ગુજરાત ગુજરાત GUJARAT

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તારીખ: 21 APR 2016

રજીસ્ટર્ડ: દિનેશકુમાર વાસુદેવપ્રસાદ ત્રિવેદી

લા. નં.:- ઓફ. લા.- ૬૭/૧૯૮૬

અમદાવાદ-સીટી સીવીલ કોર્ટના સભાંડી

લેનાર ની સહી:

Karmic Lifesciences LLP
Unit No.-02, Ground Floor,
Reliable Plaza, Plot No.-K10
Thane Belapur Road, Airoli,
Navi Mumbai-400708

CLINICAL TRIAL AGREEMENT

PROTOCOL No. KLS-PH-041604

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

KARMIC LIFESCIENCES LLP, a limited liability partnership, incorporated under the Limited Liability Partnership Act, 2008 having its registered office at Unit No. G-02, Reliable Plaza, Plot No. K-10, Thane-Belapur Road, MIDC, Airoli, Navi Mumbai – 400 708 (hereinafter referred to as **"CRO"** which expression, unless repugnant to the context or meaning thereof shall mean and include its Affiliates, partners, employees, assignees, agents and successors-in-interest) and

DR. DEEPAK SADASHIV BHOSLE, presently employed at is Department of Pharmacology, Mahatma Gandhi Mission's Medical College, N-6, CIDCO, Aurangabad – 431003, Maharashtra, 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

Mahatma Gandhi Mission's MEDICAL COLLEGE & HOSPITAL , situated at N-6, CIDCO, Aurangabad – 431003, Maharashtra, 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) and

Whereas, ITC Limited, having its registered office at Virginia House, 37, J.L. Nehru Road, Kolkata – 700 071, ("the Sponsor") through its Agent CRO desires the Institution to conduct study titled as " A Randomized, Double-blind, Parallel Group Study to Evaluate the Effect and Safety of Test Biscuits as Compared to Placebo Biscuits in Regulating Blood Glucose Level in Subjects With Type 2 Diabetes Mellitus" and the Institution is willing to perform a clinical study of the test biscuits (study product) 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);

For the purpose of this Agreement, "Affiliate" means, when associated with a Party to this Agreement, any entity which controls, is controlled by, or is under common control with, that Party. In this context, the term "Control" shall mean any one of the following: (1) Ownership by one entity, directly or indirectly, of at least fifty (50%) of the voting stock of another entity; or (2) Power of one entity to direct the management or policies of another entity, by contract or otherwise.

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 **evaluating the Effect and Safety of Test Biscuits as Compared to Placebo Biscuits in Regulating Blood Glucose Level in Subjects With Type 2 Diabetes Mellitus** shall be conducted, under the direction of the Principal Investigator, in treatment of patients (**"Subjects"**) in accordance with this Agreement and the protocol identified as **Protocol ID No. KLS-PH-041604** and entitled **"A Randomized, Double-blind, Parallel Group Study to Evaluate the Effect and Safety of Test Biscuits as Compared to Placebo Biscuits in Regulating Blood Glucose Level in Subjects With Type 2 Diabetes Mellitus**", 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. Its representatives (alone or together with representatives from Sponsor) will be allowed access to all information resulting from this Study and Sponsor will have an unrestricted right to use such information.

CRO (alone or together with representatives from Sponsor) will perform regular on-site monitoring visits throughout the Study. The tasks of the monitor include but are not limited to the following: (i) to ensure Protocol adherence, (ii) to verify the data in the CRFs against source documents (Source Document Verification "SDV"), (iii) to check progress of the Study and to motivate, if necessary, (iv) to review the CRFs for complete and accurate capture of data, including laboratory test reports and other patient records, (v) to check all data for possible SAEs and Adverse Events ("AE"(s)), (vi) to review signed informed consent forms for signatures and date of consent, (vii) to ensure accurate record of drug accountability, (viii) to ensure adequate storage of Study supplies, (ix) to collect completed CRFs, and (x) to discuss and help resolve any problems.

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 shall initiate the Study at the earliest after receiving the applicable regulatory / IEC / IRB approvals.

B. Enrollment. Principal Investigator will enroll minimum 90 Subjects (as per the randomization schedule provided) 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

C. **Study Documentation.** Case Report Forms (**"CRFs"**) must be satisfactorily completed within **5** (Five) days of each Subject visit. If any tests are to be performed after the Subject visit, CRF shall be completed within **Five (5) 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 communicated to the Sponsor and CRO in writing 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 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 three days after the last Subject visit.

3. PAYMENT

A. **BUDGET AND PAYMENT SCHEDULE**: CRO shall 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"**). Payment shall be made by cheque payable to **MGM Medical College**. 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	MGM's Medical College, N-6,CIDCO, Aurangabad-431003, Maharashtra, India
Attention to	Dr. Deepak Bhosle

The further details for the payments should be provided as:

5	Account No.	0376104000000107
6	Branch Code/BSB	NA
7	NEFT/ RTGS code	NA

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 2:1 i.e. maximum one screen failure per two 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 treatment 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.

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. Principal Investigator will also be responsible for the direction of the Study in accordance with any applicable Institution policies. The Principal Investigator shall ensure that all staff are bound by and comply with the terms of the Protocol and this Agreement. The Principal Investigator or the Institution should inform CRO and Sponsor in the event of a discrepancy between the terms of the Protocol, this Agreement and its own Institution policies within twenty one (21) days of the Effective Date of this Agreement.

If Principal Investigator is an employee of Institution and will be signing this Investigator Agreement as an acknowledgement of understanding but not as a separate party, Principal Investigator will nonetheless be deemed to be a separate party to this Investigator Agreement with respect to the provisions in this Investigator Agreement related to confidentiality, intellectual property rights and publication rights and any provisions in this Investigator Agreement that designate Principal Investigator as the sole performing party.

Any change in the designated Principal Investigator will require CRO and/or Sponsor's express written consent. Notice of a proposed change in Principal Investigator will be given to CRO and Sponsor promptly. If Institution and CRO and/or Sponsor are unable to mutually agree to a replacement, CRO and/or Sponsor may terminate this Investigator Agreement immediately.

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

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 or oral inquiries are requested by the regulatory agency concerning any aspect of the Institution and/or Principal Investigator's activities pursuant to this Agreement, the Institution and Principal Investigator shall permit representatives of the Sponsor and/or CRO to review and comment on such response prior to its being sent to the regulatory agencies. In such event, Institution and/or Principal Investigator will permit representatives from CRO and/or Sponsor to be present at any such inspections, will provide CRO and/or Sponsor with copies or transcripts of such inquiries as well as copies of correspondence between Institution and/or Principal Investigator and the applicable regulatory authority and will notify CRO immediately in writing of any violation or deficiency noted by any such authority.

E. **Supplies.** The Sponsor or Sponsor's designee shall supply to the Principal Investigator, at no charge, sufficient quantity of the nutraceutical product to conduct the Study, as well as the materials, equipment and information which the Protocol specifies. The Principal Investigator acknowledges that the nutraceutical product is experimental in nature, and therefore shall use prudence and reasonable care in the use, handling, storage, transportation, disposition and containment of the nutraceutical product and any of its derivatives. Within 30 (thirty) days following the completion or termination of the Study, all unused nutraceutical product, 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 nutraceutical product, including any materials derived therefrom and all intellectual property rights therein. The transfer of physical possession of the nutraceutical product hereunder, and/or the possession or use of the nutraceutical product by the Principal Investigator, shall neither constitute nor be construed as a sale, lease, or offer to sell or lease the nutraceutical product or other transfer of title in or to the nutraceutical product. Further, the Principal Investigator shall use the nutraceutical product 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 during and after the term of this Agreement in compliance with the Protocol and as may otherwise be required by applicable law, rule, regulation and good clinical practice ("**Study Records**"). The Institution and 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 nutraceutical product for marketing or the formal discontinuation of the clinical development of the nutraceutical product or as per instruction given by CRO/ sponsor for the same. Thereafter, prior to the disposal of the Study Records, Institution will give the Sponsor or CRO not less than sixty (60) days prior express written notice thereof, and if the Sponsor requests in writing, the Institution 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. They will then be forwarded to CRO for data management and to Sponsor as applicable. 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. The data in the CRF shall be recorded, evaluated, and stored in anonymous form in accordance with data protection regulations. The Principal Investigator shall ensure that patient names are not mentioned on any document, neither CRFs nor other documents that will be forwarded to CRO and Sponsor. If CRFs are not complete, the Principal Investigator shall be obliged to complete them on request of CRO or Sponsor.

iii *Principal Investigator Study File and Archiving*

The Investigator shall prepare and maintain complete and accurate Study documentation in compliance with ICH-GCP standards and all Applicable Laws. Therefore, an Investigator Study file shall be prepared which contains all relevant documents necessary for the conduct of the Study including but not limited to the following: (i) signed Protocol and amendments, (ii) Investigator's Brochure and updates, (iii) EC composition, approval(s)/opinion correspondence/reporting, , (iv) CVs and signature sheet for key Study personnel (e.g. investigators, Study nurses), (v) signed Study agreements including financial agreement, (vi) Trial initiation report, (vii) approved and signed informed consent forms, (viii) Study subject insurance certificate, (ix) CRFs (investigator's copy), (x) data correction forms (copies), (xi) SAE documentation and related correspondence/reporting (xii) shipping/accountability/destruction records for investigational product and material, (xiii) Certificate of analysis, (xiv) instructions for handling of investigational product and material, (xv) central laboratory accreditation/certification and up-to-date reference ranges of normal values, (xvi) screening, enrollment, and monitoring logs and Study subject identification code list, and (xvii) Study-related correspondence with Sponsor or CRO.

iv *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.

v *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 Events (SAEs) encountered in the Study within twenty four (24) hours of any SAEs in accordance with Applicable Laws, Regulations and guidelines and will cooperate with CRO and/or Sponsor in connection with any reports or filings related to such SAEs.

H. **Regulatory Compliance.**

i. Institution and Principal Investigator will comply with all applicable laws and regulations in its performance of activities under this Agreement. Institution and/or Principal Investigator will provide reasonable assistance to Sponsor so that Sponsor may comply with any applicable law or regulation in the performance of the activities under this Agreement.

ii. The Parties agree that Institution and Principal Investigator's use and disclosure of Study subject health and medical information is subject to compliance with applicable laws and regulations. The Parties, therefore, agree to take all reasonable steps to protect the confidentiality of any Study subject health and medical information that it has access to and comply with applicable laws. The obligations set forth in this Section shall survive the termination or expiration of this Agreement.

iii. If applicable, Institution and Principal Investigator will obtain a written informed consent form from each Study subject and will maintain a signed original of the written informed consent in the Study subject's records. Institution or Principal Investigator will provide CRO and/or Sponsor an opportunity to review and approve the content of the informed

iv. Institution and Principal Investigator will provide financial disclosures that may be reasonably requested by Sponsor so that Sponsor may fulfill its financial disclosure obligations under applicable laws, rules and regulations.

I. **Resignation of Principal Investigator.** The Institution shall inform CRO in case the Principal Investigator ceases to be associated with the Institution for any reason during the course of the Study. They shall also replace the Principal Investigator in case CRO so desires and render all assistance to safeguard patient safety and Study data.

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 nutraceutical product 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 nutraceutical product 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 product 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

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. Sponsor reserves the right to delay any publication for a period not to exceed sixty (60) days of receipt of draft in order to obtain patent protection.

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 nutraceutical product 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 therefrom 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 nutraceutical product 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).

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*

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 Mumbai, 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 Mumbai, India. Each of the Parties hereby expressly submits to the jurisdiction of the courts of Mumbai, India.

10. INDEMNIFICATION

A. Sponsor Indemnification. **The Sponsor shall defend, indemnify, and hold harmless the Institution and its trustees, officers, the Principal Investigator, employees and agents** (the "Institution Indemnitees") **from and against any amount paid or payable by Institution Indemnitee for any loss, damage and/or expense which would not have been suffered but for participation in the Study, but excluding treatment for any pre-existing condition due to any claim, demand, cost or judgment ("Claims") which may be made or instituted against them by a third party by reason of personal injury (including death) to any Study subject, which arises out of or is otherwise sustained as a direct result of (a) administration of nutraceutical product pursuant to the Protocol designated in the Study, (b) the performance of Study in accordance with the Protocol, (c) the failure of any covenant or representation made by the Sponsor in or in connection with the Agreement, the Protocol or the Study, (d) the negligence, error, omission or malfeasance of the Sponsor, or (e) any other material breach of this Agreement by the Sponsor; provided however, that Sponsor's indemnification obligations hereunder shall not apply to the extent that any Claim is attributable to:**

(i) the failure of any Institution Indemnitee to perform the Study in accordance with or otherwise to adhere to the terms of the Protocol or any written instructions (including, without limitation, package inserts, where appropriate) relative to the use of any drugs or devices used in the performance of the Study; or

(ii) a failure of any Institution Indemnitee to comply with all applicable federal, state, or local laws, rules, regulations, requirements and policies of regulatory authority, or

(ii) any negligence, error, omission or malfeasance of any Institution Indemnitee; or

(iv) any material breach of this Investigator Agreement by any Institution Indemnitee,

(v) in the event that Institution Indemnitee fails to cooperate with and give such assistance to Sponsor as may reasonably be required for the efficient and prompt handling of any Claim or makes any admission or offer to settle in relation to any Claim;

provided, however, that Sponsor's indemnification obligations hereunder shall not apply to the extent that a Claim relates to any matter for which Institution or Principal Investigator is required to indemnify Sponsor as provided for in Section 10 B below.

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 Indemnitees") from and against any amount paid or payable by any Sponsor Indemnitee for any Claims which may be made or instituted against any Sponsor Indemnitee by a third party by reason of personal injury (including death) to any Study subject, to the extent that such Claim is attributable to:

(i) the failure of any Institution Indemnitee to perform in accordance with or otherwise to adhere to the terms of the Protocol or any written instructions (including, without

(ii) a failure of any Institution Indemnitee to comply with all applicable federal, state, or local laws, rules, regulations, requirements and policies of regulatory authority, or

(iii) any negligence, error, omission or malfeasance of any Institution Indemnitee, or

(iv) the failure of any covenant or representation made by any Institution Indemnitee in or in connection with the Investigator Agreement, the Protocol or the Study, or

(v) any material breach of this Investigator Agreement by any Institution Indemnitee,

(vi) in the event that Sponsor Indemnitee fails to cooperate with and give such assistance to Institution as may reasonably be required for the efficient and prompt handling of any Claim or makes any admission or offer to settle in relation to any Claim;

provided, however, that the Institution's indemnification obligations hereunder shall not apply to the extent that a Claim relates to any matter for which Sponsor is required to indemnify an Institution Indemnitee as provided for in Section 10 A above.

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 Indemnitee.

F. **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 nutraceutical product 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 Institution Indemnitee or any other Institution personnel involved in the Study; and provided further that such expenses are not attributable to a failure of the Institution Indemnitee 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 Nutraceutical product; (iv) all applicable government laws, rules, regulations, requirements, and policies; (v) Study subject's primary disease or any concurrent disease not directly and solely caused by administration of the nutraceutical product in accordance with the Protocol or (vi) the Study subject's failure to comply with instructions contained in the informed consent executed by such Study subject or communicated to the Study subject by Study personnel or (vi) the manner required of a reasonable and prudent clinical investigator or physician. 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. No other compensation of any type will be provided by the Sponsor to the Subjects for injuries related to the Study. Institution agrees that it will not seek or collect, and will not assist the Study subject in seeking or collecting, reimbursement from any health insurance plan, PPO, or governmental medical plan or other government provided health coverage available to the Study subject for any medical expenses paid by Sponsor pursuant to this Agreement.

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. 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. Upon execution of this Agreement and every anniversary thereafter during the term of this Agreement, Institution shall provide the Sponsor with a certificate of insurance stating the limits of coverage. Institution shall provide to Sponsor and CRO thirty (30) days prior written notice of cancellation or material change of any insurance referred to herein.

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)(*v*), above, unless earlier terminated in accordance with this Agreement. This Agreement shall be deemed terminated when Institution and Principal Investigator have fulfilled their respective responsibilities as specified in 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 applicable regulatory authority in India;

b. 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 therefrom, 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

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 nutraceutical product 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 Study supplies, 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 : ITC Life Science and Technology Center, No.3. Phase I , Stage I,Peenya Industrial Area, Peenya, Bangalore - 560 058.

Attn: Dr. Yashwanth Pudakalakatti

Address: MGM's Medical College, N-6, CIDCO, Aurangabad – 431003, Maharashtra, India
Attn: Dr. Rajendra Bohra
Ph: +91-0240-6601100
e-mail: mgmmca@themgmgroup.com

Any notice to Principal Investigator shall be addressed as follows:

Address: MGM's Medical College, N-6, CIDCO, Aurangabad – 431003, Maharashtra, India
Attn: Dr. Deepak Bhosle
Ph: +91- 7770087870
e-mail: drdeepakbhosle@gmail.com

Any notice to CRO shall be addressed as follows:

Address: Kamic Lifesciences LLP, Unit No. 02, Ground Floor, Reliable Plaza, Plot No. K-10, Thane-Belapur Road, MIDC, Airoli, Navi Mumbai- 400 708
Attention: Dr. Prashant Kirkire
Ph: +91-9930886030
E-mail: prashant.kirkire@karmiclifesciences.com

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

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 emailed to the Medical Affairs Department of CRO for onward transmission to SPONSOR:

E-mail: safety@karmiclifesciences.com

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.

Institution and 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. Rajendra Bohra
Dean
Mahatma Gandhi Mission's Medical college and Hospital,
N-6 CIDCO, Aurangabad-431003. MH. India
04 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. Deepak Bhosle
Principal Investigator
Mahatma Gandhi Mission's Medical college and Hospital,
N-6 CIDCO, Aurangabad-431003. MH. India

KARMIC LIFESCIENCES LLP

By: _____
(Signature)

Name : Dr. Prashant Kirkire
Designation : President

13 Dec 16
(Date)

EXHIBIT A: PROTOCOL

As annexure 1

Protocol No - Attached herewith

EXHIBIT B: BUDGET AND PAYMENT SCHEDULE

BUDGET:

Principal Investigator : **Dr. Deepak Bhosle**

Site Address : Mahatma Gandhi Mission's Medical College, N-6, CIDCO, Aurangabad – 431003, Maharashtra, India

PAYMENT SCHEDULE

Payment Schedule for the total study Grant is as follows:

Overall Per Patient Budget

Amount in Indian rupees per patient	Reimbursement
14504	Includes the following • PI and site team payment including Co- Investigator (s), Phlebotomist(s), Nurse(s), Dietician as applicable • Institutional overhead • Subject Travel Compensation (max to be paid INR 250/Visit/Subject
	Total Amount

Budget Bifurcation

Study Budget			INR	Comments
A	Investigator fee & Staff fees	Visit 1 (screening visit) –in case of screen failure	1000*	to be paid per subject @ 2:1 patient (for every 2 enrolled subject 1 screen fail) *inclusive of study staff fee for screen failures
		Visit 2 (enrollment visit)	2540	to be paid per enrolled subject
		Visit 5	1000	-
		Visit 7	3540	to be paid per completed subject
B	Study Staff Fee (inclusive of Coordinator & Phlebotomist Fee)	Visit 2 (enrollment visit) – Visit 7 (End of study visit)	1500	To be paid for per completing subject
C	Subject travel reimbursement	Visit 1 (screening visit) – Visit 7 (end of treatment)	1750	max to be paid per subject @ INR 250/visit
D	**ECG fees**	**Screening Visit**	300	to be paid per screened subject
D	**% Institutional overhead (30 %)**		2874	Will be paid as per the (A+B) per completed subject
	Total		14504	per completing subject

- **EC Charges/fees will be paid separately**
- **Central lab would be utilized for protocol specific blood analysis and payment would be done by CRO on behalf of sponsor**

The Payee designated above will receive all compensation paid to the Institution in connection with the Investigator Agreement, if applicable. Payee will provide all applicable tax identification numbers and, upon reasonable request, will provide or assist CRO with forms related to applicable taxes.

Payment Schedule for the advance payment is as follows:

1 Study start up cost (Advance/ pre payment) INR. 10000/-

The advance payment (pre payment) provided to the PI will be adjusted against first three invoices raised by PI as per the PI grant.

The remaining payments will be provided on monthly basis as per the patients visit charges/ patient study completion.

Sponsor will pay only INR.1000/- amount for screen failure patients as per Exhibit A of this Agreement with the maximum ratio of 2:1 i.e. maximum one screen failure per two randomized patients. Any Study subject who has been enrolled in the Study but does not meet eligibility requirements (as set forth in the Protocol) may be withdrawn from study without any payments. CRO reserves the right to withhold payment for any Study subject: (i) for whom a signed informed consent form has not been obtained prior to enrollment, (ii) for whom reasonably complete Case Report Forms have not been obtained, or (iii) for whom the Protocol has not been followed, absent reasonable explanation from Institution and/or Principal Investigator for the Protocol deviation(s).

Payment Adjustments

If Institution's/Principal Investigator's participation is terminated because no Study subjects have been enrolled, Institution/Principal Investigator will not be entitled to reimbursement or payment for any administrative costs that were incurred prior to such termination, except to the extent such costs are set forth expressly in this Investigator Agreement.

If, upon termination of this Investigator Agreement, CRO, on behalf of Sponsor, has prepaid funds that Institution/Principal Investigator has not earned in accordance with Exhibit A, Institution/Principal Investigator (or its designated payee) will return to CRO all such prepaid funds within thirty (30) days after the effective date of termination. Prepaid funds owed to CRO, if any, will be returned pursuant to instructions provided by the CRO accountant assigned to administer payments to the Payee.

In the event this Exhibit A sets forth a maximum number of subjects that may be enrolled by Institution in the Study or a maximum payment amount to Payee pursuant to the Study, Sponsor at its discretion may authorize increases in Study subjects and/or payments.
In the event the Protocol is amended, compensation paid to the Payee may be adjusted to give effect to the Protocol amendment.

During the course of the Study, Institution will have forty five (45) days after the receipt of final payment to dispute any reasonable payment discrepancies.

Invoices

Send invoices to:
Contact Person: **Mr. Amit Pawar/Mr.Sagar Dhawale**
Address: Karmic lifesciences LLP, Unit No. G-02, Reliable Plaza, Plot No. K-10, Thane-Belapur Road, MIDC, Airoli, Navi Mumbai – 400 708

Also send copy of Invoices through mail to contact person at **amit.pawar@karmiclifesciences.com** & **sagar.dhawale@karmiclifesciences.com**

Failure to include Protocol number and Principal Investigator's name on all invoices may result in delayed payment.

Final Payment

The final payment will be made after the close-out visit by the CRO CRA, after all CRFs for all subjects have been received and accepted by a CRO project leader, and all data queries for Institution have been resolved satisfactorily.

Budget notes, payment schedule, conditions of payment and payment directions

3. Serious Adverse event related costs: Costs relating to SAE that arise due to study participation would be borne by the Sponsor on actual.

4. Each randomized subject after completion of the study visit can be given the reimbursements.
5. Please note that the total amount for three randomized patients i.e. INR. 43,512/- (fourty three thousand five hundred twelve only) will be considered as retention amount and will be paid at the end of study/ study close out; once all the study related procedure and documentation would be over.
6. All payments are subject to withholding tax under all applicable laws including Income Tax Act, 1962.

- A tax of 10% will be deducted in case a tax exemption certificate is not provided. This tax amount has been calculated and added to total grant amount. In case a tax exemption certificate is provided, then the tax amount (@ 10%) will not be applicable to be released to the site in the budget.

- In case recruitment is not initiated within a reasonable time period, unutilized amount (In keeping with the payment head above) would have to be returned to Sponsor.