YENEPOYA

(DEEMED TO BE UNIVERSITY)
Recognized under Sec 3(A) of the UGC Act 1956
Accredited by NAAC with 'A' Grade

Details of the Collaborative Activity

2019-2020

Name of the Collaborating Institute: Johnson & Johnson Private Limited, Mumbai

Name of the Collaborating Department: Department of Dermatology, Yenepoya Medical College Hospital

Activities:

Clinical Trial Project:

Dr. Manjunath Shenoy (PI), Head of the Department, Dermatology, Yenepoya Medical College and Hospital and Johnson & Johnson Pvt. Ltd, Mumbai signed a Clinical Trail Agreement to perform clinical study entitled "Itraconazole in the management of superficial fungal infections in India: A Pilot Study" dated on 28th Jun, 2019.

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

Dr. Manjunath Shenoy
Itraconazole Pivotal study
R051211FUN4058

Bombay Mercantile Co-Operative Bank Ltd.,
78, Mohammedali Road
Mumbai-400 003.
D-5/STP(V)/C.R.1056/04/05/334-339/2009

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CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement ("Agreement") by and between **Johnson & Johnson Private Limited** (hereinafter referred to as the "Sponsor"), with its corporate office at Arena Space, Behind Majas Bus Depot, Off Jogeshwari Vikhroli Link Road Jogeshwari (E), Mumbai 400 060

and

Yenepoya (Deemed to be University) (hereinafter referred to as the "Institution" located at Yenepoya (Deemed to be University), Yenepoya Medical College- constituent unit of Yenepoya (Deemed to be University), Department of Dermatology, University Road, Deralakatte, Mangalore, Karnataka – 575018, India

and

Dr. Manjunath Shenoy (hereinafter referred to as the "Principal Investigator"), an independent consultant of the Institution, located at Yenepoya (Deemed to be University), Yenepoya Medical College- constituent unit of Yenepoya (Deemed to be University), University Road, Department of Dermatology, Deralakatte, Mangalore, Karnataka – 575018, India conducting clinical research study at Institution.

is made and effective as of the date of execution that the last party signs below (hereinafter "Effective Date").

(Hereinafter each referred to as a "Party", and collectively as the "Parties")

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Background

WHEREAS, the Sponsor has requested Institution and Principal Investigator, to conduct a clinical research study involving the study drug **Itraconazole** (hereinafter referred to as the "Study Drug") according to the protocol **R051211FUN4058** (hereinafter referred to as the "Protocol") titled **"Itraconazole in the Management of Superficial Fungal Infections in India. A Pilot Study"** (hereinafter referred to as the "Study"), incorporated herein by reference as Exhibit A, and all subsequent Protocol amendments thereto; and

WHEREAS, the Principal Investigator is a qualified medical practitioner and has been engaged by the Institution to participate in the Study as an investigator and being responsible to conduct the Study, Statement issued by Institution attached hereto as Exhibit E; and

WHEREAS, the Institution is qualified and equipped with adequate facilities, equipment and personnel to undertake the Study, and the Institution and the Principal Investigator have agreed to perform the Study on the terms and conditions hereinafter set forth.

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

1. Performance of the Study.

   A. Compliance with the Agreement. The purpose of this Agreement is to conduct the Study at the study site of the Institution. The Protocol has been sponsored by the Sponsor and is approved by OR is subject to the approval of the Drug Controller General of India ("DCGI") under the Drugs & Cosmetics Act 1940 including any amendments thereof (hereinafter referred to as "Drugs and Cosmetics Act, 1940") and/or any other law or rules for the time being in force in India as well as approved by the Ethics Committee ("EC"). In the event the Protocol is amended, such change shall be notified and, if required under the law, prior approval of DCGI and/or EC shall be obtained. The Institution and the Principal Investigator agree to perform the Study in strict compliance with the Protocol and the terms and conditions of this Agreement including any amendments thereto. The Principal Investigator shall perform the Study at the study site of the Institution. The Institution and the Principal Investigator further represent, warrant and covenant that the Principal Investigator is and at all times, during the term of this Agreement, shall be: (a) in good professional standing, (b) in possession of all requisite professional licenses, approvals and permissions (c) fully qualified to conduct the Study and to act as the Principal Investigator under this Agreement, (d) fully experienced and knowledgeable with respect to all matters pertaining to the Study and (e) responsible for the supervision of all persons who may assist the Principal Investigator or otherwise be engaged in the Study. In the event that the Institution and/or the Principal Investigator use the services of sub-investigators, investigational staff, or others to conduct the Study pursuant to this Agreement, the Institution and the Principal Investigator shall be responsible for ensuring that all are appropriately licensed and credentialed and shall conduct the Study in compliance with the terms and conditions of this Agreement. The Institution and the Principal Investigator shall be liable for any breach of this Agreement by such individuals.

   B. Replacement of the Principal Investigator. In the event that the Principal Investigator will no longer be the investigator for the Study due to expiry or early termination of the engagement with the Institution, the Institution and Principal Investigator shall provide a written notice to the Sponsor within three (3) calendar days of such change. The Sponsor shall have the right to approve any new principal investigator who is responsible for the conduct of the Study. The Institution shall ensure that new principal investigator agree to the terms and conditions of this Agreement. In the event the Sponsor does not approve such new principal investigator, the Sponsor may terminate this Agreement in accordance with the Termination Section 2.B below and the Institution shall take all necessary steps to accommodate the Sponsor's decision in an efficient manner.

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C. Blinding the Study; Use of the Randomization Codes. Where the Protocol calls for the Study to be blinded, the Institution and the Principal Investigator agree to maintain the blinding of the Study Drug. The Institution and the Principal Investigator understand that the randomization codes will be released upon completion of the Study and finalization of the database by the Sponsor. For multi-center studies, data from all centers are required before the Study is considered complete. Should a medical emergency occur requiring the Principal Investigator to break the code for a specific subject, the Principal Investigator agrees to notify the Sponsor immediately informing reasons and from time to time the progress and results of such case.

D. Delegation of the Investigator Duties. The Principal Investigator will personally supervise the Study and may not delegate this duty to any other individual without the Sponsor's prior written approval. He/she may, however, delegate other duties as necessary to other investigators and qualified personnel in accordance with regulatory requirements and upon notice to the Sponsor. The Institution may not replace the Principal Investigator without the Sponsor's prior written approval. If the Principal Investigator is to be temporarily absent from the Institution, the Institution shall designate an investigator qualified and trained to assume such responsibilities to temporarily supervise the Study on the Principal Investigator's behalf. The Institution shall document this designation and if applicable, report to the DCGI and/or EC, and notify the Sponsor in writing of such designation prior to its commencement.

E. Investigator and Staff Training. The Institution and the Principal Investigator shall ensure that other investigators, and all designated staff attend all trainings conducted by the Sponsor or its designee in the proper performance of the Study under the Protocol, safety and reporting requirements, and any other applicable guidelines as determined by the Sponsor to be relevant to the conduct of the Study.

F. Use of the Study Drug or Study Product. For the performance of the Study, Sponsor shall provide the Study Drug, all Study related documents (such as case report forms) and any materials and equipment supplied/refer to Exhibit B where the materials are listed, together with the conditions of use. Neither the Institution nor the Principal Investigator shall make any use of the Study Drug, and Study related documents, materials and equipment provided by the Sponsor other than for the performance of the Study in accordance with the Protocol and this Agreement.

G. Additional Research. Institution and Principal Investigator shall not conduct any additional research, nor facilitate third parties to conduct any research, not required by the Protocol, including without limitation research on (i) Study Subjects (as defined in Section 2.B below) during the Study (including any additional research technique, procedure, questionnaire, or observation), or (ii) biological samples collected from Study Subjects during the Study, or (iii) the data derived from the Study , in each case, without the prior written consent of Sponsor. Hereinafter, the research described in the previous sentence shall be referred to as "Additional Research". In any case where Sponsor gives such approval, the approved Additional Research shall be the subject of another written agreement between Sponsor and Institution. Institution and Principal Investigator shall conduct all such Additional Research in compliance with all applicable laws, rules, regulations and guidelines, including without limitation to Schedule Y to Drugs & Cosmetic Rules 1945 under Drugs & Cosmetics Act 1940 including any amendment(s), thereof (hereinafter "Drugs and Cosmetic Rules, 1945") and/or any other law or rules for the time being in force in India, Guidelines of Indian Council for Medical Research, Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002, Good Clinical Practices For Clinical Research In India issued by Central Drugs Standards Control Organization, ICH Guideline for Good Clinical Practice, and requirements for obtaining approval from Licensing Authority as defined in clause(b) of Rule 21 of Drugs and Cosmetic Rules 1945 and/or EC approval and subject informed consent. Without limiting any other remedy available by law to Sponsor, if Institution conducts Additional Research in breach of this section, and such Additional Research results in an invention, Institution hereby grants to Sponsor

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or its designee an irrevocable, worldwide, paid up, royalty-free, exclusive license, with the right of sub-license, to make, have made, use, have used, sell, have sold, and import any invention that results from such Additional Research.

2. Term and Termination.

A. Term. The term of this Agreement shall begin on the Effective Date and shall end on the later of (i) Global Trial End Date (as defined in the Protocol) or (ii) six (6) months following final database lock (hereinafter "Expiration Date"). The Parties agree that the term may be extended by mutual written agreement if events beyond the Parties' control delay the completion of the Study beyond the Expiration Date.

B. Termination. The Agreement may be terminated by the Sponsor at any time in the exercise of its sole discretion upon thirty (30) calendar days prior written notice to the Institution. Reasons for the Study termination may include but are not limited to:

(i) breach of contract, including failure to comply with the Protocol and applicable laws and regulations
(ii) absence of the Principal Investigator including the Sponsor's disapproval of a new principal investigator under section 1.B herein
(iii) receipt of safety information that makes it prudent to do so or
(iv) if no subjects have been recruited at the Study Site within 6 months following the initiation of the Study at the Institution, a motivational visit will be conducted at the site. Thereafter, the site will be given a period of 3 months to recruit subjects. If the site still fails to recruit even a single subject, the site could be considered for closure.

Notwithstanding the above, the Sponsor may immediately terminate the Study if, within its sole judgment, such immediate termination is necessary based upon considerations of patient's safety or, upon receipt of data suggesting lack of sufficient efficacy or breach of section 8.D and 8.F herein without Sponsor having any financial liability or other liability of any nature whatsoever resulting from any such termination. Upon receipt of notice of such termination, the Institution and the Principal Investigator agree to promptly terminate conduct of the Study to the extent medically permissible for any individual who participates in the Study (the "Study Subject").

C. Payment Upon Termination. Upon any early termination for any reason other than the breach of this Agreement by the Institution or by the Principal Investigator, the Sponsor shall reimburse the Institution for non-cancellable commitments made or incurred in accordance with this Agreement, prior to Institution's receipt of a notice of termination (reduced by all applicable prior payments made by the Sponsor under this Agreement). No cancellation penalty payments shall apply. Upon receipt of such notice of termination, the Institution and the Principal Investigator shall use all reasonable efforts to avoid incurring additional costs and expenses and shall apply all payments made by the Sponsor for this Agreement toward actual fees and costs incurred as of the effective date of termination. In the event the Sponsor has prepaid any portion of payment for work pursuant to this Agreement that is not actually performed as a result of termination hereunder, the Institution and Principal Investigator shall return such prepaid payment to the Sponsor for such unperformed services or unexpended or cancelled fees.

D. Disposition of the Study Drug or Study Product and Confidential Information. The Study Drug is provided solely for the Institution's conduct of the Study. Institution and Principal Investigator shall not use the Study Drug other than for performance of the Study in strict accordance with the Protocol and this Agreement. The Institution and the Principal Investigator shall account for and return to Sponsor, or otherwise dispose of in accordance with the Sponsor's instructions, any unused Study Drug, including any materials and equipment provided by the Sponsor and all Sponsor Confidential Information, as defined in the Confidentiality Section (i.e., Section 4.B) of this Agreement, at the earlier of the conclusion of the Study or termination of this Agreement. In the

event that unused Study Drug is destroyed at the Institution, the Institution shall promptly provide the Sponsor with a copy of its "Certificate of Destruction". This provision does not apply to those documents that should be maintained and retained in a secure manner by the Principal Investigator at the Institution, as specified in the Protocol or the Agreement and as required by applicable guidelines, laws and regulations.

3. Institutional Ethics Committee /Informed Consent.

A. Institutional Ethics Committee ("EC"). In accordance with applicable laws and regulations, the Institution and the Principal Investigator shall be responsible for obtaining approval of the Protocol and its amendments, informed consent forms, Study advertisements (if any), Study recruitment procedures (e.g., announcements, financial statements, waiver of any patient authorization permitting the disclosure of confidential patient information in connection with the Study if any), any alteration to or waiver of any Study Subject's authorization permitting the disclosure of Study Subject's confidential information in connection with the Study, any matter involving questions of human subject protections, and any other relevant documents in connection with the Study, from the appropriate EC prior to commencement of and during the performance of the Study. In the event the EC requires changes in the Protocol or informed consent forms, such changes shall not be implemented until the Sponsor is notified and gives its approval. The Protocol, the informed consent, and any advertising or recruitment procedures shall not be revised without the prior written agreement of the Sponsor and the EC.

B. Informed Consent. The Institution and the Principal Investigator shall also be responsible for obtaining an informed consent form signed by or on behalf of each Study Subject, as per the applicable guidelines, rules and regulations in this regard, which informed consent form shall be the document approved by the Sponsor and the EC, prior to the Study Subject's participation in the Study. The informed consent form shall include the right for the Sponsor and its designees and applicable government authorities to review raw Study data, including original Study Subject records, in all monitoring and auditing activities required to ensure quality assurance and compliance with the Protocol as well as all legal and regulatory requirements applicable in the country.

C. Sponsor shall be responsible for the fulfillment of all other authorization formalities related to the conduct of the Study (such as submitting a clinical trial application) and related to the manufacturing, supply or importation of the Study Product, and if required, for obtaining the written authorization from the competent health authorities prior to commencement of the Study.

4. Ownership of Data, Confidentiality, Publication and Registration

A. Ownership. All case report forms and other data (including without limitation, written, printed, graphic, video and audio material, and information contained in any computer data base or computer readable form, including, but not limited to, all Study results and other details called for in the Protocol) generated by the Institution, the Principal Investigator, and any other designated personnel in the course of conducting the Study (the "Data") shall be the sole property of the Sponsor or its designee, which may utilize the Data in any way it deems appropriate, subject to and in accordance with applicable (a) Indian laws and regulations and (b) privacy and security laws of India and other countries as aftermentioned and regulations and the terms of this Agreement. Any copyrightable work created in connection with the performance of the Study (except any publication by the Principal Investigator as provided for hereafter) shall be property of Sponsor as author and owner of copyright in such work and be considered a "work made for hire" to the fullest extent permitted by law, and owned by the Sponsor or its designee. The Institution and the Principal Investigator may not use the Data for any commercial purposes including the filing of a patent application or the filing of the Data in support of any pending or future patent application or for the benefit of any for-profit entity, including use of Data in support of research for or in collaboration with a for-profit entity.

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B. Confidentiality. All information, including, but not limited to, the Study Drug, the terms and conditions of this Agreement, the Protocol, or the Sponsor's operations, such as the Sponsor's patent application, formulas, manufacturing processes, basic scientific data, prior clinical research data and formulation information supplied by the Sponsor to the Institution or the Principal Investigator or other personnel involved with the Study and not previously published (the "Sponsor Confidential Information") as well as any Data are considered confidential and shall remain the sole property of the Sponsor. Both during and after the term of this Agreement, the Institution and the Principal Investigator will use diligent efforts to maintain in confidence and use only for the purposes contemplated in this Agreement:

(i) the Sponsor Confidential Information;
(ii) all information which is identified as confidential or which a reasonable person would conclude is the confidential and proprietary property of the Sponsor or its designee and which is disclosed on behalf of the Sponsor to the Institution or the Principal Investigator, and
(iii) the Data.

The preceding obligations shall not apply to Data, Sponsor Confidential Information or the information that falls under Section 4B(ii);

a) which has been published through no fault of the Institution or the Principal Investigator,
b) which the Sponsor agrees in writing, may be used or disclosed, or
c) which is published in accordance with the Publication Section of this Agreement.
d) which the Institution can demonstrate through contemporaneous written records was in its possession prior to disclosure by the Sponsor,
e) which is in the public domain or which later becomes part of the public domain other than by breach of this Agreement by the Institution,
f) which is lawfully disclosed to Institution by a third party not obligated to Sponsor to keep the information confidential, and
g) which as evidenced by contemporaneous written records is independently discovered by the Institution without access to Sponsor Confidential Information.

Institution and/or the Principal Investigator may disclose to its employees, its agents or consultants to the extent required on a need-to-know basis to accomplish the purposes of this Agreement provided that Institution and/or the Principal Investigator obtains prior agreement from such employees, agents and consultants to whom disclosure is to be made to be bound by obligations of confidentiality and non-use at least as stringent as those in this Agreement and not make use of such Confidential information for any purpose other than those permitted by this Agreement. The Institution and Principal Investigator warrant the compliance of all such employees, agents, and consultants involved in the Study with the provisions of this Section.

C. Compelled Disclosures. In the event the Institution or the Principal Investigator including but not limited to any person to whom it has transmitted the Sponsor Confidential Information received hereunder is required by law or legal process to disclose any of such Sponsor Confidential Information, the Institution will (i) provide the Sponsor with prompt notice of such event so that the Sponsor may take appropriate steps, including intervening, to protect the confidentiality of the Sponsor Confidential Information and (ii) use reasonable efforts to obtain assurance that confidential treatment will be afforded to the Sponsor Confidential Information to be disclosed. Institution shall furnish only that portion of the Sponsor Confidential Information which is legally required to be disclosed.

D. Publication. In connection with any Data or other information generated from the services conducted hereunder by or on behalf of the Institution or Principal Investigator or other personnel associated

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with this Study, the Sponsor shall have the right to publish such Data and information without approval from the Institution or Principal Investigator, and may do so in a timely manner to meet obligations for such data disclosure under the Food and Drug Administration Amendments Act (42 U.S.C. § 282) or any other applicable laws or regulations. Moreover, if publication of the Study to the peer reviewed literature has not occurred within twelve (12) months from the date of Study completion, the Sponsor may post the results of the Study to a clinical research trial results web site in the form of a Clinical Research Study Report Synopsis in ICH-E-3 format, if applicable. Subject to the terms of this Agreement, the Institution, through the Principal Investigator, shall have the right to publish the results of the research and any background information provided by the Sponsor that is necessary to include in any publication of research results or necessary for other scholars to verify such research results. The Principal Investigator will include a statement that creation of the Data was supported in part by the Sponsor. Prior to submission for any public disclosure of the Data or results generated in accordance with this Agreement, including but not limited to disclosure of manuscripts, abstracts, posters and other materials (hereinafter, "Publication"), the Institution will ensure that the Principal Investigator provides the Sponsor with at least sixty (60) days for review of the Publication. Upon request, the Sponsor, the Institution and the Principal Investigator will arrange expedited reviews for abstracts, poster presentations or other materials as appropriate. Notwithstanding the foregoing, no Publication that incorporates the Sponsor Confidential Information will be submitted for publication without prior written consent of the Sponsor. If requested in writing by the Sponsor, the Institution shall ensure that the Principal Investigator withholds such Publication for up to an additional sixty (60) days to allow for filing of a patent application. The Institution warrants the compliance of all investigators and other personnel involved with the Study with the provisions of this paragraph. If a particular Study is part of a multicenter study, the Institution agrees that the first Publication of the results of such Study shall be made as a joint, multicenter Publication of the Study results, with investigators and institutions from all participating sites contributing data. However, if such a multicenter Publication is not submitted within eighteen (18) months after conclusion, abandonment or termination of the Study at all sites, or after the Sponsor confirms there will be no multicenter Study Publication, the Institution, through the Principal Investigator, may publish the results from the Institution site individually in accordance with this paragraph.

If the Principal Investigator is invited to participate as an author of a manuscript for publication, the Principal Investigator shall meet the criteria established by International Committee of Medical Journal Editors ("ICMJE") guidelines and shall have opportunity to guide, review, and modify the scientific manuscript throughout the development process. As an author, the Principal Investigator shall help ensure that the scientific manuscript is objective and unbiased. Moreover, the final version of the scientific manuscript shall include a disclosure of Sponsor's involvement in the preparation of the scientific manuscript, consistent with the ICMJE guidelines.

If the Principal Investigator is not chosen as author, then the Institution shall ensure that he or she grants permission to be acknowledged in a Publication as contributing to the Data collection for the study. If the Principal Investigator does not wish his or her name to appear as part of the acknowledgments, he/she shall submit this request in writing to the Sponsor.

Institution and Principal Investigator warrant the compliance of all co-investigators and other personnel involved with the Study with the provisions of this Section.

E. Registration and Related Information.

The Sponsor has the right to publicly register in the website of Clinical Trial Registry of India (www.ctri.in) company sponsored Studies and to disclose results in accordance with the company's Policy and Standard Operating Procedure (SOP) on public registration and results disclosure. The policy and SOP imposes:

(i) the disclosure of all interventional clinical trials with a Sponsor's product conducted in patients during all phases of development,

(ii) the disclosure of any clinical trials conducted in healthy volunteers or in patients whereby results are planned to be published in a peer reviewed scientific or medical journal,
(iii) clinical trials to be registered before first site open expected and,
(iv) the public disclosure of company sponsored clinical trial results of an approved drug or biologic product conducted in patients within pre-defined timelines.

Where local laws and customs provide stricter and/or additional standards than those contained in the Sponsor's policy and SOP, the Sponsor will adhere to the local requirements.

Protocol summaries requiring disclosure on CTRI shall always be disclosed in alignment with the CTRI dataset requirements and with the WHO International Clinical Trials Registry Platform (ICTRP) dataset requirements.

In addition to the registration on CTRI, studies will/can also be registered on:

- www.clinicaltrials.gov; when in scope of the Sponsor's company policy,
- other clinical trial registries; when mandated by a local disclosure requirement, and
- Sponsor's websites.

The Sponsor's primary registry for protocol and results disclosure is the United States registry www.clinicaltrials.gov owned by the National Library of Medicines. If a local requirement allows for multiple public registry websites disclosure, of which clinicaltrials.gov is one, then the Sponsor will disclose on www.clinicaltrials.gov. In addition, the Sponsor has also the right to disclose company-sponsored studies on its company website.

Any person accessing a clinical trial listing for a Clinical trial on www.clinicaltrials.gov may elect to complete an online eligibility-screening questionnaire made available through Sponsor funding. For Trial Subjects screened as potentially eligible in the Institution's geographical area, Principal Investigator will receive a report with the completed screen and the Trial Subject's contact information. Principal Investigator agrees to follow-up on the report and to document such follow-up in source records.

5. Patents. All rights to any discovery or invention, whether patentable or not, conceived and/or reduced to practice as a result of the work conducted under this Agreement (an "Invention") shall belong to the Sponsor. The Institution and Principal Investigator hereby assign (and shall cause all Study investigators and other personnel involved with the Study to assign) to the Sponsor or its designee, the sole and exclusive ownership of all Inventions. Sponsor or its designee shall have the sole right, but not the obligation, to file, prosecute and enforce any patents related to any Invention. The Institution and the Principal Investigator shall promptly disclose to the Sponsor any Invention. The Institution and the Principal Investigator shall execute and shall have all Study investigators and other personnel involved with this Study execute, all documents necessary to transfer all right, title and interest in and to any such Invention to the Sponsor or its designee.

Institution and the Principal Investigator warrants that Principal Investigator and all others performing services under this Agreement are obligated to assign to Institution all Inventions made in the course of performance of the Study, as specified in terms and conditions of the written agreement executed between the Institution and the Principal Investigator

Nothing set forth in this Agreement shall affect the ownership or any right, title, or interest in any inventions, any patents and patent applications related to any inventions that exist on the Effective Date.

Institution shall be solely responsible for providing to its workers, investigators, agents and the Principal Investigator all wages, compensations, awards, remunerations and benefits that are required under the applicable law, including all inventor award and remuneration. Other than the compensation specifically and expressly stated in this Agreement, Institution and its workers, investigators, agents and the Principal Investigator will not ask the Sponsor or its affiliates or its designee for any further payment

related to the assignment of any rights of any patent applications or patents that arise out of the Study.

6. Reporting of Data.

The Institution and/or the Principal Investigator agrees to provide the Sponsor periodically and in a timely manner with all Data called for in the Protocol on properly completed (written or electronic) case report forms (the "CRF").

A. **Electronic Data Capture ("EDC")**: The Institution and/or Principal Investigator will submit Data using the electronic system, provided by the Sponsor. The Institution shall prevent unauthorized access to the Data by maintaining physical and digital security of the computers and ensuring that investigational staff maintains the confidentiality of their passwords. Institution and/or Principal Investigator shall also comply with Sponsor's instructions for Data entry into the system, which includes that investigational staff using the system understands that their electronic signatures are the legally binding equivalent of handwritten signatures, and they attest to the accuracy and completeness of the Data entered.

The Principal Investigator and/or the Institution agrees to collect all Data in source documentation (electronic or paper) prior to entering it into the electronic Case Report Form ("**eCRF**"). The eCRF shall be completed within five (5) working days after visit procedures have been completed or test results are available, unless otherwise specified in the Protocol. The Principal Investigator/Institution also agrees to provide appropriate responses to queries received within five (5) working days of receipt, unless otherwise specified in the Protocol.

In the event the Principal Investigator/Institution do not enter Data into the eCRF or respond to queries in the timeframe set forth for each above, Sponsor may, in its sole discretion, immediately take corrective actions. These actions may include but are not limited to, temporary suspension of screening/enrollment, additional monitoring visits, consideration of site audit, and possible termination of site participation in the Study.

OR

A-2. **Case Report Form ("CRF")**: In the event an EDC system is not used for Data reporting, Institution and/or Principal Investigator agrees to provide Sponsor periodically and in a timely manner during the term of this Agreement with the Data called for in the Protocol on properly completed paper CRFs. Paper CRFs shall be submitted pursuant to the Protocol and as follows: Institution and/or Principal Investigator agrees to provide Sponsor a facsimile (fax) copy of the following CRF pages within twenty-four (24) hours of conditions for each page having been met: Front page (screening), randomization page, DNA page, and Trial Termination page. All original paper CRFs should be sent via courier to Sponsor on a visit-by-visit basis, no later than five (5) working days after visit procedures have been completed. When queries of paper CRF Data are warranted, Institution also agrees to resolve and return, via fax, each Data Correction Form ("**DCF**") within five (5) working days of DCF receipt.

B. Adverse Experience Reporting. Principal Investigator and Institution also agree to report to Licensing Authority as defined in clause(b) of Rule 21 of Drugs and Cosmetic Rules 1945 including any amendment thereof, Ethics Committee and Sponsor immediately, but not later than twenty-four (24) hours or within such other mandatory timelines as amended from time to time and specifically mentioned under Schedule Y of the Drugs and Cosmetics Rules, 1945 , after learning of any adverse events and all other important medical events, including but not limited to adverse reactions, as identified in the Protocol, affecting any Study Subject. Principal Investigator and Institution further agree to follow up such report with detailed written reports in compliance with all applicable legal and regulatory requirements.

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C. Timely Data Submissions and Query Responses. Timely, accurate and complete Data submission and query responses in accordance with this Section 6 are necessary to ensure payment in accordance with the Payment Schedule, Exhibit B of this Agreement.

D. Archiving of Study Documents. The Institution and the Principal Investigator shall be responsible for (i) archiving the "Study Documents" for at least fifteen (15) years after the completion of the Study at the study site or (ii) disposing the Study Documents at the direction and written request of the Sponsor or its designee, unless the Study Documents are otherwise required to be stored or maintained by the Institution and the Principal Investigator subject to the applicable laws and regulations. The Institution and Principal Investigator agree to retain Study Documents for such longer period as reasonably required by the Sponsor or its designee. "Study Documents" means all documents related to the Study, required to be maintained at the study site including but not limited to signed Informed Consent Forms, Case Report Forms, Protocol, information relating to the Study Drug excluding hospital patient records, provided that, subject to all applicable laws, regulations, codes and guidelines, the Institution and the Principal Investigator, if applicable, shall ensure that a copy of the relevant hospital patient records is included in the Study Documents. No Study Documents shall be destroyed in no event before or after the expiration of this time period of fifteen(15) years without giving the Sponsor or its designee thirty(30) days prior notice if an intent to do so and obtaining written approval of the Sponsor or its designee. In the event that the Institution or the Principal Investigator is unable to retain the Study Documents for the agreed period herein from the completion of the Study at the study site owing to the lack of storage space or other reasons, the Institution or the Principal Investigator shall notify the Sponsor or its designee as soon as possible, and mutually agree on alternative methods of storing the Study Documents in writing.

E. Use of the Institution Computers for EDC. In the event that the Institution is using its own computer(s) to connect to and access the EDC system, the Institution shall be responsible for supporting and promptly resolving any technical issues with the Institution's own computing environment (i.e., computer hardware, non-study related software). The Institution shall be responsible for reporting any technical issues preventing use of the EDC system, that appear to be outside the scope of its own computing environment, to the EDC helpdesk number that shall be provided by the Sponsor with the EDC system.

The Institution or the Principal Investigator shall be responsible for obtaining Internet connectivity prior to the Study initiation, and promptly resolving any connectivity issues with the internet service provider or own computing environment.

7. Monitoring of Study

A. Monitoring/Audits. During and after the term of this Agreement, the Principal Investigator and the Institution agree to permit representatives of the Sponsor, Central Drugs Standard Control Organization (hereinafter "CDSCO") and/or any other regulatory authority having jurisdiction under applicable law(s) (including but not limited to India, US Federal Drug Administration and other appropriate governmental or regulatory authorities) to examine at any reasonable time during normal business hours:

(i) the facilities where the Study is being conducted,
raw Study data including original Study Subject records, if allowed under the terms of the informed consent form and the applicable laws, and
(ii) any other relevant information necessary to confirm that the Study is being conducted in conformance with the Protocol, this Agreement and in compliance with applicable legal and regulatory requirements, including privacy and security laws and regulations.

B. Inspections. The Institution and the Principal Investigator shall immediately notify the Sponsor if representative of CDSCO and/or any other regulatory authority having jurisdiction under applicable

law(s) schedules or without scheduling begins an inspection and shall promptly, upon issuance, provide the Sponsor a copy of CDSCO's and/or any other regulatory authority having jurisdiction under applicable law(s) correspondence resulting from any such inspection.

C. Corrective Action. The Institution and the Principal Investigator agree to take all reasonable actions requested by the Sponsor to cure deficiencies noted during an audit or inspection to the Study. In addition, the Sponsor shall have the right to review and approve any correspondence to CDSCO and/or any other regulatory authority having jurisdiction under applicable law(s) generated as a result of an inspection or audit prior to submission by Institution or Principal Investigator.

D. The provisions and obligations set forth in this Section shall survive the termination or expiration of this Agreement.

8. Compliance with Applicable Laws.

A. Laws and Regulations.

(i) Principal Investigator and Institution agree to conduct the Study and maintain records and Data during and after the term of this Agreement in compliance with the Protocol, DCGI and EC approval and all applicable legal and regulatory requirements, including without limitation, any applicable requirements of the applicable health authorities and relevant laws and regulations in the country.

(ii) Institution and the Principal Investigator agree to conduct the Study and maintain records and data during and after the term of this Agreement in compliance with all applicable Laws, Rules and Regulations, including without limitation the Schedule Y to Drugs & Cosmetic Rules 1945 including any amendment(s) thereof, Drugs & Cosmetics Act 1940 including any amendment(s) thereof Guidelines of Indian Council for Medical Research, Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002, Indian Good Clinical Practice of the Central Drugs Standards Control Organization, ICH Guidance for Good Clinical Practice, as well as with generally accepted conventions such as the Declaration of Helsinki and the ICH-GCP guidelines.

(iii) Parties agree that the collection, processing and disclosure of personal data and medical information related to the Study Subjects and personal data related to Principal Investigator and any investigational staff (e.g., name, hospital or clinic address and phone number, curriculum vitae) is subject to compliance with applicable personal data protection, privacy and security laws and regulations of India, USA and EU. When collecting and processing personal data, the parties agree to take appropriate measures to safeguard these data, to maintain the confidentiality of Study Subjects and their related health and medical information and to properly inform the concerned Study Subjects about the collection and processing of their personal data, to grant Study Subjects reasonable access to their personal data and to prevent access by unauthorized persons. Personal data related to Principal Investigator and any investigational staff (e.g., name, hospital or clinic address and phone number, curriculum vitae) may be transferred to other Johnson & Johnson's affiliates dedicated to clinical research with the purposes of drug monitoring, implementation, documentation and control of clinical trials, as well as for contacting them and their respective agencies around the world in case of other future studies or investigations in which they may be involved. The parties also agree that the Sponsor can use personal data provided by the Principal Investigator and/or Institution for managing internal studies and ensuring that their contact information is contained in a faithful and complete way in other systems used by the Sponsor and its affiliates, in compliance with this Section.

(iv) The Sponsor may transmit personal data to other affiliates of the Sponsor and their

ATTESTED
Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore 575 018

respective agents worldwide only for the limited purpose of and in relation to the Study. Accordingly, personal data may be transmitted to countries outside India, such as to the United States and EU, subject to providing an adequate level of privacy protection in terms of applicable privacy laws of those countries. Nonetheless, Sponsor and its affiliates of the Sponsor and respective agents will apply adequate privacy safeguards to protect such personal data. Personal data may also be disclosed, as required by individual regulatory agencies or applicable law, such as to report serious adverse events. Institution and Principal Investigator agree to inform their investigational staff that their personal data will be collected as stated in (iii).

(v) Protection of the data. The Sponsor shall, with respect to the information contained in the data (i) not use or further disclose the information other than as permitted or required by this Agreement or as otherwise required by law; (ii) use appropriate safeguards to prevent use or disclosure of the information other than as provided for by this Agreement; (iii) report to Principal Investigator and Institution any use or disclosure of the information not provided for by this Agreement of which it becomes aware; (iv) ensure that any agent or assignee, including a subcontractor, to whom it provides the information agrees to the same restrictions and conditions that apply to the Sponsor with respect to the data and (v) not identify the information or contact of the individuals to whom it pertains.

B. Labour Legislations. The Institution shall comply with all applicable labour legislations and other applicable laws and undertakes to make all statutory payments on time, including but not limited to minimum wages, ESI, PF, bonus, gratuity and other benefits, as may be due. Further, the Institution undertakes to maintain all the statutory records for its personnel and the Institution will be responsible or liable for non-compliance of these obligations by the Institution. In the event the Institution engages personnel of any vendors to provide the services under this Agreement, then the Institution shall be responsible for and shall ensure that vendors and their employees or persons engaged by them comply with all applicable labour legislations. Notwithstanding anything contained in this Agreement, the Sponsor shall not be responsible for any claims that may arise with regard to payment of statutory dues by the Institution.

C. Privacy Laws.

(i) Principal Investigator Notice. The Institution and the Principal Investigator shall inform any personnel performing services under this Agreement, in case that the Sponsor collect the following personal information: name, hospital or clinic address and phone number, and curriculum vitae, and may transfer this information to the Sponsor's affiliates and their respective agents worldwide for internal study management purposes and obtain the consent in compliance with applicable laws and regulations in this regard. Nonetheless, the Sponsor and its affiliates and agents will apply adequate privacy safeguards to protect such information. The Sponsor, its affiliates, its agents and business partners may also use and disclose personal information as required by individual regulatory agencies or applicable law, such as to report serious adverse events. Upon written request, the Sponsor will provide any individual performing services under this Agreement with reasonable access to his or her information that is held by the Sponsor. Such individual may also request correction of information that he or she demonstrates to be inaccurate or incomplete. Institution and Principal Investigator shall be responsible for obtaining consent from personnel for the collection and use of their personal information as described herein

(ii) The Principal Investigator and the Institution shall ensure that the Sponsor may add Data collected under the Protocol to its research databases so that it, and/or its development partner(s) with regard to the Study Drug, may conduct additional reviews of the Data in order to study the safety and effectiveness of the Study Drug and other products and treatments, to develop a better understanding of disease, or to improve the efficiency of future clinical

trials (collectively referred to as "further research uses"). The Principal Investigator and the Institution shall obtain an informed consent form signed by each Study Subject in the Study that addresses such further research uses.

D. Anti-Corruption Laws.

(i) Institution represents and warrants that neither the Institution, nor any of its affiliates, nor any of their respective directors, officers, employees, agents and Principal Investigator (all of the foregoing, including affiliates collectively, "Institution Representatives") has taken any action that would result in a violation by such persons of local or international anti-bribery laws, rules or regulations applicable to either or both the Institution and Sponsor (collectively the "Anti-Corruption Laws").

(ii) Institution shall not, directly or indirectly, make any payment, or offer or transfer anything of value, or agree or promise to make any payment or offer or transfer anything of value, to a government official or government employee, to any political party or any candidate for political office or to any other third party with the purpose of influencing decisions related to the Sponsor and/or its business in a manner that would violate Anti-Corruption Laws.

(iii) Institution and Institution's Representatives have conducted and will conduct their businesses in compliance with the Anti-Corruption Laws, and Institution will have necessary procedures in place to prevent bribery and corrupt conduct by Institution Representatives, which includes anti-corruption training.

(iv) Institution shall maintain effective internal accounting control and shall make sure all aspects of this Study are recorded in its books and records in an accurate, complete and truthful way and that the documents on which such books and records are based are in all major aspects accurate, complete and true. Institution shall maintain and provide Sponsor and its auditors and other representatives with access to records (financial and otherwise) and supporting documentation related to the subject matter of the Agreement as may be requested by Sponsor in order to document or verify compliance with the provisions of this section; and

(v) Notwithstanding section 2.B Termination and section 9 Indemnification, if Institution fails to comply with any of the provisions of this section, such failure shall be deemed to be a material breach of the Agreement and, upon any such failure, Sponsor shall have the right to terminate the Agreement with immediate effect upon written notice to Institution without Sponsor having any financial liability or other liability of any nature whatsoever resulting from any such termination.

E. Noncompliance. In the event that any part of this Agreement is determined to violate local laws, rules, or regulations, the Parties agree to negotiate in good faith revisions to the provision or provisions that are in violation. In the event the Parties are unable to agree to new or modified terms as required to bring the entire Agreement into compliance, any Party may terminate this Agreement on sixty (60) days written notice to the other Parties.

F. No Participation of Excluded/ Debarred Persons in Performance of this Agreement. The Institution and the Principal Investigator shall not employ, contract with or retain any person directly or indirectly to perform services under this Agreement if such a person

a. is debarred by a competent health authority or
b. has been sentenced for malpractice related to the conduct of clinical trials.

Upon written request from the Sponsor, the Institution and/or the Principal Investigator shall, within ten (10) days, provide written confirmation that it has complied with the foregoing obligation. This shall be an ongoing representation and warranty during the term of this Agreement and Institution shall immediately notify Sponsor of any change in the status of the representation and warranty set forth in this Section.

In the event that the Institution or the Principal Investigator becomes aware that any person identified above becomes excluded or debarred or receives notice of the threat of an action with respect to such exclusion or debarment, the Institution and the Principal Investigator shall promptly provide the Sponsor with written notice. Upon receipt of such notice, Sponsor shall have the right to terminate this Agreement immediately in accordance with Section 2.B.

G. Employment of Young Persons: The Institution shall comply with the Sponsor's Policy on Employment of Young Persons as set out in Exhibit C.

H. Conflict of Interest: The Institution and the Principal Investigator agree and undertake that they shall observe and abide by the Sponsor's Business Conduct Policy relating to Conflict of Interest, copy of which is hereto attached as Exhibit D.

I. Representations and Warranties: Conflict of Interest Obligations.

(i) Where the performance of the Study under this Agreement is subject to professional and/or employment rules (such as conflicts of interest or ethics policies) established by the Institution or a professional organization or other institution with which the Principal Investigator or other investigator(s) are affiliated, Institution shall cause the Principal Investigator and other investigator(s) to warrant that he or she shall comply fully with such rules, including, as applicable, obtaining any required approval(s) prior to initiating the Study and making any required reports. Further, the Institution and the Principal Investigator have received no offer by the Sponsor or its affiliates or agents of extra benefit for participation in the Study, including offers to family members. The Institution will promptly notify the Sponsor if any conflict of interest arises during the term of this Agreement. Neither Institution nor any investigator performing services under this Agreement shall enter into a financial security transaction based on Data or results. The Institution warrants that it has policies and procedures with respect to conflicts of interest and will promptly report to the Sponsor any such conflicts relating to the Principal Investigator or any other investigator(s) duties under this Agreement.

(ii) The Institution and Principal Investigator shall also provide all information to the Sponsor necessary to comply with any disclosure requirements mandated by any competent health authority (including, if applicable, the US FDA), relevant trade association or similar body, or other applicable national or local laws, including any information required to be disclosed in connection with any financial relationship between the Sponsor and the Principal Investigator and any other Investigator involved in the Study and any other agent or employee of the Institution and the Sponsor. This disclosure requirement may require disclosure of information involving immediate family members of those involved in the Study.

(iii) The Institution and the Principal Investigator represent and warrant that it is under no agreement or obligation to any third party and has no material conflict of interest that would prevent it from performing its duties and obligations under this Agreement.

(iv) Principal Investigator's Representations and Warranties:

a. The execution, delivery, and performance of this Agreement by the Principal Investigator shall not conflict with, breach, cause a default under, or result in the termination of any contract, employment relationship, grant or funding, agreement

or understanding, oral or written, with any third party, including without limitation any noncompetition covenant to which the Principal Investigator is a party or by which the Principal Investigator is bound. The Principal Investigator further represents and warrants that neither he/she nor Institution personnel involved in the conduct of the Study have any obligation, whether express or implied, to any third party that would interfere with, hamper or limit its ability to provide the services or to comply with any other obligations under this Agreement.

b. If the Principal Investigator is a government employee, he/she shall comply with applicable government ethics rules and has secured any necessary approval of an appropriate ethics officer, legal authority and, as necessary, supervisor, to enter into this Agreement.

c. If the Principal Investigator is a member of a pharmacy and therapeutics committee ("P&T Committee") of a health plan, pharmacy benefit manager or other health care provider or payor, whether public or private, he/she represents and warrants compliance with applicable ethics rules of his/her P&T Committee, including standards for conflict of interest, disclosure and recusal, and that he/she has secured any necessary approval of an appropriate ethics officer to enter into this Agreement.

J. Professional/Employment Rules. Where the provision of the services pursuant to this Agreement by Institution and Principal Investigator are subject to professional and/or employment rules requiring approval, the Institution and the Principal Investigator warrant that they shall obtain such approval, prior to performing the Study under this Agreement. Institution and Principal Investigator shall provide, without delay, written evidence of the relevant approval(s).

K. Institution and the Principal Investigator shall carry out their obligations under this Agreement in a professional and ethical manner consistent with the standards of practice existing within the community; the standards, rules and regulations of applicable accrediting organizations; and all applicable laws and regulations of the Central, State and local Governments, including, but not limited to Johnson & Johnson's Employment of Young Persons Policy and Healthcare Compliance Business Integrity guide as informed and explained to the Institution and Principal Investigator by the Sponsor.

L. If the Institution fails to comply with any of the provisions of any clauses within this section of the Agreement (irrespective of the size, nature or materiality of such violation), such failure shall be deemed to be a material breach of this Agreement and, upon any such failure, the Sponsor shall have the right to terminate this Agreement with immediate effect upon written notice to Institution, without penalty or liability of any nature whatsoever.

9. Indemnification.

A. The Sponsor shall indemnify, defend, and hold harmless Institution, its trustees, officers, agents and employees (including the Principal Investigator and co-investigators) ("Indemnitees") from any and all direct losses, costs, expenses, liabilities, claims, actions and damages based on a personal injury to a subject directly caused by use of the Study Drug during the course of the Study.

B. The above obligation of the Sponsor, as stated in Section 9.A, shall not apply and the Sponsor shall not be liable for any indemnification or expenses, and in fact, the Institution and Principal Investigator shall defend, indemnify and hold harmless the Sponsor, for actions or claims in any way arising from or caused by the willful, reckless, or negligent acts or omissions, or professional malpractice of the Indemnitees, or arising from or caused by any of their failures to comply with the Protocol, with

Sponsor's written recommendations and instructions related to the use of the Study Drug, or with the Drugs & Cosmetics Act 1940 including any amendment(s) thereof or any other applicable legal and regulatory requirements in this regard.

C. The obligation of the Sponsor hereunder shall apply only if the Indemnitees provides prompt notification upon receipt of notice of any claim or suit, permits the Sponsor and its attorneys and personnel to handle and control the defense of such claims or suits, including pretrial, trial or settlement, and the Indemnitees fully cooperates and assists in such defense. The Indemnitees further agrees that it will not settle or compromise any such claim or suit without the prior written consent of the Sponsor.

10. Insurance.

A. The Institution and the Principal Investigator shall secure and maintain in full force and effect through the performance of the Study (and following termination of the Study to cover any claims arising from the Study) insurance coverage for: (i) general liability; and (ii) workmen's compensation, each such insurance coverage in amounts appropriate to the conduct of Institution's and Principal Investigator's business activities and the services contemplated by the Study and in compliance with minimum amounts of insurance required by applicable laws or regulations. The failure of any Party to secure appropriate coverage shall in no way limit the respective liability of that Party. For any avoidance of doubt, Institution and Principal Investigator warrant that they have sufficient financial resources to cover all liability associated with their obligations under this Agreement

B. The Sponsor shall secure and maintain in full force and effect through the performance of the Study (and following termination of the Study to cover any claims arising from the Study) insurance coverage required for clinical trials or as otherwise required by applicable law in amounts appropriate to the conduct of Sponsor's business activities and in compliance with the applicable legal and regulatory requirements.

C. Upon request, each Party shall provide the other Party with certificates of insurance evidencing the required insurance coverage.

11. Payment.

A. Budget and Compensation. The compensation and fees to be paid by the Sponsor for the Study is contained in the budget described in Exhibit B, attached hereto and incorporated by reference in this Agreement. Payment shall be due and payable in accordance with the schedule set forth in Exhibit B.

B. Fair Market Value. The Parties acknowledge and agree that the compensation and support provided by the Sponsor to the Institution pursuant to this Agreement represents the fair market value for the research services conducted by the Institution and the Principal Investigator, has been negotiated in an arms-length transaction, and has not been determined in a manner that takes into account the volume or value of any referrals or other business otherwise generated between the Sponsor and the Institution or the Principal Investigator.

C. Meetings related to the Study. The Sponsor may recommend or obligate the Principal Investigator and/or any other investigators and/or other personnel of the Institution engaged in the Study to attend meetings held by the Sponsor, including but not limited to an Investigator's Meeting. The Sponsor shall provide and pay all reasonable and appropriate travel expenses, including modest lodging and meals associated with such meetings in compliance with the relevant policies or regulations of the Sponsor. The Parties agree that attending such meetings is reasonable and necessary to ensure all parties engaged in the Study have a clear understanding of the Protocol and its requirements.

D. Third Party Payor Billing. Neither the Institution nor the Principal Investigator shall bill any third party for the Study Drug or any other items or services furnished by the Sponsor in connection with the Study, or any services provided to subjects in connection with the Study for which payment is made as part of the Study except as may be specifically authorized by compensation standards set forth in Exhibit B.

E. No part of any consideration paid hereunder is a prohibited payment for the recommending or arranging for the referral of business or the ordering of items or services; nor are the payments intended to induce illegal referrals of business. Nothing contained in this Agreement shall be construed in any manner as an obligation or inducement for the Institution or Principal Investigator to recommend that any person or entity purchase Sponsor's products or those of any entity affiliated with Sponsor.

12. Independent Contractor.

The Institution and the Principal Investigator are acting in the capacity of independent contractors hereunder and not as employees or agents of the Sponsor. Neither Institution nor Principal Investigator shall make any claim against the Sponsor for compensation, vacation pay, sick leave, retirement benefits, social security benefits, workers' compensation, disability or unemployment benefits or employee benefits of any kind.

The Institution and the Principal Investigator shall conduct the Study as independent contractors and not as partners of Sponsor and shall not be nor hold them out to be agents of Sponsor and shall have no power to bind Sponsor.

The Principal Investigator or any other investigational staff on the Study shall not be considered, under the provisions of this Agreement or otherwise, as having an employee status with the Sponsor and the Sponsor shall not be obligated to pay or withhold any income, social security contributions, unemployment or other employee tax for amounts payable to Institution.

The parties have entered into this agreement on the understanding that the Study shall involve the personal direction and effort of the Principal Investigator. Consequently, it is agreed that the work may not be assigned or delegated to any third party without the prior written approval of the Sponsor.

13. Publicity. Institution and Principal Investigator shall not use the name of Sponsor, for promotional purposes without the prior written consent of the Party whose name is proposed to be used except as required by law.

14. Dispute Resolution and Controlling Law. In the event of any dispute arising between the Parties in relation to the terms of this Agreement, the Parties shall use their best endeavors to resolve the matter on an amicable basis. This Agreement shall be governed by and construed in accordance with the laws of India without regard to any conflicts of law provisions. In the event of any dispute arising between the Parties in relation to the terms of this Agreement, the Parties shall use their best endeavors to resolve the matter on amicable basis. The Parties consent to the exclusive jurisdiction of the courts of competent jurisdiction in Mumbai for the resolution of all disputes or controversies between the Parties hereto that Parties are unable to settle amicably.

15. Notice. Any notices given hereunder shall be deposited in the, postage prepaid, personally delivered or recognized courier service, as follows:

TO: Head, Global Clinical Operations (India)
Johnson & Johnson Private Limited
Arena Space, Behind Majas Bus Depot,

Off Jogeshwari Vikhroli Link Road Jogeshwari (E),
Mumbai 400 060, India

TO: Dr. Gangadhar Somayji (Registrar), Yenepoya (Deemed to be University), Yenepoya Medical College- constituent unit of Yenepoya (Deemed to be University), University Road, Department of Dermatology, Deralakatte, Mangalore, Karnataka – 575018, India

TO: Dr. Manjunath Shenoy (Principal Investigator), Yenepoya (Deemed to be University), Yenepoya Medical College- constituent unit of Yenepoya (Deemed to be University), University Road, Department of Dermatology, Deralakatte, Mangalore, Karnataka – 575018, India

16. Force Majeure. If the performance of this Agreement by the Parties is prevented, restricted, interfered with or delayed, (either totally or in part) by reason of any cause beyond the reasonable control of the Parties (such as acts of God, explosion, disease, weather, war, terrorism, insurrection, civil strike, riots or power failure), the Party so affected shall, upon giving written notice to the other Party, be excused from such performance to the extent of such prevention, restriction, interference or delay, provided that the affected Party shall use its reasonable best efforts to avoid or remove such causes of non-performance and shall continue performance with the utmost dispatch whenever such causes are removed. For purposes of this section, a lack of funds shall not be considered a cause beyond the reasonable control of the Parties.

17. Position of Influence. If permitted by local laws, regulations and Institution's contractual obligations, Institution shall notify the Sponsor if the Institution or any of the directors or partners or employees of the Institution attain a position to influence purchasing decisions of a government entity or health care related institution, owned or substantially controlled by a government or public body. Such purchasing decisions may relate, for instance, to tenders issued by health authorities or decisions of formulary committee of public hospitals. In case of such notification by Institution, the Sponsor has the right to terminate this Agreement with immediate effect by written notice. Where such notification to the Sponsor is not permitted by local laws, regulations or Institution's contractual obligations, Institution shall notify the purchase decision-maker in said government entity, institution or hospital of Institution's financial relationship with the Sponsor before any purchasing decision is made.

18. Agreement Modifications. This Agreement, or any of its exhibits, may not be altered, amended or modified except by written document signed by all Parties hereto.

19. Assignment. The Sponsor shall have the right to assign this Agreement and shall use reasonable efforts to provide written notice thereof to the Principal Investigator and the Institution. Neither Institution nor Principal Investigator shall assign its rights or duties under this Agreement without the prior written consent of the Sponsor. Subject to the foregoing, this Agreement shall bind and inure to the benefit of the respective Parties and, subject to the foregoing limitation on assignment, their successors and assigns.

20. Conflict with Protocol. If a provisions of this Agreement conflicts with a provision of the Protocol, the Protocol takes precedence on matters of medicine, science and conduct of the Study. This Agreement takes precedence in any and all other conflicts.

21. Waiver and Severability. No waiver by any Party of any breach of any provision hereof shall constitute a waiver of any other breach of that or of any other provision hereof. In the event that a court of competent jurisdiction holds any provision of this Agreement to be invalid, such holding shall have no effect on the remaining provisions of this Agreement, and they shall continue in full force and effect.

22. Survival. The following provisions and any other term or condition which by its nature is clearly intended

to survive the termination or expiration of this Agreement will survive the termination or expiration of this Agreement: 1G, 2D, 4, 5, 6, 7, 8, 9, 10, 13, 14, 19, 22, 23, 24 and 26.

23. Warranty. The Institution and the Principal Investigator understand and agree that the Sponsor makes no warranty, either expressed or implied, regarding the use of the product in the Study. Without limiting the foregoing, the Sponsor expressly disclaims any implied warranties of merchantability or fitness for a particular purpose.

24. Disclosure of Compensation. The Parties acknowledge and accept that certain countries require pharmaceutical companies to disclose information on compensation, gifts or other remuneration provided to physicians and other health care professionals if such disclosure is required by applicable local law or government authorities. In case of such request the Parties shall give each other a written notice as soon as possible. The Sponsor may report as required by law, or may voluntarily disclose or make public, information about remuneration provided under this Agreement.

25. Headings. Headings used in this Agreement are for the purpose of convenience only and do not affect the interpretation or construction of the Agreement itself.

26. Entire Agreement. It is the mutual desire and intent of the Parties to provide certainty as to their respective future rights and remedies against each other by defining the extent of their mutual undertakings as provided herein. Accordingly, this Agreement (i) supersedes all previous understandings, agreements and representations between the Parties, written or oral and (ii) constitutes the entire agreement and understanding between the Parties with respect to the subject matter thereof and incorporates all representations, warranties, covenants, commitments and understandings on which they have relied in entering into this Agreement, and, except as provided for herein, neither Party makes any covenant or other commitment concerning its future action nor does any Party make any promises, representations, conditions, provisions or terms related thereto.

27. Authorized Representatives. Each signatory to this Agreement personally represents that, he/she has authority to legally bind his/her respective Party to this Agreement.

28. Counterparts. This Agreement may be executed in counterparts, each of which shall be an original and all such counterparts together shall constitute the entire Agreement.

[Signatures follow on the next page.]

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives.

Johnson & Johnson Private Limited

Signature_____ Date and Stamp 2/Aug/2019.
Dr. Murtuza Bughediwala
(Head, Global Clinical Operations, India)

Yenepoya (Deemed to be University)

Signature_____ Date and Stamp 16/8/19
Dr. Gangadhar Somayji
Registrar

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore 575 018

Dr. Manjunath Shenoy

Signature_____ Date and Stamp 16 AUG 2019.
Principal Investigator

Dr. Manjunath Shenoy M.
Reg. No.35098
Prof. & HOD, Dermatology
Yenepoya Medical College

Attachments:
Exhibit A: Protocol, and all subsequent amendments by reference
Exhibit B: Budget and Payment Schedule
Exhibit C: J & J's Policy on Employment of Young Persons
Exhibit D: Code of Conduct-Conflict of Interest
Exhibit E: Statement issued by Institution

ATTESTED
Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore 575 018

Exhibit A

Protocol and all subsequent amendments by reference only; (page intentionally left blank).

ATTESTED
Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

Exhibit B

Budget & Payment Schedule
Protocol No. R051211FUN4058 "Itraconazole in the Management of Superficial Fungal Infections in India. A Pilot Study"

(1) The **"Per-Subject Fee"** represents all fixed and variable costs associated with the Study, excluding those items specified in Section 3 (Site Costs) and Section 4 (Other Compensation) below, provided that all visits described in Section 2 are completed. The Per-Subject Fee for this Study is: **Rs 45,300 (Inclusive of Institutional overhead as applicable)**

(2) **Payment Milestone Table(s):**
Milestone payments in the below table(s) represent fair market value for performance of research services detailed in the Time and Events Schedule of the Protocol provided herein by reference in Exhibit A. Parties agree in the event subsequent protocol amendments result in a material change to the research services, compensation will be adjusted to reflect the new fair market value of the research services through a written amendment signed by all parties hereto.

MILESTONES	Visit Amount (Rs)	30 % Institutional overhead (Rs)	Subject Stipend (Rs)	Total Visit Amount (Rs)
Screening	15,000	4500	800	20,300
Day 7	10,000	3000	800	13,800
Day 14	8,000	2400	800	11,200
Per-Subject Fee	33,000	9900	2,400	45,300

Subject Stipends: The subject stipend is intended to offset the Study subject's costs associated with travel expenses and meals, where appropriate, incurred as a result of Study participation, and shall be reflected in the Informed Consent Form, as it will be provided to the Study subject.

(3) **Site Costs**

- **Local Ethics Committee/Institutional Review Board (EC/IRB) Fees**: EC/IRB fees shall be reimbursed. Processing of payment will begin upon receipt of original invoice or alternative supporting documentation, detailing actual charges without markup. SPONSOR WILL NOT PAY LOCAL IRB DIRECTLY.

- **Screen Failure Payments:**
Sponsor shall reimburse Institution for screen failures at a rate listed for Screening in the milestone table in Section 2 above per screen failure. Rescreen Visits line as defined below will be paid at the visit cost specified in the line item. Screen fails will be paid with a cap of 5 Screen failure payments per site. Processing of payment shall begin upon receipt of invoice detailing subject number and date of screen failure and in accordance with Section 5 below and upon approval by the Local Trial Manager. As the study progresses, Sponsor may increase the screen fail cap beyond the original 5 subjects. Institution will be notified in writing if an increased cap is approved.

- **Rescreening Visit:**
  Individuals who do not meet the criteria for participation in this study may be rescreened in accordance with the Protocol. Sponsor shall reimburse **Rs 14,000** for the rescreening visit and **Rs 1,400** for reconsenting as required per the protocol. These costs are not included in the per subject fee. Reimbursement will be provided upon receipt of invoice and supporting documentation in accordance with Section 5 below and approval of the Local Trial Manager.

- For screen failures beyond the defined maximum number, which are not reimbursable to Institution, a subject stipend for the Study subjects in the amount of **Rs 800** will be paid to offset the Study subject's costs associated with travel expenses and meals, where appropriate, incurred as a result of Study participation, and shall be reflected in the Informed Consent Form, as it will be provided to the Study subject. Processing of payment shall begin upon receipt of invoice detailing subject number and date of screen failure and in accordance with Section 5 below and upon approval by the Local Trial Manager.

- **Start-up Payment**: A non-refundable payment of Rs 25,000 for start-up related activities (e.g. preparation of regulatory documents, administration and submission of protocol and related documents to the Institutional Review Board (IRB), etc. will be made upon execution of the Clinical Trial Agreement. This payment is considered full and final compensation for all activities associated with study initiation.

- **Archiving Cost (Record Retention, Document Storage):**
  Sponsor will pay the Institution onetime cost of Rs 10,000 upon completion of the Study for Record Retention/ Document Storage Fee as mentioned in the Clinical Trial Agreement, upon the receipt of an invoice from Institution and approval of the Local Trial Manager.

(4) **Other Compensation**:

- Processing of payment for Other Compensation will begin upon receipt of invoice in accordance with Section 5 below and approval by the Local Trial Manager. Each cost listed in the table below (Inclusive of Institutional overhead as applicable) is a per item cost unless otherwise specified in the Additional Information column.

  Note: Any claims for reimbursement of adverse events must be submitted in a separate invoice.

Item	Additional Information	Amount (Rs)	30 % Institutional overhead (Rs)	Subject Stipend (Rs)	Total Amount (Rs)
Re-Consenting of a Subject at a regularly scheduled study	Sponsor pre-approved	**1,400**	**420**	**N/A**	**1,820**
Re-Consenting of a Subject outside a regularly scheduled study visit	Sponsor pre-approved	**3,300**	**990**	**800**	**5,090**
Repeat Pregnancy Test	As required per local standard or at the discretion of the investigator. May not be invoiced in conjunction with Rescreening	**1,300**	**390**	**N/A**	**1,690**

Item	Additional Information	Amount (Rs)	30 % Institutional overhead (Rs)	Subject Stipend (Rs)	Total Amount (Rs)
	Visit				
Sample Collection and Preparation/ Shipment to Central Lab (Plasma Drug Level) per sample	1. Repeat for safety reasons or technical issues with samples. 2. Open-label observation, Day 14: For subjects continuing to receive intraconazole at the discretion of the investigator.	**900**	**270**	**N/A**	**1170**
Unscheduled Visit	Visit cost to be invoiced in conjunction with the repeat pregnancy test and/or the sample collection above when conducted outside of a regularly scheduled visit. This fee covers the cost of personnel time.	**2,600**	**780**	**800**	**4,180**
Concomitant Therapy Collection and Treatment Compliance	End of Study, Day 14: For subjects continuing to receive intraconazole at the discretion of the investigator.	**900**	**270**	**N/A**	**1170**
Lost to Follow up Contact	Subject lost to follow up: contact to determine the reason for discontinuation/ withdrawal. A maximum of 3 attempts will be reimbursed.	**700**	**210**	**N/A**	**910**

N/A=not applicable

Subject Stipends: The subject stipend is intended to offset the Study subject's costs associated with travel expenses and meals, where appropriate, incurred as a result of Study participation, and shall be reflected in the Informed Consent Form, as it will be provided to the Study subject.

(5) **Payment Terms:**

a) This EXHIBIT B is for completed records for up to **12** valid subjects. A valid subject is defined as a subject who meets eligibility requirements to enroll in the Study and does not have significant Protocol violations that would exclude his/her Data from analysis. This Study is being conducted under a policy of competitive enrollment. Sponsor anticipates closure of enrollment upon enrollment of a total of 50 valid subjects. In the event 50 total valid subjects are enrolled prior to a site's reaching its valid subject goal of **12** , further recruitment will be suspended. Subjects not completing the trial will be paid for on a prorated basis according to confirmed completed visits and CRFs received by Sponsor. All payments will be made for subject visits according to the milestone table in Section 2 above. No payment will be made for any subject excluded from analysis because of Protocol violations within the Study

personnel's control. Reimbursement for expenses related to screen failures will be made as outlined in Section 3 above.

b) Institution acknowledges this is a multicenter Study designed to evaluate a defined number of Study subjects. It is anticipated each institution participating in the Study will enroll the number of Study subjects provided for under their agreement for this Study. If required as the Study progresses, Sponsor may invite an institution to enroll more Study subjects than reflected in the original agreement. In such a circumstance, Sponsor may notify Institution via written request to allow for the enrollment of additional Study subjects. Conversely, Institution may not have the opportunity to enroll the number of Study subjects set forth above. When enrollment of the target number of Study subjects in the Study is complete, those sites that have not enrolled the contracted number of Study subjects will be notified and instructed to discontinue enrolling Study subjects.

c) Equipment Calibration: Institution shall be responsible for ensuring Institution-owned equipment utilized by Institution in accordance with this Agreement, is serviced and/or calibrated as per manufacturer's recommendation or more frequently as required by Sponsor. Records verifying the equipment calibration and maintenance shall be provided to Sponsor upon request. For calibrations that are performed solely at the request of Sponsor, and that are not part of the recommended scheduled maintenance suggested by manufacturer, Sponsor will reimburse Institution for the actual cost without mark-up for each calibration. Processing of payment will begin upon receipt of invoice and supporting documentation in accordance with paragraph (d) below.

d) To be eligible for any payment, the procedures must be performed in full compliance with the Protocol and this Agreement, and Data submitted must be complete, correct and entered into the Electronic Data Capture (EDC)in accordance with Sponsor's instructions and this Agreement. Payments will be made, at a minimum in 90 days once the corrected invoices are received.These payments will include milestone payments, as well as, all invoiced and approved costs from the prior payment cycle. Ongoing reconciliations will be performed during the course of the Study. Any payments made in error will be applied to any pending or future payments due. No payments will be made until all erroneous payments have been offset. If no pending or future payments exist, Institution will promptly refund overpayment, according to Sponsor's instructions.

Original invoices pertaining to this study should be submitted for reimbursement to the following address:

TO: **Local Trial Manager**
Johnson & Johnson Private Limited
Arena Space, Behind Majas Bus Depot,
Off Jogeshwari Vikhroli Link Road Jogeshwari (E),
Mumbai 400 060, India

AND

A copy of the invoice, together with the supporting documentation, should be emailed to **JNJINDIA-GCOPayments@its.jnj.com** and failure to do so, might delay the payment process.

Please note that invoices must contain the following information or they will be returned, delaying payment:

- Institution name
- Principal Investigator name

- Protocol number
- Invoice number and date
- Date & description of services provided
- Supporting documentation (i.e. third party invoices, receipts)
- Any claims for reimbursement of adverse events must be submitted in a separate invoice
- Site Purchase Order (PO) number
- JNJ GST Number - 27AAACJ0866E1ZR
- PAN (permanent account number)
- Site (micro, small and medium enterprises) MSME number (If applicable)
- Site GST number (if applicable)
- HSN/SAC (Harmonized System of Nomenclature/ Service Account Code)

e) This agreement reflects all fixed and variable costs related to Study activities. Items not specifically referenced in Section 3 or Section 4 above, which might include, for example, staff costs, training costs, laboratory fees, x-rays, scales and questionnaires, data coordinator fees and travel fees, are reflected in the Per-Subject Fee as detailed in the milestone tables in Section 2 above. No additional reimbursement for these costs is otherwise provided.

f) For the avoidance of doubt, the Principal Investigator and/or the Institution are responsible for providing any and all compensation, benefits and/or insurance to the investigational staff. It is also understood and expressly acknowledged that the Investigator and the investigational staff are not eligible to participate in, nor are they eligible for coverage under, any of the Sponsor's benefit plans, programs, employment policies, procedures or workers compensation insurance.

g) The parties agree this EXHIBIT B is part of the Agreement and clarifies the payment schedule associated with this Agreement. Payments shall be made in accordance with the provisions set forth in this EXHIBIT B, with the last payment being made after the site completes all of its obligations under the Agreement and any exhibits thereto. The Principal Investigator acknowledges and agrees his or her judgment with respect to his or her advice to and care of each subject is not affected by the compensation the site receives hereunder. The parties agree the payee designated below is the proper payee for this Agreement and payments under this Agreement will be made only to the following payee:

PAYEE NAME: *(This should be a business name and must match the business name used to file for your tax EIN or other tax ID number)*	YENEPOYA UNIVERSITY
TAX ID NUMBER: *(Tax ID must exactly match the payee name indicated above)*	GST: 29AAATY1645F1ZC PAN: AAATY1645F
CONTACT INFORMATION: *(Name, phone number, e-mail address)*	Dr. Gangadhar Somayji
	Contact no: 08242206000 Ext 5004
	Email ID: Registrar@Yenepoya.edu.in

PAYEE ADDRESS:	Yenepoya (Deemed to be University), Yenepoya Medical College- constituent unit of Yenepoya (Deemed to be University), University Road Department of Dermatology, Deralakatte, Mangalore, Karnataka – 575018, India

Institution will have thirty (30) days from the Last Subject Out (LSO) date of the Study to resolve any payment discrepancies, which have arisen during the course of the Study.

PART- 2 TAXES

1. Notwithstanding anything contained in the Agreement, the Institution agrees that it is eligible to receive part of the consideration being the Goods and Services Tax(GST) charged in respect of the supply only after the details of such supply are uploaded by the Institution in the Form GSTR-1(or such other form as may be notified in lieu thereof from time to time), which is subsequently reflected in Form GSTR-2A(or such other form as may be notified in lieu thereof from time to time), made available electronically to the Sponsor, and are considered as matched with the corresponding details furnished by the Sponsor in its returns, in terms of the relevant provisions of the GST laws.

2. The Institution agrees to indemnify the Sponsor and keep it indemnified from and against any or all Liabilities, as defined in Explanation below, that may accrue or be demanded by a Taxing Authority, in respect of or in connection with the execution of scope of work or payments made/due to the Institution, arising under the said Agreement or anything done pursuant to the same. Any such compensation towards indemnification of Liabilities by the Institution to the Sponsor will be made within 15 days of the Liabilities accruing / demanded raised by Tax Authorities on the Sponsor either by way of issuance of demand or show cause notice or order or decree.

   Explanation –

   i. 'Liabilities' in this Agreement means, "any kind of taxes / duties, disallowance of input tax credit, loss, damage, legal expenses, demands, claims, costs, interest, penalties including in relation to compliances arising under respective Taxing Statute in course of execution of scope of work"

   ii. 'Liabilities accruing / demanded' in this Agreement means, "any Liabilities proposed to be imposed either during investigation or audit or by way of issuance of show cause notice or demanded by way of issuance of order or decree by Taxing Authority."

3. The Institution undertakes to be compliant with the anti-profiteering provision under Section 171 of the Central Goods and Services Act, 2017.

4. Other terms:
   (a) The consideration payable under this Agreement shall be exclusive of applicable Goods and Services Tax (GST) including but not limited to CGST and SGST/UTGST or IGST, and/or applicable cess, as the case may be.
   (b) The Institution shall periodically pay its tax liabilities in compliance with the GST Laws in connection with the goods / services supplied under this Agreement, such that the Sponsor is entitled to claim such credit of input tax with respect to the goods/services supplied under this Agreement as permitted under the GST Laws.
   (c) The Institution hereby undertakes that it will make timely payments of all taxes, duties, levies imposed by Government (including but not limited to GST), be responsible for filing of all necessary tax returns and undertake all necessary compliances in accordance with applicable statutory requirements under the relevant statute in relation to sum received from the Sponsor.
   (d) The Institution hereby undertakes that it will issue the tax invoices within the statutory time limits as prescribed under the GST laws and in the manner and with all the prescribed particulars as are required to be specified as per the GST Laws.
   (e) The Institution hereby undertakes that 'the address / location' of the Sponsor to which the invoice will be issued by the Institution will be as per the address mentioned in the Purchase Order (PO) issued by the Sponsor. Separately, prior to issue of an invoice, the Institution

PART- 2 TAXES

1. Notwithstanding anything contained in the Agreement, the Institution agrees that it is eligible to receive part of the consideration being the Goods and Services Tax(GST) charged in respect of the supply only after the details of such supply are uploaded by the Institution in the Form GSTR-1(or such other form as may be notified in lieu thereof from time to time), which is subsequently reflected in Form GSTR-2A(or such other form as may be notified in lieu thereof from time to time), made available electronically to the Sponsor, and are considered as matched with the corresponding details furnished by the Sponsor in its returns, in terms of the relevant provisions of the GST laws.

2. The Institution agrees to indemnify the Sponsor and keep it indemnified from and against any or all Liabilities, as defined in Explanation below, that may accrue or be demanded by a Taxing Authority, in respect of or in connection with the execution of scope of work or payments made/due to the Institution, arising under the said Agreement or anything done pursuant to the same. Any such compensation towards indemnification of Liabilities by the Institution to the Sponsor will be made within 15 days of the Liabilities accruing / demanded raised by Tax Authorities on the Sponsor either by way of issuance of demand or show cause notice or order or decree.

   Explanation –

   i. 'Liabilities' in this Agreement means, "any kind of taxes / duties, disallowance of input tax credit, loss, damage, legal expenses, demands, claims, costs, interest, penalties including in relation to compliances arising under respective Taxing Statute in course of execution of scope of work"

   ii. 'Liabilities accruing / demanded' in this Agreement means, "any Liabilities proposed to be imposed either during investigation or audit or by way of issuance of show cause notice or demanded by way of issuance of order or decree by Taxing Authority."

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   (a) The consideration payable under this Agreement shall be exclusive of applicable Goods and Services Tax (GST) including but not limited to CGST and SGST/UTGST or IGST, and/or applicable cess, as the case may be.
   (b) The Institution shall periodically pay its tax liabilities in compliance with the GST Laws in connection with the goods / services supplied under this Agreement, such that the Sponsor is entitled to claim such credit of input tax with respect to the goods/services supplied under this Agreement as permitted under the GST Laws.
   (c) The Institution hereby undertakes that it will make timely payments of all taxes, duties, levies imposed by Government (including but not limited to GST), be responsible for filing of all necessary tax returns and undertake all necessary compliances in accordance with applicable statutory requirements under the relevant statute in relation to sum received from the Sponsor.
   (d) The Institution hereby undertakes that it will issue the tax invoices within the statutory time limits as prescribed under the GST laws and in the manner and with all the prescribed particulars as are required to be specified as per the GST Laws.
   (e) The Institution hereby undertakes that 'the address / location' of the Sponsor to which the invoice will be issued by the Institution will be as per the address mentioned in the Purchase Order (PO) issued by the Sponsor. Separately, prior to issue of an invoice, the Institution

shall intimate the Sponsor about 'the address / location' of the Sponsor to which the invoice will be issued and a prior approval from the Sponsor in this respect will be taken by the Institution.

(f) The Institution undertakes that a debit note/ supplementary invoice/credit note with appropriate references to the original invoice will be issued only in such circumstances as agreed between the parties.

(g) Post supply of goods / services under this Agreement, the Institution shall cooperate with the Sponsor and provide any information that may be reasonably requested by the Sponsor in connection with claiming such credit of input tax under the GST Laws such as tax invoice or debit note issued by the Institution or such other taxpaying document(s) as may be required as proof of payment of applicable GST by the Institution

(h) Where, transactions in respect of which the Sponsor has claimed input tax credit are notified as unmatched vis-à-vis the corresponding disclosures made by the Institution in his periodic returns, the Institution would extend necessary assistance including inter alia carrying out revision/ rectification of its returns, to enable the Sponsor to retain such claimed credits

(i) The Institution undertakes that it has secured required GST Registration(s), which is/are in full force and effect and no action or claim is pending nor threatened to revoke or terminate such registration(s) or declare such registration(s) as invalid.

Exhibit C

JOHNSON & JOHNSON'S POLICY ON EMPLOYMENT OF YOUNG PERSONS

Institution and Principal Investigator shall comply with Johnson & Johnson's Policy on Employment of Young People as follows:

This policy applies to the employment by Institution of persons under the age of 18 ("Young Persons") in the Institution/study site or providing any services to the Sponsor.

a) Age, Health & Safety: No person under the age of 16 shall be employed. No person between the ages of 16 and 18 shall be employed unless such employment is in compliance with the health, safety and moral provisions of the International Labour Organization Convention 138 Concerning Minimum Age.

b) Hours: No Young Person shall be required to work more than 48 hours of regularly scheduled time and 12 hours of overtime per week, nor more than six days per week.

c) Law & Regulations: No Young Person shall be employed unless such employment is in compliance with all applicable laws and regulations concerning age, hours, compensation, health and safety.

Exhibit D

CODE OF CONDUCT – CONFLICT OF INTEREST

The Institution and its personnel and Principal Investigator shall prevent conflict of interest and avoid circumstances pertain thereto.

Any circumstance that could cast doubt or the appearance of doubt on any employee of the Sponsor to act with total objectivity with regard to the interests of the Sponsor is considered a potential conflict of interest.

The Institution and Principal Investigator should not:

i. Offer gifts, gratuities, entertainment, travel or hospitality to employees or relatives of the Sponsor's employees. Dinners and luncheons, which provide a continuity of business discussions, are allowed as time saving expediency. Gifts of inconsequential value, such as calendars, pens, note pads, appointment books, may be given in circumstances where such minor gifts are customary.

ii. Seek to profit or gain advantage over other Institution and Investigators from confidential information or business opportunities made known to them as a result of their relationship with the Sponsor. This includes, but is not limited to, product volumes, new products, and other personal business ventures. Institution and Principal Investigator shall not solicit from any Sponsor's employee, without a need to know, confidential information of any kind with respect to strategies, decisions, pricing, proceedings or other activities of the Sponsor.

iii. Give fees, commissions or other compensation to any Sponsor's employee or members of their family.

iv. Deliberately hide the fact that Institution is owned, controlled or represented by an employee or relative of an employee of the Sponsor. Director, officer, partner, employee, agent or consultant of the Institution, with or without compensation, who is an employee or relative of the Sponsor's employee, shall not be considered for qualification unless such circumstance had been previously disclosed and formally cleared.

In appropriate cases, after full written disclosure of the facts, an exception to the foregoing standards may be authorized by the Head – Global Clinical Operations, Asia Pacific, if it is determined that no material conflict of interest exist.

Exhibit E

Statement issued by Institution

a) That the PI- Dr. Manjunath Shenoy is one of the consultant of the Institution and has signed an Agreement or equivalent document to this effect.

b) The PI is obligated to assign to the Institution all inventions and discoveries made in the course of their Consultancy arrangement, explicitly mentioned in the Agreement signed by both the Parties.

c) Institution approves and agrees PI to be the investigator for the study and responsible to the conduct of the study.

Yenepoya (Deemed to be University)

Signature _____ Date and Stamp 16/08/19

Dr. Gangadhar Somayji
Registrar

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore 575 018

Dr. Manjunath Shenoy

Signature _____ Date and Stamp _____
Principal Investigator

16 AUG 2019

Dr. Manjunath Shenoy M.
Reg. No.35098
Prof. & HOD, Dermatology
Yenepoya Medical College

ATTESTED

Dr.Gangadhar Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore 575 018