9547 Distt. Meerut GOVT. OF INDIA

The CRO shall have no obligation under this Article, however, unless: (i) the CRO is promptly notified of any such claim or suit; (ii) the Indemnities cooperate fully in the handling thereof; and (iii) the CRO has sole control over the disposition of such claim or suit, including the selection of counsel and any settlement thereof, provided, however, that no settlement shall include an admission of liability on the part of the Indemnities without their prior written consent, which consent shall not be unreasonably withheld.

ARTICLE 17.AUDITS AND INSPECTIONS.

17.1 For the purpose of ensuring compliance with the Protocol, Good Clinical Practice and applicable regulatory requirements, the INVESTIGATORS and the INSTITUTION shall permit audits by CRO and inspections by applicable regulatory authorities.

The INVESTIGATORS agrees to allow the auditors and/or inspectors to have direct access to his/her Study records and to Subjects files for review, being understood that this personnel is bound by professional secrecy, and as such will not disclose any personal identity or personal medical information.

17.2 The INVESTIGATORS and the INSTITUTION shall devote their best efforts to facilitate the performance of any audit and inspection and shall give to the CRO or to any person designated by the CRO access to all necessary facilities, data and documents.

17.3 As soon as either the INVESTIGATORS or the INSTITUTION is notified of a future inspection by the authorities, they shall inform the CRO for any such inspection/audit. The information that arises from the inspections by the regulatory authorities will be immediately communicated by the INVESTIGATORS and/or INSTITUTION to the CRO.

17.4 The INVESTIGATORS and the INSTITUTION shall take appropriate measures required by the CRO to take corrective and preventive actions without delay in order to resolve the findings.

17.5 It is expressly agreed between the Parties that the CRO will not compensate the INVESTIGATORS and/or the INSTITUTION for the audits and inspections and that the assistance and availability of the any or all the INVESTIGATORS or the INSTITUTION for the audits and inspections, if any, is included in the amount mentioned in financial disclosure agreement with study sites.

17.6 The rights and obligations under this Article shall remain in effect for ten (10) years after the end of the Study.

ARTICLE 18.TERMINATION OF THE CONTRACT.

This Contract may be terminated: (1) by a mutual written consent of the CRO, INVESTIGATORS and the INSTITUTION upon thirty (30) days prior written notice if Study Site or the INVESTIGATORS for any reason becomes unable to perform or complete this Study, to the CRO; or (2) by the CRO upon thirty (30) days prior written notice to the INVESTIGATORS and the INSTITUTION.

In the event this Contract is terminated, the CRO will be responsible for compensating INVESTIGATORS and/or the INSTITUTION for actual activities performed hereunder in accordance with the terms of this Contract and reasonable non-cancellable expenses incurred

prior to notice of termination if such expenses were required under the Protocol and contemplated within financial disclosure agreement with study sites. Any funds paid in advance will be prorated and any excess funds will be returned to the CRO. The INVESTIGATORS shall provide the CRO with all documentation required by the Protocol and applicable laws and regulations and any equipment provided by the CRO in connection with the Study no later than ninety (90) days after the completion or early termination of the Contract.The terms and conditions of Articles 3, 11, 13, 14,15,16,19 shall survive the expiration or earlier termination of this Contract.

ARTICLE 19.DEBARMENT AND SENTENCING FOR MALPRACTICE.

The INVESTIGATORS and the INSTITUTION represent and warrants that neither he/she nor any Collaborators /INSTITUTION involved in conducting the Study nor any member of the staff of the INSTITUTION, has been debarred, excluded, disqualified or restricted in their ability to practice medicine, participate in a clinical trial, or perform services in connection with the evaluation of a pharmaceutical product under any laws, regulations or professional code of conduct.

The INVESTIGATORS shall immediately notify the CRO should he/she or any Collaborators involved in conducting the Study, be so debarred, excluded, disqualified or restricted, or should a procedure or action be initiated against any of them that could result in their being so debarred, excluded, disqualified or restricted, at any time during the term of this Contract and during the twelve months following the expiration or termination of the Contract.

ARTICLE 20.CONFLICT OF INTERESTS AND FINANCIAL DISCLOSURE.

The INVESTIGATORS shall ensure that he/she and the Collaborators involved in this Study at the INVESTIGATORS' Study Site provide the CRO with the appropriate financial disclosures required for compliance with DCGI, on such forms as the CRO may supply or approve.

NOTARY AKHILESH KUMAR Reg No 4547 Distt Meerut GOVT. OF INDIA

ARTICLE 20.MISCELLANEOUS.

21.1 The Protocol, the Contract and all others documents exchanged between the Parties constitutes the whole undertaking of the Parties. All appendices attached hereto shall be deemed to be incorporated herein.

21.2 Any work performed by the INVESTIGATORS, the Collaborators and/or the INSTITUTION under this Contract shall be considered to be performed by them as independent contractors and not as employees, partners or agents of the CRO. No Party shall have the authority, either express, implied or apparent, to bind the other Party, except to the extent that same may be

consistent with the performance of that Party's obligations in accordance with the terms of this Contract.

21.3 Except as otherwise expressly mentioned hereinabove; any notification shall be made by mail or fax.

21.4 If either Party is prevented from fulfilling its obligations in accordance with the terms of this Contract due to force majeure (as defined by competent law and/or competent court), this Party shall be released from performance to the extent that it is so prevented from doing so for the duration of the intervening circumstances. The Party wishing to claim relief on the grounds of the said circumstances shall notify the other Party in writing without delay on the intervention or cessation thereof. The Party so prevented from fulfilling its obligation shall devote its best endeavors to remove or avoid the impediment as soon as possible. If the Party is prevented from fulfilling its obligations under this Contract due to force majeure for a period exceeding two (2) running months, each Party shall have the right to terminate this Contract by registered mail with acknowledgment of receipt. The termination will become effective forthwith.

21.5 No indulgence granted by either Party to the other in relation to any term hereof shall be deemed a waiver of such term or prejudice the later enforcement of that or any other term hereof.

21.6 Should a provision of this Contract in any manner whatsoever contravene any applicable laws and regulations, such provision shall be deemed to be severable and shall not affect any other provision of this Contract, nor affect the enforceability of those remaining provisions which are not in contravention of any law and regulation.

21.7 The Contract is concluded by the CRO intuit personae. Hence, the INVESTIGATORS and the INSTITUTION shall not be allowed to transfer totally or partially the obligations the CRO charged them with, nor to subcontract them without the prior written consent of the CRO. The INVESTIGATORS and the INSTITUTION shall, where applicable, transmit to the Collaborators the Contract and shall cause them to abide by its terms and conditions. The CRO may transfer this Contract to a successor in interest to its business by reason of any merger, acquisition, partnership, license agreement or otherwise, provided that the assignee is subject to the terms and obligations provided in this Contract.

21.8 This Contract constitutes the entire agreement between the Parties relative to the subject matter hereof and supersedes all representations, warranties, agreements or undertakings previously made relative to such subject matter, and no such representations, warranties, agreements or undertakings shall be any force and effect unless contained herein. No variation of

any terms and conditions of this Contract will be binding upon the Parties unless committed in writing and signed by them respectively.

21.9 This Contract shall be governed by the laws of India. Prior to taking any legal action, the Parties shall endeavor to settle by amicable arrangement any disputes arising between them regarding this Contract. Should the Parties fail to reach an amicable settlement, the Parties agree to submit to the exclusive jurisdiction of the courts of Meerut and they waive any other forum to which they may be entitled by reason of their present or future address or for any other reason.

IN WITNESS WHEREOF, the Parties hereto have caused this Contract to be duly executed on their behalf in three counterparts, each of which shall be deemed to be an original, as of the Effective Date.

KPS CLINICAL SERVICES PVT. LTD.
Mr. MUKESH KUMAR
CEO & Director-Clinical Operations.

Signature: 30/07/2015

In the presence of: Nishant Khais

Signature/Date(Witness): 30/Jul/2015

THE INVESTIGATORS

1.Dr. Abhay S Dube,
Professor and Head, Department of Orthopaedic Surgery,
Subharti Medical College & Hospital Subhartipuram NH-58 Meerut (U.P)- Principal Investigator

Signature with date: 15/7/15

2.Dr. Prem Prakash Khosla
Professor and Head,
Department of Pharmacology,
Subharti Medical College & Hospital Subhartipuram NH-58 Meerut (U.P)

Signature with date: Premkhosla

NOTARY AKHILESH KUMAR Regd. No. 7547 Distt. Meerut GOVT OF INDIA

3.Dr. Hina Lal Bhalla,
Associate Professor,
Department of Pharmacology,
Subharti Medical College & Hospital Subhartipuram NH-58 Meerut (U.P)

Signature with date: HinaBhalla 15/July/2015 15/Jul/2015 (RE) HinaBhalla 15/Jul/2015

4. Yashpal Monga,
Professor and Head,
Department of Surgery,
Subharti Medical College & Hospital Subhartipuram NH-58 Meerut (U.P)

Signature with date:

5. Dr. Abhishek Gupta,
Assistant Professor,
Department of Medicine

Signature with date: ..... 15 July 2015 .....

Dr. Molly Madan,
Professor and HOD, Department of Microbiology
Subharti Medical College & Hospital, Meerut.

Signature with date: ..... For Hina Bhalla 15 July 2015 .....

Dr. Gaurav Mittal,
Resident
Department of Pharmacology
Subharti Medical College & Hospital, Meerut

Signature with date: ..... 14/7/2015 .....

In the presence of: _____

Signature/Date(Witness): _____

THE INSTITUTION

PrincipalSubharti Medical College & Hospital **Subhartipuram NH-58 Meerut(U.P)**

Signature: _____

In the presence of: _____

Signature/Date(Witness): Hina Bhalla 23 July 2015

NOTARY AKHILESH KUMAR Advocate Regd No 4547 Distt. Meerut GOVT. OF INDIA

Annexure-A

Budget Approval Sheet

Study Title: "A Multicentre, open label, Randomized, Comparative, parallel –group, Active Controlled Phase III clinical Trial to evaluate safety and Efficacy of ArbekacinSulphate injection versus Vancomycin injection in patients diagnosed with MRSA infection".

Study Protocol No: Alkem/CT/Arbk/032012

Particulars:

- Total No of Patients Twenty Seven(27)
- Total No of Visit Eleven (11)
- Total Study Duration Twenty one days (21)
- Screening Duration (-3 to-1 days)

- Active Duration Minimum 7 days, Maximum up to 14 days
- Follow up Period Fifteen to twenty one days(15-21 days)

Remuneration for Principal Investigator and study Team:

Particulars	Cost Per Patient(In INR)	No Of Patients	Total Amount (In INR)	Sub-Total (IN INR)
Screening	2000X1=2000	27	54,000.00	4,75,200.00
Active Duration	900X14*=12600	27	3,40,200.00	
Follow Up	1500X2=3000	27	81,000	
Total Cost	**17,600**	**27**	**4,75,200.00**	
Institutional Over Head Charges (Bill-Fax, Telephone, Internet etc)			**20,000**	**20,000**
Study Archival Charge (almirah cost)			**10000.00**	**10000.00**
Lab cost(will be paid on actual as per invoice)				**NA**
Ethics Committee Charges(as per IEC fees)				
Grand Total				**5,05,200.00**

IN words: Five Lakh Five Thousand Two Hundred only.

NOTE: Applicable TDS will be deductable

Treatment failure for maximum of five (5) subjects will be given

***For treatment duration the payment will be made on actual treatment days completed by the subject**

Term of Payments:

- 25% at the time of site initiation.
- 25% at the time of 50% Patient recruitment.
- 25% at the time of 100% Patient recruitment.
- 25% at the time of site closeout.
- [illegible] after approved by sponsor/CDSCO

NOTARY GOVT. OF INDIA AKHILESH KUMAR Advocate Reg No 454/ Distt. Meerut

Registrar Swami Vivekanand Subharti University MEERUT

Account Details of Site

Name of Payee	Subharti Medical College
Account No	00171010003340
Name of Bank	Oriental Bank of Commerce
Branch Address	Subharti Dental College, NH 58, Subhartipuram, Meerut
Contact Details of Payee	Dr. A.K.Asthana; Mobile number – 96390101205
PAN No.	AADTS2638D in the name of Subharti KKB Charitable trust

NOTARY
AKHILESH KUMAR
ADVOCATE
Reg No 4547
Distt. Meerut
GOVT. OF INDIA

ATTESTED
7-7-15
AKHILESH KUMAR
NOTARY, MEERUT

Registrar
Swami Vivekanand
Subharti University
MEERUT

Initials CRO Initials INSTITUTION Initials INVESTIGATORS

SUBAGREEMENT
MODIFICATION No. 1

WHEREAS, Johns Hopkins University on behalf of its Bloomberg School of Public Health ("JHSPH") has embarked on a project entitled: "HarvestPlus Challenge Program – Phase II" ("Challenge Program") under Grant # 8277 as sponsored by the Centro Internacional de Agricultura Tropical ("CIAT") and the International Food Policy Research Institute ("IFPRI") (CIAT and IFPRI, together, ("Sponsor") for various donors, in particular, the Bill and Melinda Gates Foundation ("Foundation"); and,

WHEREAS, JHSPH has entered into a Subagreement with Subharti Medical College, Swami Vivekanand Subharti University ("Subrecipient") under Purchase Order # 2002131149; and,

WHEREAS, it is desired to modify this Subagreement;

NOW, THEREFORE, JHSPH and Subrecipient mutually agree as follows:

Clause 2. **PERIOD OF PERFORMANCE** is amended as follows:

Delete existing termination date of "December 31, 2013" and replace with new termination date of "December 31, 2014".

All other terms and conditions remain unchanged and in full force and effect.
ACCEPTED FOR:

THE JOHNS HOPKINS UNIVERSITY

Name: Debra Brodlie, JD
Assistant Director, JHU
Research Administration

Date: _____

SUBHARTI MEDICAL COLLEGE, SWAMI VIVEKANAND SUBHARTI UNIVERSITY

Name: RAJESH KUMAR MISHRA

Title: Finance Officer
Swami Vivekanand Subharti University

Date: 20th Oct 2014

Swanval, Natalia, 10.14.14, Subharti, 114666, 4637

Registrar
Swami Vivekanand
Subharti University
MEERUT

Subagreement Modification #2

WHEREAS, Johns Hopkins University ("JHU") has embarked on a project entitled, "Harvest Plus Challenge Program-Phase II" under Grant # 8277 as sponsored by the Centro Internacional de Agricultura Tropical and the International Food Policy Research Institute, for various donors, in particular the Bill and Melinda Gates Foundation ; and

WHEREAS, JHU has entered into a Subagreement with Subharti Medical College, Swami VivekanandSubharti University ("Subrecipient") under PO # 2002131149; and

WHEREAS, it is desired to modify this Subagreement;

NOW THEREFORE, JHU and Subrecipient mutually agree as follows:

Clause 2. PERIOD OF PERFORMANCE is amended as follows:

Delete the existing termination date of "December 31, 2014" and replace with new end date of" May 31, 2015."

All other terms and conditions remain unchanged and in full force and effect.

Accepted for:

Johns Hopkins University

Debra Brodlie, JD

Associate Director, JHURA

Date: 5/14/15

Subharti Medical College, Swami VivekanandSubharti University

Finance Officer
Swami Vivekanand Subharti University

Name: RAJESH KUMAR MISHRA

Title:

Date:

SUBAGREEMENT
MODIFICATION NO. 3

WHEREAS, The Johns Hopkins University ("JHU") has embarked on a project entitled: "HarvestPlus Challenge Program – Phase II," under Grant # 8277 as sponsored by the Centro Internacional de Agricultura Tropical ("CIAT") and the International Food Policy Research Institute ("IFPRI"), for various donors, in particular the Bill and Melinda Gates Foundation ; and

WHEREAS, JHU has entered into a Subagreement with Subharti Medical College, Swami Vivekanand Subharti University ("Subrecipient") under Purchase Order # 2002131149; and,

WHEREAS, it is desired to modify this Subagreement,

NOW, THEREFORE, JHU and Subrecipient mutually agree as follows:

Clause 1. **STATEMENT OF WORK** is amended as follows:

1.1 Amend existing Statement of Work (SOW) with updated version set forth as Exhibit A-1, attached herein and incorporated hereto.

Clause 2. **PERIOD OF PERFORMANCE** is amended as follows:

Delete the existing termination date of "May 31, 2015" and replace with new end date of "March 31, 2016".

Clause 3. **COST, PAYMENT AND AVAILABILITY OF FUNDS** is amended as follows:

3.1 Delete the existing total amount of $391,000 USD and replace with the new total amount of $416,318 USD, representing an increase in the amount of $25,318 USD. See Exhibit B-1 attached hereto and incorporated herein.

Clause 6. **APPROVALS AND NOTICES** is amended as follows:

6.1 Delete existing contact "Anthony Maranto" and replace with the following:
Gene Rutherford
JHURA
Phone: 443-997-1905
gene@jhu.edu

All other terms and conditions remain unchanged and in full force and effect.

[SIGNATURE PAGE FOLLOWS]

...HARITABLE TRUST

...250001

...DIA

ORIENTAL BANK OF COMMERCE
TRANSPORT NAGAR,MEERUT
DELHI-MUSSOORIE RD.
TRANSPORT NAGAR,TEH.MEERUT
MEERUT, UTTAR PRADESH
250002

21-07-2016

INWARD REMITTANCE TRANSACTION ADVICE

FB Type: INWMG/IRTT
Bill No. 038640002840116
Transaction Id : AA342798

Operation : Realisation
Transaction Date : 11-07-2016

Currency Conversion Details are as below :

	From Currency	/ Amount	Rate	To Currency	/ Amount
Purchase :	USD	49696.54	66.94	INR	3259746.00

Other Party Name : THE JOHNS HOPKINS UNIVERSITY
Bill Country : UNITED STATES OF AMERICA
Invoice Number :
LcNumber : NOT UNDER DC

Forward Contract No.(1) :
Forward Contract No.(2) :
Forward Contract No.(3) :

Transaction Details are as below :

Account Type	Account Number	Account Name	Transaction Currency --	Cr/ Dr	Amount
Realisation	03880074050001	INWARD REMITT.SUSPEN	INR	Dr	3259746.00
Operative	03880025500010	CONSOLIDATION ACCOUN	INR	Cr	3259746.00
Commission	03880043030002	COMM.RECD. FCY DD-TT	INR	Cr	[illegible]
Comm. Misc.	03880043230001	COMM RECD - SERVICE	INR	Cr	[illegible]
Comm. Misc.	03880043230002	SERVICE TAX ON FOREX	INR	Cr	[illegible]
Operative	03882191016971	SWAMI VIVEKANAND SUB	INR	Cr	[illegible]

Registrar
Swami Vivekanand
Subharti University
MEERUT

ગુજરાત ગુજરાત GUJARAT

AZ 517122

નંબર: ૨૮૪૫૫ રૂ. ૧૦૦

તારીખ: ૨૩ માહે ૯ સને ૨૦૧૬

નામ:

સરનામું: 23 SEP 2016

રૈલેષકુમાર વાસુદેવભાઈ ત્રિવેદી

લા. નં.:- ઓલ. બી.- ૬૩/૧૯૮૬

અમદાવાદ-સીટી સીવીલ કોર્ટનુ સનંદી

લેનાર ની સહીx:.....

Cliantha Research Limited
Opp. Pushparaj Towers,
Nr Judges Bunglows,
Bodakdev, Ahmedabad-380054.
Ph. : +91-79-26863088-92
Fax : +91-79-26863093

CLINICAL TRIAL AGREEMENT

PROTOCOL Number: CP/04/12

This Clinical Trial Agreement (the **"Agreement"**) is effective on the date 22 Aug 16 fully executed by the parties (the **"Effective Date"**) and entered into by and between

CLIANTHA RESEARCH LIMITED, a part of Cliantha Group, a company incorporated under the Companies Act, 1956 having its Registered Office at Opp. Pushparaj Towers, Nr. Judges Bungalows, 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

DR. SHASHI PRATEEK whose principal place of business is **SUBHARTI MEDICAL COLLEGE,** Subharti Puram, NH-58, Delhi Haridwar Bypass Road, Meerut, Uttar Pradesh 250005 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

Principal Dr. A.K Asthana on behalf of Subharti Medical College and Hospital an institute registered under the law of India having its registered office at Subharti Puram, NH-58, Delhi Haridwar Bypass Road, Meerut, Uttar Pradesh 250005 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).

CRO, Institution and Principal Investigator are referred to herein individually as a "Party" and collectively as "Parties".

Whereas, Cipla Limited, Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai - 400 013. (hereinafter referred to as the **"Sponsor"**) through its Agent **CRO** desires the Institution to study the Comparative clinical study of Ulipristal acetate 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 (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

The study of Ulipristal acetate (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. CP/04/12 and entitled "A randomized, open label, parallel-group, active-comparator controlled, multi-center study to evaluate the efficacy and safety of Ulipristal acetate (5 mg tablets), as compared with Leuprolide acetate (3.75 mg intramuscular injection) for 12 weeks, in the preoperative treatment of moderate to severe symptomatic uterine fibroids" 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 on behalf of the Sponsor by the CRO.

Institution's obligation to conduct the Study is expressly conditioned upon the approval of the Protocol by an IEC/IRB that complies with the requirements of Drug Controller General of India and Schedule Y and applicable regulatory requirements. Sponsor, Principal Investigator and Institution shall cooperate in preparing and filing the Protocol, Informed Consent Form and other information with the reviewing IEC (Individual Ethics Committee) or IRB (Institutional Review Board).

2. THE STUDY SCHEDULE

A. **Study Initiation.** All contractual and regulatory documentation must be received by Sponsor and CRO before the initiation of the Study. The Principal Investigator and CRO shall initiate the Study at the earliest after receiving the applicable regulatory / IEC / IRB approvals.

B. **Enrollment.** Principal Investigator will enroll minimum 5 Subjects (as per the randomization schedule provided) and not more than 15 Subjects (as per the randomization schedule provided) (the **"Site Maximum"**) for the duration of enrollment. The Principal Investigator shall commence enrollment of the

Subjects once all the contractual and regulatory obligations have been met. Enrollment of, and payment for, each Subject over the Site Maximum shall require prior written consent of the Sponsor. Notwithstanding the foregoing, the Institution immediately shall cease enrolling the Subjects upon receipt of notice from the Sponsor, or the Sponsor's designee, that, in the sole determination of the Sponsor:

i. the Complete Study enrollment has been achieved; or

ii. the Sponsor has placed the Study on hold, for any reason; or

iii. the Study has been placed on hold by the DCGI or applicable regulatory agency for any reason.

C. **Study Documentation.** Case Report Forms **("CRFs")** must be satisfactorily completed within 3 (Three) days of each Subject visit. If any tests are to be performed after the Subject visit, CRF shall be completed within **Three (3) days** of receipt of test results for each Subject, provided, however, that with respect to the last Subject enrolled at the Site, CRF for such Subject must be completed within **three (3) days** of such Subject's last visit to the Site. The Principal Investigator shall ensure the accuracy, completeness, legibility and timeliness of the data reported to the Sponsor in the CRFs and in all required reports. Safety data (Serious Adverse Event Report Forms) will be faxed to Sponsor, DCGI and CRO within 24 hours of (i) the Subjects visit and (ii) receipt of the test results at, or from which, such event was reported, noted or recognized. Data Clarification Forms Queries **("DCFs")** must be completed and returned to Sponsor and CRO within **Three days** of its receipt.

D. **Subject Samples.** All biological samples collected from the Subjects shall be prepared and shipped in accordance with appropriate reference of the Protocol / Study requirements / Study manuals.

E. **Study Completion.** The Institution **shall make best efforts to complete** the enrollment of all the Subjects within the specified timeline given or informed by the Sponsor/ CRO. The Institution shall input all final CRF data and complete the final CRFs not later than five days after the last Subject visit.

3. PAYMENT

A. **BUDGET AND PAYMENT SCHEDULE**: CRO, on behalf of the Sponsor reimburse the Institution all direct and indirect costs 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"**). CRO shall make payments to the investigator and Institution in accordance with the payment schedule set forth in Exhibit b and incorporated herein . Cheque(s) shall be made payable and sent to the:

Payee Name: SUBHARATI K. K. B. CHARITABLE TRUST
PAN: AADTS2638D

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.

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 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:

Address: **Dr H. L Bhalla, Project manager & investigator**
Department of Pharmacology
SUBHARTI MEDICAL COLLEGE,
Subharti Puram, NH-58, Delhi Haridwar Bypass Road, Meerut,
Uttar Pradesh 250005
Ph : 9761715236 , 9927971349

Attn: **Dr. Shashi Prateek**

PAYMENT DETAILS **Annexure IA**

Head	Cheque to be drawn in favor of	PAN
Full payment	SUBHARATI K. K. B. CHARITABLE TRUST	AADTS2638D

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:** Sponsor will pay only Rs. 1000/- (Rupees one thousand only) per Subject for screen failure. The maximum ratio for screen failure Subjects shall be 3:1 i.e. maximum one screen failure per three randomized Subjects.

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 Sponsor, for obtaining approval from the IEC / IRB of the Protocol and the Subject's Informed Consent Form. The Principal Investigator shall provide the Sponsor or Sponsor's designee with written confirmation of the IEC / IRB's approval prior to the **screening** of Subjects. If the IEC / IRB withdraw 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 and provide standard care cost of which shall be borne by the CRO.**

B. **Performance of the Study.** The Principal Investigator shall conduct the Study solely at the Institution. The Principal Investigator shall exercise due care in the conduct of the Study, and represent and warrant that it will be conducted in accordance with (i) generally accepted standards of good clinical and research practice (including, without limitation, the guidelines set forth by the International Conference on Harmonization, if applicable); (ii) this Agreement; (iii) the Protocol; (iv) written instructions provided by the Sponsor or Sponsor's designee; and (v) all applicable local, state and federal laws, regulations, and policies governing the performance of clinical investigations, including, but not limited to local regulatory requirements. In the event of a conflict between any requirements in (i) through (v) above, the Principal Investigator shall comply with the most stringent requirement. The Principal Investigator shall make no changes to the Protocol, except as agreed to and approved in writing by the Sponsor and, where required, the IEC / IRB. Neither the Institution nor the Principal Investigator shall subcontract any of its obligations or any portion of this Agreement to any other individual or entity without the prior written consent of the Sponsor.

C. **Key Personnel.** The Parties acknowledge that the participation of the Principal Investigator is essential to the successful performance and completion of the Study. If, for any reason, the Principal Investigator withdraws from the Study, becomes unavailable, or is otherwise unable to complete his responsibilities under this Agreement, the Principal Investigator shall immediately notify the Sponsor or Sponsor's designee and the Sponsor or Sponsor's designee shall endeavor to agree upon a successor. Absent prompt agreement upon a successor, the Sponsor may terminate this Agreement as set forth in Clause 12(B) below.

D. **Sponsor Visits.** The Sponsor's representatives may conduct periodic visits, at mutually acceptable times during normal business hours, to: (i) inspect and examine the Institution's facilities at which the Study is being conducted or was conducted; (ii) review the progress of the Study (including 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) day** of its receipt.

E. **Supplies.** The Sponsor 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 30 (thirty) 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 hereunder, 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.

F. Study Records, Reports, and Data.

i. *Study Records.* The Principal Investigator and the Institution shall, in a timely manner, prepare and maintain complete and accurate Study records as set forth in the Protocol and as may otherwise be required by applicable law, rule, regulation and good clinical practice (**"Study Records"**). The Principal Investigator shall make all Study Records, including, without limitation, source documents, signed Informed Consents, laboratory data, Drug inventory records, available to representatives of the Sponsor at the Sponsor's request. Except as otherwise expressly provided for in the Protocol or elsewhere herein, all Study Records shall be retained by the Principal Investigator for a period of **two (2) years** after the approval of the Study Drug for marketing or the formal discontinuation of the clinical development of the Study Drug or as per instruction given by CRO/ sponsor for the same or as per applicable regulatory requirement. Thereafter, prior to the disposal of the Study Records, Principal Investigator (as applicable) shall give the Sponsor not less than sixty (60) days prior express written notice thereof, and if the Sponsor requests in writing, the Principal Investigator shall transfer the Study Records to the Sponsor at Sponsor's expense. Study Records shall in no event be destroyed without Sponsor's prior written permission.

ii. *Case Report Forms.* The Principal Investigator shall complete full clinical evaluations and original CRFs on each Subject in accordance with the Protocol. The Principal Investigator shall ensure the accuracy, completeness, legibility and timeliness of the data reported to the Sponsor in the CRFs and in all required reports. In addition, the Principal Investigator shall deliver to the Sponsor or Sponsor's designee each completed CRF from monitoring visits as provided for in Clause 2(C) of this Agreement.

iii *Annual Reports*
The Principal Investigator shall submit written summaries of the status of the Study to the IEC / IRB annually, or more frequently, if requested by the IEC / IRB.

Iv *Final Reports*
Upon completion of the Study, the Principal Investigator will provide a summary of the Study's outcome (**"Final Report"**) to the IEC / IRB. In addition, any Serious Adverse Events will be reported to the IEC / IRB.

G. Reporting of Serious Adverse Event. The Institution and Principal Investigator shall notify Sponsor of any Serious Adverse Event encountered in the Study within twenty four (24) hours of becoming aware of it in accordance with the instructions set forth in the Protocol. Each such notice shall be given by fax/ mail, whether or not notification was initially given by telephone. The SAE reporting and follow up would be as per the current local applicable regulatory requirements.

5. CONFIDENTIALITY

A. Confidential Information: The term "Confidential Information" shall mean any and all information, data or know-how, trade secrets whether written or oral, technical or non-technical, as well as tangible materials including without limitation (i) financial, accounting, and business information, (ii) information relating to samples, compounds, procedures, Protocol, the Study Drug and all reports, documents, data and other information generated in connection with the Study or other information which the Institution or the Principal Investigator receives, directly or indirectly, from Sponsor and/or CRO and (iii) any other data or

information that is generated by the Institution as required by the Protocol and/or this Agreement, including Case Report Forms, laboratory data and Study results, but not including the medical records of the Institution. Subject to the provisions of Clause 5(A)(*i*) through 5(A)(*iv*), the Parties shall not disclose Confidential Information without prior written authorization from the Disclosing Party for any purpose other than those specified in this Agreement. The obligations of non-disclosure shall not apply to the following:

i. Confidential Information that is already in the public domain at time of disclosure or becomes publicly available through no fault of the Receiving Party;

ii. Confidential Information that is already known to or independently developed by the Receiving Party as shown by its prior written records, provided that Receiving Party informs the Disclosing Party promptly upon the Receiving Party's discovery that the Confidential Information is already independently known to the Receiving Party;

iii. Confidential Information that lawfully and in good faith received from a third party who did not derive it, directly or indirectly, from the Disclosing Party; and

iv. Confidential Information required to be disclosed to a governmental or regulatory agency to the extent necessary for the required disclosure.

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.

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 five (5) years thereafter, the Parties shall not disclose to any third party Confidential Information and shall not use for any purpose other than as expressly provided for herein any such Confidential Information, without the express written consent of the Disclosing Party. Without limiting the foregoing, the Parties shall disclose Confidential Information only to those employees of the respective Party who require such Confidential Information for the purposes of this Agreement and who are bound by an obligation of confidentiality and non-use no less stringent than set forth herein. Upon disclosing Confidential Information to any employee, the employing Party shall advise them of the confidential nature of the information, and shall require them to take all necessary and reasonable precautions to prevent the unauthorized disclosure thereof. In the event that the Parties are required to disclose Confidential Information pursuant to an order or requirement of a court, administrative agency, or other governmental body, the Parties, as the case may be, may disclose the Confidential Information provided that the Receiving Party provides the Disclosing Party with reasonable advance notice thereof to enable the Disclosing Party to seek an appropriate protective order or to prevent the disclosure. In such a situation, the Receiving Party shall provide reasonable assistance to the other Party to obtain a protective order or to prevent disclosure.

D. **Medical Confidentiality.** Notwithstanding any of the foregoing, Sponsor 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. **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.

6. 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 his part, the prior written approval from Sponsor is required.

7. 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 sole property of the Sponsor. Accordingly, the Sponsor shall have, in its sole discretion, the right to publish, disclose, disseminate, and use, in whole or in part, the same for any and all purposes, including, without limitation, in and for submissions to the FDA or other regulatory agencies.

B. **Patents and Inventions.**

i. All right, title and interest in and to, whether domestic or foreign any inventions or discoveries (collectively, **"Inventions"**) first conceived of and reduced to practice prior to the Effective Date of this Agreement by the Principal Investigator, Institution or CRO as expressed in protocols, lab notebooks, or other written records, the know-how incidental thereto, and any patent applications and resulting patents derived there from shall be the exclusive property of that Party.

ii. "New Invention or Discovery" shall mean any invention or discovery conceived and reduced to practice during and as a part of Study by the Principal Investigator or any faculty, staff, employees, students or agents of the Institution or the Principal Investigator, or jointly by such an individual or individuals with one or more employees or consultants of the Sponsor.

iii. New Inventions or Discoveries made jointly by the Institution, Principal Investigator, or any of their respective agents with one or more employees or consultants of the Sponsor that: (a) are improvements to, new uses of, or (where applicable) new dosages or dosage forms of the Study Drug or device that arise from the performance of the research; or (b) occur during the performance of the Study and are based upon or subject to the claims of Sponsor's patentable Inventions shall be the sole property of Sponsor.

iv. New Inventions or Discoveries arising out of the research performed under this Agreement solely by Institution, Principal Investigator, and/or any of their respective agents that is not covered by the provisions of Clause 7(B)(*iii*) (an **"Institution Invention"**) shall be the sole property of Institution (subject to any agreement between the Institution and Principal Investigator regarding the ownership of inventions).

v. Institution and / or the Principal Investigator shall promptly notify the Sponsor a full written description of any New Inventions or Discoveries described in either Clause 7(B)(*iii*) or 7(B)(*iv*) of which they become aware. Sponsor shall have a time-limited, first option to negotiate an exclusive,

worldwide, royalty-bearing license to any Institution Invention. Any such exclusive license shall include a reasonable royalty based on Sponsor's and Institution's respective contributions to Institution Invention and other terms that are typical in licenses of similar technology. Sponsor shall advise Institution in writing of its interest in obtaining an exclusive license to any Institution Invention within sixty (60) days of Sponsor's receipt of notice of Institution Invention. If Sponsor fails to notify the Institution within sixty (60) days or provides notice that it elects not to obtain an exclusive license, then Sponsor's option shall expire with respect to that particular Institution Invention and Institution shall 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.

8. 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 Sponsor (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 federal law relating to clinical studies that has not been disclosed to the Sponsor 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 Sponsor 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 immediately terminate. If the Principal Investigator receives a notice or threat of action with respect to its debarment or a Notice of Intent to Disqualify, the Sponsor 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 Sponsor immediately and the Sponsor shall have the right to terminate this Agreement immediately without further cost or liability.

B. **Of the Sponsor.** The Sponsor 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 Sponsor'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.

Sponsor 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) Sponsor 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, Sponsor 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 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.

9. 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 Meerut, UP, India**. It is expressly agreed that the arbitral award shall be final and binding upon both the Parties hereto. However, the final jurisdiction shall lie with the **courts of Meerut, UP, India**. Each of the Parties hereby expressly submits to the jurisdiction of the courts of **Meerut**, India.

10. INDEMNIFICATION

A. **Sponsor Indemnification.** The Sponsor shall defend, indemnify, and hold harmless the Institution and its trustees, officers, the Investigators, employees and agents (the **"Institution Indemnities"**) from and against any liability, loss, damage, or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the Institution Indemnities or any one of them in connection with any third party claims, suits, actions, demands, or judgments but only to the extent such claims, suits, actions, demands or judgments arise from or are caused by the Study Drug or study related procedures and are not covered by insurance or self-insurance as set forth in Clause 11 and provided that the Study is conducted in accordance with (i) this Agreement and the Protocol; (ii) all written instructions provided by the Sponsor concerning the Study; (iii) all applicable federal, state, or local laws, rules, regulations, requirements, and policies; and (iv) the manner required of reasonable and prudent clinical investigators and physicians; and such loss does not arise out of the negligent or reckless conduct or omission or intentional misconduct or malfeasance of any Institution Indemnities, or any other person on the Institution's property or under its control, exclusive of the Sponsor's employees; and the Sponsor is notified within ten (10) working days of any complaint, claim, or injury relating to any loss for which indemnification and/or defense under this Agreement might be sought; and Principal Investigator and the Institution and its directors, officers, and employees fully cooperate with the Sponsor and its legal representatives in the investigation and defense of any claim or suit covered under this Agreement.

B. **Institution Indemnification**. The Institution shall defend, indemnify, and hold harmless the Sponsor and its affiliates and their respective directors, officers, employees, agents, successors, and assigns (**"Sponsor Indemnities"**) from and against any and all third party liability, loss, damage, or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the Sponsor Indemnities or any one of them in connection with any third party claims, suits, actions, demands, or judgments to the

extent such claims, suits, actions, demands, or judgments arise out of: (i) a failure to conduct the Study in accordance with this Agreement and the Protocol, all written instructions provided by the Sponsor concerning the Study, all applicable federal, state, or local laws, rules, regulations, requirements, and policies, and in the manner required of reasonable and prudent clinical investigators and physicians; and (ii) the negligent or reckless conduct or omission or intentional misconduct or malfeasance of any Institutional Indemnity, or any other person on the Institution's property or under its control, exclusive of the Sponsor's employees.

C. **Notification.** The Parties shall promptly notify each other of any such claims, suits, actions, demands, or judgments and the Parties shall reasonably cooperate with each other in the handling thereof.

D. **Claims.** The indemnifying Party, at its own expense, shall have the exclusive right to manage claims, control investigation and litigation, and select counsel, including the right to compromise or settle any claims, actions, suits, demands, or judgments, provided that it shall not compromise 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 Indemnity.

G. **Subject Injury.** The Sponsor shall reimburse the Principal Investigator or the Institution for reasonable and necessary medical expenses that are directly and reasonably incurred by Subjects in the treatment of adverse events caused by the Study Drug or Study related procedures following their administration or use in accordance with the Protocol and that are not covered by the Subject's insurance or governmental programs providing such coverage, provided that such expenses are not attributable to the negligence or misconduct of the Principal Investigator or any agent or employee of the Institution or other person engaged in performing the Study; and provided further that such expenses are not attributable to a failure of the Principal Investigator or any agent or employee of Institution to conduct the Study in accordance with (i) this Agreement; (ii) the Protocol; (iii) all written instructions delivered by the Sponsor concerning administration of the Study Drug; (iv) all applicable government laws, rules, regulations, requirements, and policies; and (v) the manner required of a reasonable and prudent clinical investigator or physician; and provided, further, that the Sponsor shall not be obligated to reimburse the Institution for such costs if such illness or injury arises out of or is related to a pre-existing abnormal medical condition or underlying disease of the Subject. Institution and Principal Investigator shall ensure that the amounts charged to the Sponsor in connection with such reimbursed treatments do not exceed the reasonable and customary amount allowed by Institution to any third party for such treatments. All such payments by the Sponsor shall be secondary to the insurance of the Subject and contingent on the Subject reasonably cooperating with the Sponsor's investigation of the injury and its causes. Subject shall be entitled to financial compensation from the Sponsor, Institution or the Principal Investigator in case of 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.

11. INSURANCE

A. **Sponsor Insurance.** Sponsor shall maintain during the term of this Agreement and for a period of One (1) year thereafter, general liability insurance (with product liability endorsements) and professional clinical trial liability insurance coverage sufficient to meet its indemnification obligations in the amount of **INR 12,00,00,000/- (INR Twelve Crore Only)** in the aggregate. Sponsor will provide evidence of its insurance upon request and will provide to the Institution, thirty (30) days prior written notice of cancellation of its coverage. Sponsor further agrees to include Institution and Principal Investigator as additional insured on such policy.

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 11 shall survive termination of this Agreement.

12. 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.**

i. Either Party may terminate this Agreement immediately upon written notice to the other if:

a. the authorization and approval to perform the Study in India is withdrawn by the DCGI and/or other applicable regulatory authority in India;

b. animal, human and/or toxicological test results, in the opinion of either Sponsor or Institution, support termination of the Study; or

c. 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 to continue to serve and a successor acceptable to both Institution and Sponsor is not available.

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 there from, Sponsor 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 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 Sponsor, to the extent medically permissible.

vi. **Immediate Termination by the Sponsor.** The 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. **Effect of Termination.** In the event this Agreement is terminated prior to completion of the Study, for any reason, the Principal Investigator shall a) notify the IRB that the Study has been terminated; b) cease enrolling Subjects in the Study; c) cease treating Subjects under the Protocol as directed by the Sponsor 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 Sponsor's request, the Institution and the Principal Investigator shall continue to collect data and prepare and complete CRFs for Subjects treated in the Study prior to termination. Within ninety (90) days from the effective date of any such termination, the Institution and the Principal Investigator shall provide to the Sponsor all 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. The Sponsor 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.

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.

13. MISCELLANEOUS

A. **Use of Names; Publicity.** Except as otherwise required by applicable law, regulation or court order, no Party to this Agreement will use the name or other identifying marks of any other Party or its affiliates or its employees in any advertisement, press release, or other public statement without prior written approval of the other Party; provided however that Sponsor may identify the Institution as a participating clinical site and the Principal Investigator as an investigator in a Study. The Institution and the Principal Investigator shall have the right to acknowledge the Sponsor's support of the research performed under this Agreement in scientific publications and other scientific communications (any such publications or communications shall be made in accordance with Article 6). Each of the Parties hereto shall not disclose to any third party the terms of this Agreement without the prior written consent of the other Party, except to advisors, investors, and others on a need-to-know basis under circumstances that reasonably ensure the confidentiality thereof, or to the extent required by law, regulation or court order.

B. **Independent Contractors.** The Parties acknowledge that the relationship between the Sponsor, CRO, Institution and Principal Investigator created by this Agreement is that of independent contractors and that neither the Principal Investigator nor Institution or CRO may create or 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 special, incidental, or consequential damages arising out of or relating to this Agreement, or the subject matter hereof, however caused and whether such claim is based in contract, tort (including negligence), or otherwise, even if an authorized representative of the Sponsor is advised of the possibility of such damages.

D. **Notices.** Any notices required or permitted to be given hereunder shall be in writing, shall be addressed to the Party to whom such notice is intended as follows, or such other address and/or number as such Party may substitute by written notice hereunder, and shall be effective on receipt.

Any notice to the Sponsor shall be addressed as follows:

Address: Cipla Limited, Cipla House,
Peninsula Business Park,
Ganpatrao Kadam Marg,
Lower Parel, Mumbai - 400 013.

Attention: Ms. Pallavi Phopale
Email: pallavi.londhe@cipla.com
Contact: 022-25787825

Any notice to Institution shall be addressed as follows:

Address: SUBHARTI MEDICAL COLLEGE,
Subharti Puram, NH-58,
Delhi Haridwar Bypass Road,
Meerut, Uttar Pradesh 250005
Attn: Dr. Hira Lal Bhalla
(Phone/mobile): +91- 9761715236

Any notice to Principal Investigator shall be addressed as follows:

Address: SUBHARTI MEDICAL COLLEGE,
Subharti Puram, NH-58,
Delhi Haridwar Bypass Road,
Meerut, Uttar Pradesh 250005
Attn: Dr. Shashi Prateek , Dr Hira Bhalla
(Phone/mobile): +91- 9313700855, 9761715236

Any notice to CRO shall be addressed as follows:

Cliantha Research Ltd.,
Garden View Corporate House No.8,
Opposite Auda Garden,
Bodakdev, Ahmedabad- 380054

Attn: Dr. Chirag Shah, Associate Director – Clinical Trials
+91-79-66219531 (phone)
+91-79-66219549 (fax)"

E. **Assignment.** This Agreement shall be binding upon and inure to the benefit of the Parties hereto, their respective successors, assigns, legal representatives and heirs. The Sponsor may assign this Agreement to any successor to all or substantially all of the business of the Sponsor, or in connection with its merger, consolidation, change in control or similar transaction. Except as otherwise set forth above, this Agreement may not otherwise be assigned by a Party (whether voluntarily, by operation of law or otherwise) without the prior written consent of the other Parties. Any purported assignment of this Agreement in violation of this section shall be void.

F. **Modification; Waiver.** This Agreement may not be altered, amended or modified in any way except in writing signed by the Sponsor, the Institution and the Principal Investigator. The failure of a Party to enforce any provision of the Agreement shall not be construed to be a waiver of the right of such Party to thereafter enforce the provision or any other provision or right.

G. **Entire Agreement.** This Agreement and its Exhibits constitute the entire agreement between the Parties with respect to the subject matter hereof and supersede all prior discussions, negotiations, communications, understandings, agreements, representations and writings with respect to all matters covered by the Agreement. In any conflict between the terms of this Agreement and the documents incorporated herein, the terms of this Agreement shall take precedence except as otherwise specifically set forth in this Agreement.

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 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 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.

L. **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 and current applicable local regulatory requirements. 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 to the Medical Affairs Department of CRO for onward transmission to SPONSOR:

Name:	Dr. Ripal Gharia
SAE Fax number:	+91-79-66219549
Telephone numbers:	+91-79-66219543
Cell number:	+91 9016435609
E-mail:	rgharia@cliantha.in

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.

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 ethics committee of SAEs reportable according to its national requirements and timelines, and of findings that could adversely affect the Subject's safety, could have an impact on the conduct of 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.

IN WITNESS WHEREOF, the undersigned have entered into this Agreement as of the date first set forth above.

INSTITUTE

By: _____
(Signature)

Dr. A.K. Asthana
(Printed Name)

Head of the Institute
(Title)

15 Nov 2016
(Date)

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: _____
(Signature)

Dr. Shashi Prateek
Principal Investigator

15.11.16.
(Date)

CLIANTHA RESEARCH LIMITED

By: _____
(Signature)

Dr. CHIRAG SHAH
Head of the Department, Clinical Trials

24/Oct/2016
(Date)

Registrar
Swami Vivekanand
Subharti University
MEERUT

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For CLIANTHA RESEARCH LIMITED

Authorised Signatories

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For CLIANTHA RESEARCH LIMITED

Authorised Signatories

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Fibroid.

Registrar
Swami Vivekanand
Subharti University
MEERUT

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	2018/779916-0
Purchase Order	201906573
Unit Reference	MCA/MRD

DR.Sunil Sawazal
CENTER FOR PUBLIC HEALTH KINETICS
VINOBAPURI,LA
214 A BASEMENT
VINOBA PURI,LAJPAT NAGAR-
100024
India

TECHNICAL SERVICES AGREEMENT (TSA)

Re: ESTABLISHING THE OPTIMAL DOSE OF THERAPEUTIC ZINC SUPPLEMENTATION FOR THE TREATMENT OF ACUTE DIARRHEA IN UNDER FIVE CHILDREN - A DOSE RESPONSE TRIAL IN A SOUTH ASIAN AND A SUB-SAHARAN AFRICAN SETTING - ZINC THERAPEUTIC DOSING TRIAL (ZTDT)

We are enclosing the Technical Services Agreement between the World Health Organization and CENTER FOR PUBLIC HEALTH KINETICS, VINOBAPURI,LA, in the amount of INR 64.08 (Sixty-Four), for conducting the above-mentioned work. We also enclosed zero 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, Jonathon SIMON, +41 79 210 38 56, simonjo@who.int.

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

WHO Global Service Centre

Cc: WHO Representative, India

Concerne: ESTABLISHING THE OPTIMAL DOSE OF THERAPEUTIC ZINC SUPPLEMENTATION FOR THE TREATMENT OF ACUTE DIARRHEA IN UNDER FIVE CHILDREN - A DOSE RESPONSE TRIAL IN A SOUTH ASIAN AND A SUB-SAHARAN AFRICAN SETTING - ZINC THERAPEUTIC DOSING TRIAL (ZTDT)

Veuillez trouver ci-joint l'Accord de Services Techniques entre l'Organisation Mondiale de la Santé et CENTER FOR PUBLIC HEALTH KINETICS, VINOBAPURI,LA, pour un montant de INR 64.08 (Sixty-Four), vous permettant de mener à bien le travail susmentionné. Veuillez également trouver zero 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 Jonathon SIMON, +41 79 210 38 56, simonjo@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

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INDIA GUJRAT 7816250

CLINICAL STUDY AGREEMENT

CLINICAL STUDY AGREEMENT BETWEEN THE SPONSOR, CADILA HEALTHCARE LIMITED, ZYDUS TOWERS, SATELLITE CROSS ROADS, AHMEDABAD-380015, INDIA and

Dr. Abhishek Gupta, Subharti Medical College, Subhartipuram, NH 58, Delhi-Haridwar Bypass Road, Meerut-250005
And

Subharti Medical College, Subhartipuram, NH 58, Delhi-Haridwar Bypass Road, Meerut-250005

Project : **RABIMAMBs**
Protocol No.: **RABIMABs.16.001.01**

This Clinical Study Agreement ("Agreement") between

1. CADILA HEALTHCARE LIMITED, ZYDUS TOWERS, SATELLITE CROSS ROADS, AHMEDABAD-380015, INDIA (HEREAFTER REFERED AS "THE SPONSOR") AND
2. Dr. Abhishek Gupta, Subharti Medical College, Subhartipuram, NH 58, Delhi-Haridwar Bypass Road, Meerut-250005, and
3. Subharti Medical College, Subhartipuram, NH 58, Delhi-Haridwar Bypass Road, Meerut-250005

When signed by all parties, is effective from the last signature date

THE SPONSOR wishes to sponsor a clinical study entitled "Randomized, multi-centric, open-label, comparator-controlled study to evaluate the efficacy and safety of RABIMABs administered in conjunction with Vaxirab N for post-exposure prophylaxis in patients following potential rabies exposure"., Centre Subharti Medical College, Meerut to be conducted at Institution. This agreement also covers any companion protocol(s), later developed and approved by both/three parties, that are conducted concurrently with the protocol identified above (collectively, "Protocol") and that involve some or all of the same subjects (collectively, "Study"). The sponsor hereby declares that all the necessary permissions and licenses required under the provision of relevant acts and rules namely Drug & Cosmetics Act and Drug & Cosmetic Rules 1945 and their subsequent amendments (including Schedule Y) are obtained by them for the use of the same on the study subjects.

THE PARTIES AGREE AS FOLLOWS

1. The sponsor would like to test the drug namely RABIMABs which will be used in patients suffering from Rabies. The sponsor hereby declares that all the necessary permissions and licenses required under the provision of relevant acts and rules namely Drug & Cosmetics Act and Drug & Cosmetic Rules 1945 and their subsequent amendments (including Schedule Y) are obtained by them for the use of the same on the study subjects.
2. The sponsor have approached the investigator as they desire to perform the study in regards to the said drug in accordance with the applicable guidelines on Good Clinical Practice, ethics and local regulations.
   The Principal Investigator hereby confirms that he has read and understood the Clinical Trail protocol entitled "Randomized, multi-centric, open-label, comparator-controlled study to evaluate the efficacy and safety of RABIMABs administered in conjunction with Vaxirab N for post-exposure prophylaxis in patients following potential rabies exposure"..
   3. All amendments and appendices have also been read and understood. The investigator agrees to the protocol Randomized, multi-centric, open-label, comparator-controlled study to evaluate the efficacy and safety of RABIMABs administered in conjunction with Vaxirab N for post-exposure prophylaxis in patients following potential rabies exposure"., and will perform the study in accordance with the applicable guidelines on Good Clinical Practice, ethics and local regulations.
3. Investigators and Research Staff.
3.1. Principal Investigator. The Study will be conducted by Dr. Abhishek Gupta (HEREAFTER REFERED AS "PRINCIPAL INVESTIGATOR") at Subharti Medical College, Subhartipuram, NH58 Delhi-Haridwar Bypass road, Meerut. The term "Investigator" as used in this Agreement refers, as applicable, to the Principal Investigator, subinvestigators, research staff or the Institution or all or any of them.
3.2. Subinvestigators and Research Staff. Investigator will ensure that only individuals, who are appropriately trained and qualified, assist in the conduct of the Study as subinvestigators or research staff.
3.3. Obligations. Institution will ensure that all personnel, who assist in the conduct of the Study, are informed of and agree to abide by all terms of this Agreement applicable to the activities they perform. Institution is responsible to THE SPONSOR for compliance by all Study personnel, including THE PRINCIPAL INVESTIGATOR, with the terms of this Agreement.
3.4. No Substitution. Institution shall not reassign the conduct of the Study to a different Principal Investigator without prior written authorization from THE SPONSOR
3.5. Delegation of Duties by Principal Investigator. Principal Investigator may delegate duties and responsibilities to subinvestigators or research staff only to the extent permitted by the relevant laws and regulations governing the conduct of clinical investigations in India.
3.6. Compliance with Institutional Policies. Principal Investigator will comply with the policies and procedures of the organization(s) with which Principal Investigator is affiliated, including any applicable financial policies. Principal Investigator will notify THE SPONSOR promptly of any conflict between the terms of this Agreement and any such policy or procedure, and the parties will attempt to reach an appropriate accommodation.
4. Funding. THE SPONSOR will provide mutually agreed upon funding in support of this Study as set out in Attachment A and subject to the terms specified in that Attachment.
5. Protocol. Investigator will conduct the Study in accordance with the Protocol, ICH GCP guidelines and applicable rules and regulations in India.
5.1. Amendments. The Protocol may be modified only by a written Amendment, signed by both THE SPONSOR and THE PRINCIPAL INVESTIGATOR.
5.2. Emergency Amendments. If it is necessary to change the Protocol on an emergency basis for the safety of the subjects, Investigator will notify THE SPONSOR and the responsible Independent Ethics Committee or Institutional Review Board (as applicable) as soon as practicable but, in any event, not later than five working days after the change is implemented. Any emergency change to the Protocol must be followed by a written Amendment.
5.3. No Additional Research. No additional research may be conducted on Study subjects during the conduct of the Study unless it is approved and documented as a sub-study protocol or an Amendment to the original Protocol. Such prohibited research activities include, but are not limited to, analyses of biological samples from Study subjects for any non-therapeutic purpose.
6. Subject Enrollment. Investigator has agreed to enroll in Study a minimum of 20 subjects by 3 months unless THE SPONSOR extends this enrollment period by written notification. A qualified subject is one who meets all Protocol criteria such as d
7. inclusion & exclusion criteria and agrees to participate in the study through informed consent in writing.
7.1. Excess Enrollment. If Investigator enrolls the maximum number of qualified subjects before the deadline, THE SPONSOR may or may not invite Investigator to enroll additional subjects. However, The Institution and/or THE PRINCIPAL INVESTIGATOR shall not enroll more than 50 subjects without prior approval by THE SPONSOR.

7.2. Failure to Enroll. If Investigator fails to enroll subjects at a rate adequate to meet the enrollment requirement, THE SPONSOR shall be free to terminate the Study early (see Section 25, Termination).

8. Study Conduct. Investigator will conduct Study in accordance with the Protocol, THE SPONSOR's written instructions, International Conference on Harmonization Good Clinical Practice (ICH GCP) guidelines and all applicable governmental laws, rules, and regulations.

8.1. No Charge for Investigational Drug or Reimbursed Services. Investigator will not charge a Study subject or third-party payer for Investigational Drug (see Section 13, Investigational Drug) or for any services reimbursed by THE SPONSOR under this Agreement.

9. Independent Ethics Committee/Institutional Review Board. Before the Study is initiated, Investigator will ensure that both the Study and the informed consent form are approved by an Independent Ethics Committee or Institutional Review Board (as applicable)(both referred to as a 'IRB') that complies with all applicable laws and regulations. Investigator will further ensure that the Study is subject to continuing oversight by the IRB throughout its conduct.

9.1. Study Disapproval. If, through no fault of Investigator, the Study is disapproved by the IRB, this Agreement will immediately terminate with no penalty to the Investigator, as provided in Section 25.1a, Disapproval by IRB, below.

10. Data Protection. Data collected in Study may include personal data and sensitive personal data which is subject to specific legislation relating to the processing, storage, transfer and use of such data Investigator will comply with all relevant laws relating to the protection and use of personal data and data privacy in its conduct and reporting of the Study. The Investigator shall take all technical and organizational measures to prevent unauthorized or unlawful processing or accidental loss or destruction of, or damage to, or disclosure of such data. THE SPONSOR will take appropriate measures to protect the confidentiality and security of all personal data that it receives from Investigator in connection with the Study. Personal data relating to the Investigator shall be processed and used for the purposes of administration of this agreement and in connection with the Study and will be held on one or more databases for the purposes of determining the Investigator's involvement in future research and in order to comply with any regulatory requirements. Such data may be disclosed or transferred to other members of Cadila Healthcare Limited group of companies, to representatives and contractors working on behalf of THE SPONSOR group and to regulatory authorities across the world. The Investigator shall ensure that all necessary consents are in place to comply with the provisions of this clause.

11. Informed Consent and Authorization to Use and Disclose Health Information

11.1. Informed Consent: Investigator will provide THE SPONSOR an opportunity to review and approve the content of the informed consent form (including any revisions made during the course of the Study) before it is used. Investigator will obtain a written informed consent from each Study subject and will maintain a signed original of that consent in the subject's record. Investigator will allow THE SPONSOR to inspect signed informed consent forms or photocopies there of during monitoring visits or audits (see Monitoring and Audits, Section 17).

12. Adverse Events. Investigator will report adverse events experienced by Study subjects in accordance with instructions in the Protocol and applicable regulations. This includes, where required, prompt reporting by telephone or facsimile. THE SPONSOR shall, so far as is lawful, have full responsibility for the reporting of all adverse events to local and international regulatory and/or health authorities.

13. Investigational Drug. THE SPONSOR will provide Investigator with sufficient quantities of the investigational drug(s) needed to conduct the study.

13.1. Custody and Dispensing THE PRINCIPAL INVESTIGATOR will maintain appropriate control of supplies of Investigational Drug and will not provide it to anyone else except subinvestigators or research staff. THE PRINCIPAL INVESTIGATOR shall maintain the records of inventory of the Investigational drug.

13.2. Use. Investigator will use Investigational Drug only as specified in the Protocol. Any other use of Investigational Drug constitutes a material breach of this Agreement.

13.3. Ownership of Investigational drug. Investigational drug and remains the property of THE SPONSOR except for, and limited to, the use specified in the Protocol. THE SPONSOR grants Investigator no express or implied intellectual property rights in investigational drug or in any methods of making or using Investigational drug.

14. Equipment. The SPONSOR may provide certain equipment for use by the Investigator during the conduct of the study ("Equipment").

14.1. Ownership and Use. Equipment is and remains the property of THE SPONSOR and INVESTIGATOR may use Equipment only for purposes of the study.

14.2. Investigator Responsibilities. Investigator will comply with any operating and maintenance instructions provided by THE SPONSOR or the manufacturer and will store Equipment under conditions that are appropriate to the nature f the Equipment and that minimize the risk of loss or damage.

14.3. Liability. THE SPONSOR has no liability for damages of any sort, including personal injury or property damage, resulting from the use of Equipment except to the extent that such damages were caused by negligence or willful misconduct of THE SPONSOR.

15. Confidential Information. During the course of the Study, Investigator may receive or generate information that is confidential to THE SPONSOR.

15.1. Definition. Except as specified in Section 15.2, Exclusions, below, "Confidential Information" includes

a. the Protocol,
b. the Investigator Brochure,
c. Study Data (as defined in Section 16, Study Data, Biological Samples, and Study Records, below), subject to Investigator's right to publish the results of the Study (as described in Section 19, Publications, below),
d. Biological Sample Analysis Data (as defined in Section 15, Study Data, Biological Samples, and Study Records, below),
e. Any other information related to the study, the investigator drug or Sponsor technology, research or business plans that sponsor provides to the investigator in writing or other tangible form and marks as CONFIDENTIAL or initially discloses orally and then summarize and confirms in writing as CONFIDENTIAL within 90 days after the date of oral disclosure

15.2. Exclusions. Confidential Information does not include information that (i) is known or open to the public or otherwise in the public domain at the time of disclosure or (ii) becomes part of the public domain during the term of this confidentiality obligation by any means other than breach of this Agreement by Investigator (iii) is already known to Investigator at the time of disclosure and is free of any obligations of confidentiality, or (iv)is obtained by Investigator, free of any obligations of confidentiality, from a third party that has a lawful right to disclose it.

15.3. Obligations of Confidentiality. Unless THE SPONSOR provides prior written consent, Investigator may not use Confidential Information for any purpose other than that authorized in this Agreement, nor may Investigator and or Institute disclose Confidential Information to any third party except as authorized in this Agreement or as required by law.

a. Required disclosure of Confidential Information to the IRB or to regulatory representatives is specifically authorized.
b. Publication of the results of the Study based on Study Data collected or generated by Investigator is specifically authorized, of this Agreement.

15.4. Disclosure Required by Law. If disclosure of Confidential Information to any party other than the Independent Ethics Committee, relevant regulatory authority is required by law, that disclosure does not constitute a breach of this Agreement so long as Investigator

a. notifies THE SPONSOR in writing in 15 working days advance of the disclosure so as to allow THE SPONSOR to take legal action to protect its Confidential Information,
b. discloses only that Confidential Information required to comply with the legal requirement, and
c. continues to maintain the confidentiality of this Confidential Information with respect to all other third parties.

15.5. Individually Identifiable Health Information. If, in connection with this Study or performance of this Agreement, THE SPONSOR comes into contact with individuality identifiable health information relating to subjects who are not Study subjects, THE SPONSOR agrees to maintain the confidentiality of such information and not to use it for any purpose.

15.6. Survival of Obligations. These obligations of confidentiality survive termination of this Agreement and continue for a period of five years after completion of the study or termination, which ever is earlier.

15.7. Return of Confidential Information. If requested by THE SPONSOR in writing, Investigator will return all Confidential Information except that required to be retained at the Study site by law. However, Investigator may retain a single archival copy of the Confidential Information for the sole purpose of determining the scope of obligations incurred under this Agreement.

16. Study Data, Biological Samples and Study Records.

16.1. Study Data. During the course of the Study, Investigator will collect and submit certain data to THE SPONSOR or its agent, as specified in the Protocol. This may include case report forms or their equivalent ("Case Report Forms"), or other types of medical images, ECG, or other types of tracings or printouts, data summaries, or any combination of these (collectively, "Study Data"). Investigator will ensure accurate and timely collection, recording, and submission of Study Data. Investigator will deliver Study Data to THE SPONSOR or its agent within the time periods specified below:

a. Ownership of Study Data. Subject to Investigator's right to publish the results of the Study (see Section 19, Publications), THE SPONSOR is the exclusive owner of all Study Data.

b. Non-exclusive License. THE SPONSOR grants Institution a royalty free non-exclusive license, with no right to sublicense, to use Study Data (not related with the investigator drug) for internal research or educational purposes.

c. Data Management and statistical Analysis: THE SPONSOR or its representative shall carry out the data management and statistical analysis. THE SPONSOR may consult and / or provide THE PRINCIPAL INVESTIGATOR for interpretation during report writing.

d. THE SPONSOR is the exclusive owner of study data.

16.2. Biological Samples. If so specified in the Protocol, Investigator may collect and provide to THE SPONSOR or its designee biological samples (e.g., blood, urine, tissue, saliva, etc.) obtained from Study subjects for testing that is directly related to subject care or safety monitoring, including pharmacokinetic, pharmacogenomic, or biomarker testing ("Biological Samples").

a. Use. Investigator will not use Biological Samples collected under the Protocol in any manner or for any purpose other than that described in the Protocol.

b. Analysis samples. THE SPONSOR or its designees will test Biological Samples as described in the Protocol. Unless otherwise specified in the Protocol, THE SPONSOR will provide the results of these tests ("Biological Sample Analysis Data") to the Investigator or Study subject.

c. Ownership. THE SPONSOR is the exclusive owner of all Biological Samples and Biological Sample Analysis Data.

16.3. Study Records. Investigator will ensure that subject's Study records, which include the Investigator's copies of all Study Data as well as relevant source documents (collectively, "Study Records"), are kept up to date and maintained in accordance with applicable regulations and institutional guidelines.

a. Retention. Investigator will retain Study Records, under storage conditions conducive to their stability and protection, for a period of 15 years after termination of the Study unless THE SPONSOR authorizes, in writing, earlier destruction. Investigator agrees to notify THE SPONSOR before destroying any Study Records after the required retention period. Investigator further agrees to permit THE SPONSOR to ensure that the records are retained for a longer period if necessary, at THE SPONSOR expense, under an arrangement that protects the confidentiality of the records (e.g., secure off-site storage).

17. Monitoring, Inspections and Audits.

17.1. Monitoring. THE SPONSOR shall be entitled at its absolute discretion (and in such form as THE SPONSOR sees fit) to monitor and audit the conduct of the Study. Upon reasonable notice, Institution will permit THE SPONSOR representatives access to the premises, facilities, procedures and records relating to the Study, investigators, and research staff as required to accomplish this. The Institution agrees to co-operate and provide all reasonable assistance with any monitoring and/or auditing activity. No such monitoring and/or auditing by THE SPONSOR will relieve the Investigator of any of its obligations hereunder.

17.2. Inspections and Audits. The Study is subject to inspection by regulatory agencies worldwide. Regulatory inspections may occur after completion of the Study and may include auditing of Study Records. Auditing involves comparison of Case Report Forms or Data Records with the source documentation on which they are based. THE SPONSOR may also choose to audit Study Records as part of its monitoring of Study conduct.

a. Notification. Investigator will notify THE SPONSOR as soon as reasonably possible if the site is inspected or scheduled to be inspected by a regulatory agency.

b. Cooperation. Investigator will cooperate with regulatory agency or THE SPONSOR representatives in the conduct of inspections and audits and will ensure that Study Records are maintained in a way that facilitates such activities.

c. Resolution of Discrepancies. Investigator will promptly resolve any discrepancies that are identified between the Study Case Report Forms and the subject's medical records.

d. Inspection Findings and Responses. Investigator will promptly forward to THE SPONSOR copies of any inspection findings that Investigator receives from a regulatory, agency. Whenever feasible, Investigator will also provide THE SPONSOR with an opportunity to prospectively review and comment on any Investigator responses to regulatory agency inspections.

e. Data Clarification Form: THE SPONSOR may raise data clarification forms (queries) during or after the monitoring and/or auditing and/or statistical review of the study, which THE INSTIUTION OR THE PRINCIPAL INVESTIGATOR shall clarify within 7 working days.

f. Study Conduct Evaluations. THE SPONSOR or its external service providers may document and evaluate the performance of Investigator in the conduct of the Study. THE SPONSOR will use these evaluations solely for internal purposes.

18. Inventions.

18.1. Notification. If the conduct of Study results in any invention or discovery whether patentable or not ("Invention"), Investigator will promptly inform THE SPONSOR.

18.2. Assignment. Investigator will assign all interest in any such Invention to THE SPONSOR, free of any obligation or consideration beyond that provided for in this Agreement.

18.3. Assistance. Investigator will provide reasonable assistance to THE SPONSOR in filing and prosecuting any patent applications relating to Invention, at THE SPONSOR's expense.

19. Publications.

19.1. Prepublication Review. THE SPONSOR has no objection to publication by Investigator of any information collected or generated by Investigator, whether or not the results are favorable to the Investigational Drug. However, to ensure against inadvertent disclosure of Confidential Information or unprotected Inventions, Investigator will provide THE SPONSOR, an opportunity to review any proposed publication or other type of disclosure before it is submitted or otherwise disclosed. The timing of such publication shall be mutually agreed upon.

a. Submission to THE SPONSOR: Investigator will provide manuscripts, abstracts, or the full text of any other intended disclosure (poster presentation, invited speaker or guest lecturer presentation; etc.) to THE SPONSOR at least 90 days before they are submitted for publication or otherwise disclosed. If any patent action is required to protect intellectual property rights, Investigator agrees to delay the disclosure for a period not to exceed an additional 360 days.

b. Redaction of Confidential Information. Investigator will, on request, remove any previously undisclosed Confidential Information (other than the Study results themselves) before disclosure.

20. Indemnification. THE SPONSOR will provide an indemnity to the Institution in respect of the Study (Annexure B).

21. Debarment and Exclusion. Institution and Principal Investigator each certify that it/s/he is not debarred and that it/s/he is not and will not use in any capacity the services of any person debarred under such law with respect to services to be performed under this Agreement. During the term of this Agreement and for three years after its termination, Institution and Principal Investigator will notify THE SPONSOR promptly if either of these certifications needs to be amended in light of new information.

22. Use of Name. Neither party will use the name of the other party or any of its employees for promotional or advertising purposes without written permission from the other party. However, THE SPONSOR reserves the right to identify THE PRINCIPAL INVESTIGATOR and Institution in association with a listing of the Protocol in publicly available listings of ongoing clinical trials, or other subject recruitment services or mechanisms.

23. Assignment and Delegation.

23.1. Institution may not assign its rights or delegate or subcontract any duties under this Agreement without written permission from THE

SUBHARTI MEDICAL COLLEGE
SWAMI VIVEKANAND SUBHARTI UNIVERSITY

SUBHARTI PURAM, N.H. 58, DELHI-HARIDWAR, BY PASS ROAD, MEERUT. PIN-250005
Ph: 0121-2439056, 3058034 Ext. 2132, Tele Fax: 0121-2439127 E-mail: subhartiinstitutes@rediffmail.com, www.subharti.org

No. Med/Pharma/2016/.....
SMC/EC/2016/77

Date: 23/11/2016

To
The Principal
Subharti Medical College
Meerut

Sub: Payment of IEC fees for approval meeting

Study title: A multicentric , prospective , randomized, double-blind study to evaluate the safety and efficacy of Saroglitazar 2/4mg as compared to Fenofibrate 160mg in patients with Dyslipidemia.

Sir,

Please find the enclosed cheque for payment of IEC meeting fees. Cheque No. 057053 dated 09-11-2016 o amount Rs 27,000.

	AMOUNT	AFTER TDS
IEC FEES	Rs 25,000	Rs 22,500
CRC GRANT	Rs 5,000	Rs 4,500
TOTAL	Rs 30,000	Rs 27,000

Received
23/11/16

Kindly issue study approval letter for the above mentioned study.

Regards
Dr. PP Khosla
Professor & Head
Department of pharmacology

Registrar
Swami Vivekanand
Subharti University
MEERUT

NAME Dr A.K. Srivastava	SIGNATURE
DESIGNATION Member Secretary IEC SMC & H Meerut	STAMP Member Secretary Institutional Ethics Committee Subharti Medical College & Hospital Swami Vivekanand Subharti University MEERUT

Mr Rashmi Kant Jr.
Pl deposite this cheque in SKSB Trust, Rs 25000/- as Consultancy charge to Institutional Ethics Committee SMC & H. & Rs 2000/- Cash to Dr Ila Bhalla for CRS grant
23/11/2016

Dr. A.K. Srivastava
Ethical Comm

fw. n. a

DEPARTMENT OF PHARMACOLOGY
SUBHARTI MEDICAL COLLEGE
SWAMI VIVEKANAND SUBHARTI UNIVERSITY
SUBHARTI PURAM, NH-58, DELHI HARIDWAR BY PASS ROAD, MEERUT, PIN 250005
Ph: 0121 2490564, 3048054 Ext. 2132, Tele Fax: 0121 2490177 E mail: subhartimedicine@rediffmail.com, www.subharti.org

Ref. No. Med/Pharma/2016/.....

SMC/IEC/2016/78

Date: 22/11/16

To
The Principal
Subharti Medical College
Meerut

Sub: Payment of IEC fees for approval meeting

Study title: A multicentric , prospective , randomized, double-blind study to evaluate the safety and efficacy of Saroglitazar 2/4mg as compared to pioglitazone in type 2 Diabetes Mellitus.

Sir,

Please find the enclosed cheque for payment of IEC meeting fees. Cheque No. 057052 dated 09-11-2016 of amount Rs 27,000.

IEC FEES	AMOUNT	AFTER TDS
CRC GRANT	Rs 25,000	Rs 22,500
TOTAL	Rs 5,000	Rs 4,500
	Rs 30,000	Rs 27,000

Kindly issue study approval letter for the above mentioned study.

Regards

Dr. P P Khosla
Professor & Head
Department of pharmacology

Registrar
Swami Vivekanand
Subharti University
MEERUT

NAME Dr Ashu Srivastava	SIGNATURE
DESIGNATION Member Secretary IEC SMC & H Meerut	STAMP Member Secretary Institutional Ethics Committee Subharti Medical College & Hospital Swami Vivekanand Subharti Univ... MEERUT

Mr. Rashmi Kant Ji
Pl deposite this cheque in SVKB Trust, Rs 25000/- as Stamp charges & Institutional Ethics Committee SMC & H & Rs 2000/- Cash to Dr H.C. Bhalla for CRS Grant
23/11/2016

Dr. A.K. Srivastava
Ethical Committee

for n.o

शाक्यामुनि बुद्धा राष्ट्रीय प्रौद्योगिकी प्रबंधन एवं ग्रामीण विकास संस्थान
Sakyamuni Buddha National Institute For Rural Development, Management and Technology

Krishna Vihar, Post Jakhan, Distt-Dehradun-248001 Uttrakhand India
Email- smbnational2004@gmail.com Telephone +91-908466644

Ref.SMB/03-04/2016-17/05 Date:09-01-2017

To,

Dr. Abhishek Gupta

Department of Medicine,

Subharti Medical College

Dear Dr. Abhishek Gupta,

After thoroughly evaluating your project "**To study the autonomic dysfunction in patients of alcoholic liver cirrohsis,**" we are delighted to advise you that we are willing to fund the project up to INR 2000/- in consumables. Please submit the project's findings once it has been completed.

All the best.

Regards

Mr. Tsering Yanki

President

President/Secretary
SMB National Institute of RuDMaTech
Dehradun, Uttrakhand

शाक्यामुनि बुद्धा राष्ट्रीय प्रौद्योगिकी प्रबंधन एवं ग्रामीण विकास संस्थान
Sakyamuni Buddha National Institute For Rural Development, Management and Technology

Krishna Vihar, Post Jakhan, Distt-Dehradun-248001 Uttrakhand India
Email- smbnational2004@gmail.com Telephone +91-9084666444

Ref.SMB/03-04/2016-17/06 Date:10-01-2017

To,

Dr. BRIJ BHUSHAN THUKRAL

Department of Radio-diagnosis and Imaging.

Subharti Medical College

Dear Dr. THUKRAL.

After thoroughly evaluating your project "**Clinico-Radiological Evaluation Of Cervical Spondylosis-A Degenrative disorder** " we are delighted to advise you that we are willing to fund the project up to INR 3200/- in consumables. Please submit the project's findings once it has been completed.

All the best.

Regards

Mr. Tsering Yanki

President

President/Secretary
SMB National Institute of RuDMaTech
Dehradun, Uttrakhand

शाक्यामुनि बुद्धा राष्ट्रीय प्रौद्योगिकी प्रबंधन एवं ग्रामीण विकास संस्थान
Sakyamuni Buddha National Institute For Rural Development, Management and Technology

Krishna Vihar, Post Jakhan, Distt-Dehradun-248001 Uttrakhand India
Email- smbnational2004@gmail.com Telephone +91-908466644

Ref.SMB/03-04/2016-17/07 Date:11-01-2017

To,

DR. SAMEER R. VERMA

Department of Radio-diagnosis and Imaging,

Subharti Medical College

Dear Dr. VERMA,

After thoroughly evaluating your project **"Ultrasonographic evaluation of knee in Osteoarthritis with clinical and radiographic correlation"** we are delighted to advise you that we are willing to fund the project up to **INR 3000/-** in consumables. Please submit the project's findings once it has been completed.

All the best.

Regards

Mr. Tsering Yanki

President

President/Secretary
SMB National Institute of RuDMaTech
Dehradun, Uttrakhand

शाक्यामुनि बुद्धा राष्ट्रीय प्रौद्योगिकी प्रबंधन एवं ग्रामीण विकास संस्थान
Sakyamuni Buddha National Institute For Rural Development, Management and Technology

Krishna Vihar, Post Jakhan, Distt-Dehradun-248001 Uttrakhand India
Email- smbnational2004@gmail.com Telephone +91-9084666644

Ref.SMB/03-04/2016-17/08 Date:12-01-2017

To,

Dr. Saurabh Singhal

Department of Medicine,

Subharti Medical College

Dear Dr. Saurabh Singhal,

After thoroughly evaluating your project **"Uric acid level correlation in a patient of CKD with metabolic syndrome"** we are delighted to advise you that we are willing to fund the project up to **INR 3500/-** in consumables. Please submit the project's findings once it has been completed.

All the best.

Regards

Mr. Tsering Yanki

President

President/Secretary
National Institute of RuDMaTech
Dehradun, Uttrakhand

शाक्यामुनि बुद्धा राष्ट्रीय प्रौद्योगिकी प्रबंधन एवं ग्रामीण विकास संस्थान
Sakyamuni Buddha National Institute For Rural Development, Management and Technology

Krishna Vihar, Post Jakhan, Distt-Dehradun-248001 Uttrakhand India
Email- smbnational2004@gmail.com Telephone +91-908466644

Ref.SMB/03-04/2016-17/09 Date:13-01-2017

To,

Dr. Mamta Tyagi

Department of obstetrics & gynaecology,

Subharti medical college

Dear Dr. Mamta Tyagi,

After thoroughly evaluating your project "**Predictive value of admission and intrapartum cardiotocography in normal and high risk antenatal women**" we are delighted to advise you that we are willing to fund the project up to INR 3500/- in consumables. Please submit the project's findings once it has been completed.

All the best.

Regards

Mr. Tsering Yanki

President

President/Secretary
SMB National Institute of RuDMaTech
Dehradun, Uttrakhand

VIKRAMSHILA SHODH SANSTHAN

Ref./VSS/50-10-11/16-17/91 Date: 31-01-2017

To,

Dr. SANJIV KUMAR

Department Of Ophthalmology,

Subharti Medical College

Dear Dr. KUMAR,

We are pleased to notify you that, after carefully reviewing your project **"Optical Coherence Tomography Analysis of the Effect of Type 2 Diabetes Mellitus on the Retinal Nerve Fiber Layer in Patients With Simple Myopia** ," we are willing to fund the project up to the tune of INR 1000/- in the form of consumables. Please report the project's findings once it has been completed.

All the best.

Regards

Gyalbo

Mr. Tsering Gyalbo

CHAIRMAN / EXECUTIVE SECRETARY
VIKRAMSHILA SHODH SANSTHAN

Buddhist Colony, Dakpathar Road, Vikas Nagar, Dehradun (Uttarakhand) Pincode- 248198
Email- vikramshila4072@gmail.com Cell. No. 9568986411

ABUSHIS GRAMIN SEWA SANSTHAN

IBEI Campus, Meerut Road, Hapur-245101Panchsheel Nagar(UP) India
Tel.: +91- 9456137909, E-mail: agss1995@rediffmail.com

Ref AGSS1995/2016-17/12 Date: 07-01-2017

To,

MR. MURALI

Panna Dhai Maa Subharti Nursing College,

Subharti Medical College

Dear MR. MURALI,

We are delighted to inform you that we are willing to fund the project up to **INR 6500/-** in consumables after thoroughly evaluating your project "**A study to assess the effectiveness of skill competency program on of knowledge and practice among start nurses working in emergency sence area at selected hospital Meerut.**" Once the project is finished, please submit the findings.

Thank you

Regards

For Abushis Gramin Sewa Sansthan

President/Secretary

ABUSHIS GRAMIN SEWA SANSTHAN

IBEI Campus, Meerut Road, Hapur-245101PanchsheelNagar(UP) India
Tel.: +91- 9456137909, E-mail: agss1995@rediffmail.com

Ref AGSS1995/2016-17/13 Date: 10-01-2017

To,

Mr. Arun Unnikrishnan

Panna Dhai Maa Subharti Nursing College,

Subharti Medical College

Dear Mr. Arun Unnikrishnan,

We are delighted to inform you that we are willing to fund the project up to **INR 6500/-** in consumables after thoroughly evaluating your project "**A study to compare the efficacy and satisfaction of a new sliding mid arm circumference scale with shakir's tape among staff nurses working in selected community health centre at meerut.**" Once the project is finished, please submit the findings.

Thank you

Regards

For Abushis Gramin Sewa Sansthan

President/Secretary

ABUSHIS GRAMIN SEWA SANSTHAN

IBEI Campus, Meerut Road, Hapur-245101PanchsheelNagar(UP) India
Tel.: +91- 9456137909, E-mail: agss1995@rediffmail.com

Ref.AGSS1995/2016-17/14.... Date: 17-01-2017

To,

Dr. Geeta Parwanda

Panna Dhai Maa Subharti Nursing College,

Subharti Medical College

Dear Dr. Geeta Parwanda,

We are delighted to inform you that we are willing to fund the project up to **INR 3500/-** in consumables after thoroughly evaluating your project "**Clinico-radiological evaluation of cervical spondylosis-a degenrativedisorder**." Once the project is finished, please submit the findings.

Thank you

Regards

For Abushis Gramin Sewa Sansthan

President/Secretary

ABUSHIS GRAMIN SEWA SANSTHAN

IBEI Campus, Meerut Road, Hapur-245101Panchsheel Nagar(UP) India
Tel.: +91- 9456137909, E-mail: agss1995@rediffmail.com

Ref AGSS1995/2016-17/15 Date: 17-01-2017

To,

Ms. Hepsi Natha

Panna Dhai Maa Subharti Nursing College,

Subharti Medical College

Dear Ms. Hepsi Natha

We are delighted to inform you that we are willing to fund the project up to **INR 2500/-** in consumables after thoroughly evaluating your project "**A study to evaluate the effectiveness of modified oral nursing care guideline with subglottic suctioning in improving the quality of life among tracheostomy patients in selected hospitals, Meerut.**" Once the project is finished, please submit the findings.

Thank you

Regards

For Abushis Gramin Sewa Sansthan
President/Secretary

ABUSHIS GRAMIN SEWA SANSTHAN

IBEI Campus, Meerut Road, Hapur-245101PanchsheelNagar(UP) India
Tel.: +91- 9456137909, E-mail: agss1995@rediffmail.com

Ref. AGSS1995/2016-17/11 Date: 05-01-2017

To,

Dr.CHARU JAIN

Department Of Ophthalmology,

Subharti Medical College

Dear Dr.CHARU JAIN,

We are delighted to inform you that we are willing to fund the project up to INR 2600/- in consumables after thoroughly evaluating your project "**To compare post-operative corneal endothelial cell count in mini-extra capsular cataract extraction and manual small- incision cataract surgery.**"

Once the project is finished, please submit the findings.

Thank you

Regards

For Abushis Gramin Sewa Sansthan
President/Secretary

YBSRF

Reg.No. 1038/78-79 Reg.Date 30.06.1978

YOUNKER BUDDHIST SOCIETY AND RESEARCH FOUNDATION

A-16, Tons Colony, Dakhpathar, District Dehradun, 248125 (Uttrakhand), INDIA
e-mail : ybsrfoundation@gmail.com

Ref./YBSRF/1978/2016-17/09 Date: 06-02-2017

To,

Dr.Pradeep Bansal

Department of Radio-diagnosis and Imaging,

Subharti Medical College

Dear Dr. Pradeep Bansal,

After carefully going through the project **"Role of MRI In the Evaluation of Spinal Trauma"** submitted by you, we are glad to inform you that we are willing to fund the project up to the tune of **INR 1000/-** in the form of consumables. Kindly submit the findings of the project after the completion.

All the best.

Regards

Younker Buddhist Society And Research Foundation Secretary Dehradun

Dr Chandrakitti
Secretary

YBSRF

Reg.No. 1038/78-79 Reg.Date 30.06.1978

YOUNKER BUDDHIST SOCIETY AND RESEARCH FOUNDATION

A-16, Tons Colony, Dakhpathar, District Dehradun, 248125 (Uttrakhand), INDIA
e-mail : ybsrfoundation@gmail.com

Ref./YBSRF/1978/2016-17/10 Date: 06-02-2017

To,

Dr. Anita Pandey

Department of Microbiology,

Subharti Medical College

Dear Dr. Pandey,

After carefully going through the project "**To evaluate hepatitis b immune status in health care workers in a tertiary care hospital**" submitted by you, we are glad to inform you that we are willing to fund the project up to the tune of **INR 1000/-** in the form of consumables. Kindly submit the findings of the project after the completion.

All the best.

Regards

Younker Buddhist Society And Research Foundation Secretary Dehradun

Dr Chandrakitti
Secretary

YBSRF

Reg.No. 1038/78-79 Reg.Date 30.06.1978

YOUNKER BUDDHIST SOCIETY AND RESEARCH FOUNDATION

A-16, Tons Colony, Dakhpathar, District Dehradun, 248125 (Uttrakhand), INDIA
e-mail : ybsrfoundation@gmail.com

Ref./YBSRF/1978/2016-17/11 Date: 08-02-2017

To,

Dr. Sandeep Choudhary

Department of Psychiatry,

Subharti Medical College

Dear Dr. Choudhary,

After carefully going through the project "**Study to assess motivation to quit and abstain from alcohol and factors affecting relapse in alcohol use disorders. a cross sectional study in western u.p.** " submitted by you, we are glad to inform you that we are willing to fund the project up to the tune of **INR 2000/-** in the form of consumables. Kindly submit the findings of the project after the completion.

All the best.

Regards

Younker Buddhist Society And Research Foundation Secretary Dehradun

Dr Chandrakitti
Secretary

YBSRF

Reg.No. 1038/78-79 Reg.Date 30.06.1978

YOUNKER BUDDHIST SOCIETY AND RESEARCH FOUNDATION

A-16, Tons Colony, Dakhpathar, District Dehradun, 248125 (Ultrakhand), INDIA
e-mail : ybsrfoundation@gmail.com

Ref./YBSRF/1978/2016-17/12 Date: 08-02-2017

To,

Dr. Dr Sanjay Pandey

Department Of Gen. Surgery,

Subharti Medical College

Dear Dr. Pandey,

After carefully going through the project "**Randomised control trial to study role of fixation of urinary catheter to reduce catheter associated urinary tract infections** " submitted by you, we are glad to inform you that we are willing to fund the project up to the tune of **INR 1500/-** in the form of consumables. Kindly submit the findings of the project after the completion.

All the best.

Regards

Dr Chandrakitti
Secretary

YBSRF

Reg.No. 1038/78-79 Reg.Date 30.06.1978

YOUNKER BUDDHIST SOCIETY AND RESEARCH FOUNDATION

A-16, Tons Colony, Dakhpathar, District Dehradun, 248125 (Uttrakhand), INDIA
e-mail : ybsrfoundation@gmail.com

Ref./YBSRF/1978/2016-17/13 Date: 10-02-2017

To,

Dr. M.K Maheshwari

Department Of Gen. Surgery,

Subharti Medical College

Dear Dr. M.K Maheshwari,

After carefully going through the project "**A Comparison Between Large Tissue Bi Small Tissue Bite In Midline Abdominal V Closure** " submitted by you, we are glad to inform you that we are willing to fund the project up to the tune of INR 3500/- in the form of consumables. Kindly submit the findings of the project after the completion.

All the best.

Regards

Dr Chandrakitti
Secretary

Younker Buddhist Society And Research Foundation Secretary Dehradun

YBSRF

Reg.No. 1038/78-79 Reg.Date 30.06.1978

YOUNKER BUDDHIST SOCIETY AND RESEARCH FOUNDATION

A-16, Tons Colony, Dakhpathar, District Dehradun, 248125 (Uttrakhand), INDIA
e-mail : ybsrfoundation@gmail.com

Ref./YBSRF/1978/2016-17/15 Date: 13-02-2017

To,

Dr. SAURABH SINGHAL

Department of Medicine,,

Subharti Medical College

Dear Dr. SINGHAL,

After carefully going through the project **"A study of serum gamma glutamyl transferase (ggt) levels as a risk factor in acute stroke"** submitted by you, we are glad to inform you that we are willing to fund the project up to the tune of **INR 3200/-** in the form of consumables. Kindly submit the findings of the project after the completion.

All the best.

Regards

Younker Buddhist Society And Research Foundation
Secretary
Dehradun

Dr Chandrakitti
Secretary

YBSRF

Reg.No. 1038/78-79 Reg.Date 30.06.1978

YOUNKER BUDDHIST SOCIETY AND RESEARCH FOUNDATION

A-16, Tons Colony, Dakhpathar, District Dehradun, 248125 (Uttrakhand), INDIA
e-mail : ybsrfoundation@gmail.com

Ref./YBSRF/1978/2016-17/16 Date: 13-02-2017

To,

DR. Y. P. MONGA

Department of General Surgery,

Subharti Medical College

Dear Dr. Monga,

After carefully going through the project **"Study of post cholecystectomy syndrome in patient undergoing "open cholecystectomy versus laparoscopic cholecystectomy"** submitted by you, we are glad to inform you that we are willing to fund the project up to the tune of **INR 2200/-** in the form of consumables. Kindly submit the findings of the project after the completion.

All the best.

Regards

Younker Buddhist Society And Research Foundation Secretary Dehradun

Dr Chandrakitti
Secretary

YBSRF

Reg.No. 1038/78-79 Reg.Date 30.06.1978

YOUNKER BUDDHIST SOCIETY AND RESEARCH FOUNDATION

A-16, Tons Colony, Dakhpathar, District Dehradun, 248125 (Uttrakhand), INDIA
e-mail : ybsrfoundation@gmail.com

Ref./YBSRF/1978/2016-17/14 Date: 10-02-2017

To,

Dr.Pritish Ku Mahanta

Department of Medicine,

Subharti Medical College

Dear Dr. Mahanta,

After carefully going through the project "**A clinical and an echocardiographic evaluation of left ventricular diastolic dysfunction in type 2 diabetes mellitus patients**" submitted by you, we are glad to inform you that we are willing to fund the project up to the tune of **INR 1200/-** in the form of consumables. Kindly submit the findings of the project after the completion.

All the best.

Regards

Dr Chandrakitti
Secretary

VIKRAMSHILA SHODH SANSTHAN

Ref./VSS/50-10-11/16-17/92 Date: 02-02-2017

To,

DR. SANJAY PANDEY

Department of General Surgery,

Subharti Medical College

Dear Dr. PANDEY,

We are pleased to notify you that, after carefully reviewing your project **"Measurement of intra-abdominal pressure in pancreatitis and blunt trauma abdomen,"** we are willing to fund the project up to the tune of **INR 1700/-** in the form of consumables. Please report the project's findings once it has been completed.

All the best.

Regards

Mr. Tsering Gyalbo

CHAIRMAN / EXECUTIVE SECRETARY
VIKRAMSHILA SHODH SANSTHAN

Buddhist Colony, Dakpathar Road, Vikas Nagar, Dehradun (Uttarakhand) Pincode- 248198
Email- vikramshila4072@gmail.com Cell. No. 9568986411

VIKRAMSHILA SHODH SANSTHAN

Ref./VSS/50-10-11/16-17/93 Date: 04-02-2017

To,

Dr. SAMEER R. VERMA

Department Of Radio Diagnosis& Imaging,

Subharti Medical College

Dear Dr. Verma,

We are pleased to notify you that, after carefully reviewing your project "**Study of colour doppler ultrasound in deep vein thrombosis in lower extremities,**" we are willing to fund the project up to the tune of **INR 1400/-** in the form of consumables.

Please report the project's findings once it has been completed.

All the best.

Regards

Gyalbo

Mr. Tsering Gyalbo

CHAIRMAN / EXECUTIVE SECRETARY
VIKRAMSHILA SHODH SANSTHAN

Buddhist Colony, Dakpathar Road, Vikas Nagar, Dehradun (Uttarakhand) Pincode- 248198
Email- vikramshila4072@gmail.com Cell. No. 9568986411

BUDDHIST EDUCATION MISSION

Village & Post Harsil District- Uttarkashi (Uttarakhand) India

Phone- +91-9410522170 E-mail.: buddhistmission41@gmail.com

Ref. BEM/2016-17/02

Date: 03-01-2017

To,

Dr. Manvi Gupta

Department Of Obstetrics And Gynaecology,

Subharti Medical College

Dear Dr. Gupta,

We are pleased to notify you that, after carefully reviewing your project " **Factors affecting family planning practices among eligible couples**," we are willing to support the research up to INR 1500/- in consumables. Once the study is finished, please report the results.

All the best.

Regards

Mr Lokesh

Buddhist Education Mission

President

BUDDHIST EDUCATION MISSION

Village & Post Harsil District- Uttarkashi (Uttarakhand) India
Phone- +91-9410522170 E-mail:- buddhistmission41@gmail.com

Ref. BEM/2016-17/03 Date: 03-01-2017

To,

Ms. Pooja

Department of Paramedical Science

Subharti Medical College

Dear Ms. Pooja

We are pleased to notify you that, after carefully reviewing your project "**Evaluation of microflora diversity and antibiotic resistance profile of urinary tract,**" we are willing to support the research up to **INR 3400/-** in consumables. Once the study is finished, please report the results.

All the best.

Regards

Mr Lokesh

Buddhist Education Mission

President

VIKRAMSHILA SHODH SANSTHAN

Ref./VSS/50-10-11/16-17/94 Date: 06-02-2017

To,

Dr. KUMKUM GUPTA

Department of Anesthesiology & Critical care

Subharti Medical College

Dear Dr. GUPTA,

We are pleased to notify you that, after carefully reviewing your project **"Comparative study of clinical effect of dexmedetomidine versus fentanyl as epidural adjuvant to 0.75% ropivacaine for elective lower limb surgeries,"** we are willing to fund the project up to the tune of **INR 4000/- in** the form of consumables. Please report the project's findings once it has been completed.

All the best.

Regards

Tgyalbo

Mr. Tsering Gyalbo

CHAIRMAN / EXECUTIVE SECRETARY

VIKRAMSHILA SHODH SANSTHAN

Buddhist Colony, Dakpathar Road, Vikas Nagar, Dehradun (Uttarakhand) Pincode- 248198

Email- vikramshila4072@gmail.com Cell. No. 9568986411

VIKRAMSHILA SHODH SANSTHAN

Ref./VSS/50-10-11/16-17/95 Date: 13-02-2017

To,

Dr. Abhishake

Department of Anesthesiology & Critical care

Subharti Medical College

Dear Dr. Abhishake,

We are pleased to notify you that, after carefully reviewing your project "**A prospective randomized study of comparison of melatonin vs pregabalin vs control for attenuation of hemodynamic response to laryngoscopy and endotracheal intubation in patients undergoing general anesthesia**," we are willing to fund the project up to the tune of INR 3500/- in the form of consumables. Please report the project's findings once it has been completed. All the best.

Regards

Tgyalbo

Mr. Tsering Gyalbo

CHAIRMAN / EXECUTIVE SECRETARY

VIKRAMSHILA SHODH SANSTHAN

Buddhist Colony, Dakpathar Road, Vikas Nagar, Dehradun (Uttarakhand) Pincode- 248198

Email- vikramshila4072@gmail.com Cell. No. 9568986411

VIKRAMSHILA SHODH SANSTHAN

Ref./VSS/50-10-11/16-17/90 Date: 30-01-2017

To,

Dr. Anita Panday

Department of Microbiology

Subharti Medical College

Dear Dr. Panday,

We are pleased to notify you that, after carefully reviewing your project "**Molecular characterization of genes encoding Plasmid-Mediated AmpC beta-lactamases in Escherichia coli isolated from urinary**," we are willing to fund the project up to the tune of INR 1000/- in the form of consumables. Please report the project's findings once it has been completed.

All the best.

Regards

Gyalbo

Mr. Tsering Gyalbo

CHAIRMAN / EXECUTIVE SECRETARY
VIKRAMSHILA SHODH SANSTHAN

Buddhist Colony, Dakpathar Road, Vikas Nagar, Dehradun (Uttarakhand) Pincode- 248198
Email- vikramshila4072@gmail.com Cell. No. 9568986411

CIN No.:U74900UP2009PTC038556
Reg.No: 038556

ENTICE WAY TRADELINK PVT. LTD.

A-5, Samrat Place, Garh Road, Meerut – U.P. 250004
Phone No.: 7902134534 E-mail: ewtcpl123@gmail.com

Eway/Res/2016-17/ 5

Date: 03-04-2016

To,
Dr. GeetaParwanda,
Faculty of Nursing
Swami Vivekanand Subharti University
Meerut, Uttar Pradesh

Dear Dr. Parwanda,

As swami Vivekanand Subharti University is well known for being one of the most actively involved in several research projects. Hence, on your request, we Entice Way Tradelink Pvt. Ltd. are providing a ZIG ZAG COTTON 100GM (worth INR 1000) received from KS CARE for your research project entitled **"Utilization Of Comfort Device For Reducing Discomfort Of Breastfeeding Mothers".**
Your report will be shared with the manufacturer.

Thanking you

Sincerely

For Entice Way Tradelink Pvt. Ltd.

Authorised Signatory

CIN No.:U74900UP2009PTC038556
Reg.No: 038556

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A-5, Samrat Place, Garh Road, Meerut – U.P. 250004
Phone No.: 7902134534 E-mail: ewtcpl123@gmail.com

Eway/Res/2016-17/ 05(1)

To,
Prof. Geeta Parwanda,
Faculty of Nursing
Swami Vivekanand Subharti University
Meerut, Uttar Pradesh

Date: 30-11-2016

Dear Prof. Parwanda,

As swami Vivekanand Subharti University is well known for being one of the most actively involved in several research projects. Hence, on your request, we Entice Way Tradelink Pvt. Ltd. are providing a few samples such as S ZIG ZAG COTTON 100GM (worth INR 500) received from KS CARE for your research project entitled **"A Study To Determine The Impact Of A Comfort Device On Breast Feeding Practice And Parental Bonding Among Post-Natal Mothers Admitted To A Selected Meerut Hospital's Obstetrical Ward."**
Your report will be shared with the manufacturer.

Thanking you

Sincerely

For Entice Way Tradelink Pvt. Ltd.

Authorised Signatory

ENTICE WAY TRADELINK PVT. LTD. Meerut

Registrar
Swami Vivekanand
Subharti University
MEERUT

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CIN No.:U74900UP2009PTC038556
Reg.No: 038556

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Phone No.: 7902134534 E-mail: ewtcpl123@gmail.com

Eway/Res/2016-17/12

Date: 30-11-2016

To,
Mrs. Hepsi Natha,
Faculty of Nursing
Swami Vivekanand Subharti University
Meerut, Uttar Pradesh

Dear Mrs. Natha,

As swami Vivekanand Subharti University is well known for being one of the most actively involved in several research projects. Hence, on your request, we Entice Way Tradelink Pvt. Ltd. are providing a few samples such as ECG ELECTRODE [KENNY] (worth INR 500) received from ROMSONS for your research project entitled **"A study to assess the effectiveness of skill competency skill program in terms of knowledge regarding interpretation of ECG among nurses working in ICU at selected hospitals, Meerut".**
Your report will be shared with the manufacturer.

E-40

Thanking you

Sincerely

For Entice Way Tradelink Pvt. Ltd.

Authorised Signatory

ENTICE WAY TRADELINK PVT. LTD. Meerut

Authorised Signatory

CIN No.:U74900UP2009PTC038556
Reg.No: 038556

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Phone No.: 7902134534 E-mail: ewtcpl123@gmail.com

Eway/Res/2016-17/08

Date: 30-11-2016

To,
Mr. Murali Mohanam,
Faculty of Nursing
Swami Vivekanand Subharti University
Meerut, Uttar Pradesh

E-38

Dear Mr. Mohanam,

As swami Vivekanand Subharti University is well known for being one of the most actively involved in several research projects. Hence, on your request, we Entice Way Tradelink Pvt. Ltd. are providing a few samples such as NEBULIZER KIT [ADULT] (worth INR 500) received from ROMSONS for your research project entitled **"A study to evaluate the effectiveness of hypertonic saline nebulized suctioning on biophysiological pulmonary parameters among patients with mechanical ventilator at selected hospital at Meerut".**
Your report will be shared with the manufacturer.

Thanking you

Sincerely

For Entice Way Tradelink Pvt. Ltd.
For Entice Way Tradelink Private Limited
Authorised Signatory

Authorised Signatory

ENTICE WAY TRADELINK PVT. LTD. Meerut

CIN No.:U74900UP2009PTC038556
Reg.No: 038556

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Phone No.: 7902134534 E-mail: ewtcpl123@gmail.com

Eway/Res/2016-17/09

Date: 30-11-2016

To,
Mr. ArunUnnikrishnan,
Faculty of Nursing
Swami Vivekanand Subharti University
Meerut, Uttar Pradesh

Dear Mr.Unnikrishnan,

As swami Vivekanand Subharti University is well known for being one of the most actively involved in several research projects. Hence, on your request, we Entice Way Tradelink Pvt. Ltd. are providing a few samples such as NASOPHARYNGEAL AIRWAY NO-7 (worth INR 500) received from ROMSONS for your research project entitled **"A study to assess the effectiveness of simulation training program on knowledge and practice regarding neonatal resuscitation among BSc nursing final year student in selected nursing colleges at Meerut".** Your report will be shared with the manufacturer.

Thanking you

Sincerely

For Entice Way Tradelink Pvt. Ltd.

Authorised Signatory

ENTICE WAY TRADELINK PVT. LTD. Meerut

CIN No.:U74900UP2009PTC038556
Reg.No: 038556

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Phone No.: 7902134534 E-mail: ewtcpl123@gmail.com

Eway/Res/2016-17/ 10

Date: 30-11-2016

To,
Mrs. Hepsi Natha,
Faculty of Nursing
Swami Vivekanand Subharti University
Meerut, Uttar Pradesh

Dear Mrs. Natha,

As swami Vivekanand Subharti University is well known for being one of the most actively involved in several research projects. Hence, on your request, we Entice Way Tradelink Pvt. Ltd. are providing a few samples such as R-90[URETHRAL CATHETER] (worth INR 1500) received from ROMSONS for your research project entitled **"A study to evaluate the effectiveness of skill competency program on central venous catheter in terms of knowledge and practice among ICU nurses at selected hospital at Meerut".**
Your report will be shared with the manufacturer.

E-37

Thanking you

Sincerely

For Entice Way Tradelink Pvt. Ltd.

Authorised Signatory

ENTICE WAY TRADELINK PVT. LTD. Meerut

CIN No.:U74900UP2009PTC038556
Reg.No: 038556

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Phone No.: 7902134534 E-mail: ewtcpl123@gmail.com

Eway/Res/2016-17/ 06

Date: 30-11-2016

To,
Dr. Sumit Raghav,
Subharti College of Physiotherapy
Swami Vivekanand Subharti University
Meerut, Uttar Pradesh

E-41

Dear Dr. Raghav,

As swami Vivekanand Subharti University is well known for being one of the most actively involved in several research projects. Hence, on your request, we Entice Way Tradelink Pvt. Ltd. are providing bandage 4 inch (worth INR 1700) received from SURGITECH for your research project entitled "Eccentric loading response in achilles tendinopathy: a quasi-experimental study".
Your report will be shared with the manufacturer.

Thanking you

Sincerely
For Enticeway Tradelink Private Limited
For Entice Way Tradelink Pvt. Ltd.

Authorised Signatory

Authorised Signatory

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CIN No.:U74900UP2009PTC038556
Reg.No: 038556

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A-5, Samrat Place, Garh Road, Meerut – U.P .250004
Phone No.: 7902134534 E-mail: ewtcpl123@gmail.com

Eway/Res/2016-17/03

Date: 30-11-2016

To,
Dr. Sumit Raghav and Dr. Anshika Singh,
Subharti College of Physiotherapy
Swami Vivekanand Subharti University
Meerut, Uttar Pradesh

Dear Sir/Madam,

As swami Vivekanand Subharti University is well known for being one of the most actively involved in several research projects. Hence, on your request, we Entice Way Tradelink Pvt. Ltd. are providing KNEE BRACE BDB (worth INR 1700) received from BDB for your research project entitled "The effect of mobilization with movement (MWM) versus conventional treatment on range of motion in patients with post-traumatic stiffness of knee joint".
Your report will be shared with the manufacturer.

Thanking you

Sincerely

For Entice Way Tradelink Pvt. Ltd.

Authorised Signatory

ENTICE WAY TRADELINK PVT. LTD. Meerut

Authorised Signatory

CIN No.:U74900UP2009PTC038556
Reg.No: 038556

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A-5, Samrat Place, Garh Road, Meerut – U.P .250004
Phone No.: 7902134534 E-mail: ewtcpl123@gmail.com

Eway/Res/2016-17/ 07

Date: 30-11-2016

To,
Dr.Anshika Singh and Dr. Sumit Raghav,
Subharti College of Physiotherapy
Swami Vivekanand Subharti University
Meerut, Uttar Pradesh

E-43

Dear Sir/Madam,

As swami Vivekanand Subharti University is well known for being one of the most actively involved in several research projects. Hence, on your request, we Entice Way Tradelink Pvt. Ltd. are providing SHOULDER IMMOBILISER [MEDIUM] (worth INR 1500) received from KS CARE for your research project entitled **Effect of aging on range of motion and function of dominant shoulder joint in healthy geriatric population".**
Your report will be shared with the manufacturer.

Thanking you

Sincerely

For Entice Way Tradelink Pvt. Ltd.

Authorised Signatory

ENTICE WAY TRADELINK PVT. LTD. Meerut

Authorised Signatory

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CIN No.:U74900UP2009PTC038556
Reg.No: 038556

ENTICE WAY TRADELINK PVT. LTD.

A-5, Samrat Place, Garh Road, Meerut – U.P .250004
Phone No.: 7902134534 E-mail: ewtcpl123@gmail.com

Eway/Res/2016-17/04

Date: 30-11-2016

To,
Dr.Anshika Singh and Dr. Sumit Raghav,
Subharti College of Physiotherapy
Swami Vivekanand Subharti University
Meerut, Uttar Pradesh

E-44

Dear Sir/Madam,

As swami Vivekanand Subharti University is well known for being one of the most actively involved in several research projects. Hence, on your request, we Entice Way Tradelink Pvt. Ltd. are providing SHOULDER IMMOBILIZER (S) (worth INR 1500) received from TYNOR for your research project entitled **"Effect of Interferential therapy along with McKenzie extension bias exercises on pain, disability and spinal extensors muscles strength in chronic low back pain".**
Your report will be shared with the manufacturer.

Thanking you

Sincerely

For Entice Way Tradelink Pvt. Ltd.

Authorised Signatory

Authorised Signatory

ENTICE WAY TRADELINK PVT. LTD. Meerut

CIN No.:U74900UP2009PTC038556
Reg.No: 038556

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ENTICE WAY TRADELINK PVT. LTD.

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Phone No.: 7902134534 E-mail: ewtcpl123@gmail.com

Eway/Res/2016-17/11

Date: 30-11-2016

To,
Dr. Sumit Raghav and Ms. Rupa Singh,
Subharti College of Physiotherapy
Swami Vivekanand Subharti University
Meerut, Uttar Pradesh

Dear Dr. Raghav,

As swami Vivekanand Subharti University is well known for being one of the most actively involved in several research projects. Hence, on your request, we Entice Way Tradelink Pvt. Ltd. are providing DRAW SHEET WITH ADHESIVE (worth INR 1500) received from PRAKHER MEDICS for your research project entitled **"A comparitive study on the effect of maitland technique versus mulligan technique in patients with adhesive capsulitis".**
Your report will be shared with the manufacturer.

E-45

Thanking you

Sincerely

For Entice Way Tradelink Pvt. Ltd.

Authorised Signatory

ENTICE WAY TRADELINK PVT. LTD. Meerut

Authorised Signatory

Gyan Amrit Oral Health And Cancer Research Foundation

Ref. No.: 052/11/2016 Date: 25/11/2016

To,

Dr Vineeta Nikhil

Subharti Dental College & Hospital

Swami Vivekanand Subharti University

Meerut, Uttar Pradesh

Dear Dr. Nikhil,

We are pleased to notify you that, following a thorough review of your concept " **Effect of beverage on nanohardnesss and surface roughness of contemporary bulk fill composite material**," we are willing to grant financial assistance in the form of items up to INR 1000/-.

Once the project is finished, please submit your findings.

All the best.

Regards

Dr Ankit Goel

Registrar
Swami Vivekanand
Subharti University
MEERUT

For GYAN AMRIT ORAL HEALTH AND CANCER RESEARCH FOUNDATION

President Trustee Treasurer

Dr. Goel's Dental & Maxillofacial Diagnostics
23-26, Ground Floor, City Plaza, Hapur. Ph: 0122-2317172, 08307675707
Visit us at www.drgoelsdiagnostics.com E-mail : drankitgoel21@gmail.com

Gyan Amrit Oral Health And Cancer Research Foundation

Ref. No.: 053/11/2016 Date: 25/11/2016

To,

Dr Sachin Gupta

Subharti Dental College & Hospital

Swami Vivekanand Subharti University

Meerut, Uttar Pradesh

Dear Dr Gupta,

We are pleased to notify you that, following a thorough review of your concept " **Comparative evaluation of bond strength of resin composite to enamel using different adhesive techniques-An in vitro study**," we are willing to grant financial assistance in the form of items up to INR 1000/-.

Once the project is finished, please submit your findings.

All the best.

Regards

Dr Ankit Goel

For GYAN AMRIT ORAL HEALTH AND CANCER RESEARCH FOUNDATION

President Secretary Treasurer

Registrar
Swami Vivekanand
Subharti University
MEERUT

Dr. Goel's Dental & Maxillofacial Diagnostics
25-26, Ground Floor, City Plaza, Hapur. Ph: 0122-2317172, 08007675707
Visit us at www.drgoelsdent.com E-mail : drankitgoel21@gmail.com

Reg No. 1038/78-79 Reg Date 30.06.1978

YOUNKER BUDDHIST SOCIETY AND RESEARCH FOUNDATION

A-16, Tons Colony, Dakhpathar, District Dehradun, 248125 (Uttrakhand), INDIA
e-mail : ybsrfoundation@gmail.com

Ref./YBSRF/1978/2016-17/17 Date: 13-09-2017

To,

Dr. Ashok Kumar and Dr. Ashish Prakash

Department of Pediatrics

Subharti Medical College

Dear Sir,

After carefully going through the project "Observational Study of presentation Treatment & Outcome in Patient of Infantile west syndrome treated with oral prednisolone" submitted by you, we are glad to inform you that we are willing to fund the project up to the tune of INR 1000/- in the form of consumables. Kindly submit the findings of the project after the completion.

All the best.

Regards

Younker Buddhist Society And Research Foundation Secretary Dehradun

Dr Chandrakitti
Secretary

Regn.No. 1038/78-79 Regn.Date 30.06.1978

YOUNGER BUDDHIST SOCIETY AND RESEARCH FOUNDATION

A-16, Tons Colony, Dakhpathar, District Dehradun, 248125 (Uttrakhand), INDIA
e-mail : ybsrfoundation@gmail.com

Ref./YBSRF/1978/2016-17/18 Date: 13-08-2017

To,

Dr. Richa Aggarwala and Dr. Sneha Prabha Goel

Department of Pediatrics

Subharti Medical College

Dear Sir/Madam

After carefully going through the project "Polycythemia in neonates ; Incidence, maternal and fetal risk factors, clinical profile, umbilical cord blood haematocrit as A Screening test for polycythemia" submitted by you, we are glad to inform you that we are willing to fund the project up to the tune of INR 1000/- in the form of consumables. Kindly submit the findings of the project after the completion.

All the best.

Regards

Younger Buddhist Society And Research Foundation Secretary Dakhpathar

Dr Chandrakitti
Secretary

Jai Hind!!

Swami Vivekanand Subharti University, Meerut
(Established under U.P. Govt. Act no. 29 of 2008 and approved under section 2(f) of UGC Act 1956)