SCIENCE RESEARCH CONTRACT

Clinical testing of the efficacy and safety of:

Unigroup's callus product (Formic acid, ethyl lactate, Vitamin)

in the treatment of corn (Callus)

1) Unigroup's Callus product: Formic acid, Carrier: ethyl lactate, vitamin C; ~~Vitamin E.~~ The product consist of an applicator pen with the active ingredient as well as a pressure relief and hydrating hydrocolloid plaster.

In the treatment of corn (Callus).

The undersigned:

The private company with limited liability,**Unigroup ApS**, having its principal place of business at Diplomvej 373, DK-2800 Lyngby, Denmark (hereinafter: "UG"), CVR: 29804095 ;

and

Dr. RAMESH BHAT M (RB)
MD.,DVD.,DNB.,MNAMS.
PROFESSOR & H.O.D
Dept. of Dermatology, Venereology &Leprosy
Fr. Muller Medical College
Kankanady, Mangalore 575 002.India

And

Director, Fr Muller Charitable Institution,
Kankanady, Mangalore-575002

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Kankanady, Mangalore 575 002.India

WHEREAS:

(i) UG wishes to perform a clinical testing of corn treatment product produced by UG

(ii) RB wishes to establish and execute the study and reporting

HAS AGREED AS FOLLOWS:

1. Appointment

Subject to the conditions set forth in this Agreement, The Parties have agreed to sign this Science Research Contract with the term and conditions as stated below.

Brief Resume of the Intended Work

callus (or **callosity**) is a toughened area of skin which has become relatively thick and hard in response to repeated friction, pressure, or other irritation. Rubbing that is too frequent or forceful will cause blisters rather than allow calluses to form.

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1. **Appointment**

Subject to the conditions set forth in this Agreement, The Parties have agreed to sign this Science Research Contract with the term and conditions as stated below.

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callus (or **callosity**) is a toughened area of skin which has become relatively thick and hard in response to repeated friction, pressure, or other irritation. Rubbing that is too frequent or forceful will cause blisters rather than allow calluses to form. Since repeated contact is required, calluses are most often found on feet because of frequent walking. Calluses are generally not harmful

Hence this study is conducted to clinical testing the efficacy and safety of unigroup's corn treatment

Aims and Objectives

1. To study the efficacy and safety of Unigroup's callus product product in the treatment of callus

Materials and Methods

Source of Data :

(Patients attending the Dermatology OPD of Fr. Muller Medical College Hospital, Mangalore)

Method of Collection of Data :

Data will be collected from 72 patients with callus at the feets, attending the OPD.
An informed consent will be obtained from all patients
A detailed h/o age, sex, occupations and size (photo with linear) numbers, placement and duration of the callus problem will be taken.
A thorough systemic examination will be done in each case to exclude the existence of any other disease along with the callus.

Inclusion Criteria :

1. age above 8 years
2. both sexes
3. patient willing to come for regular follow up.

Exclusion criteria :

1. age less than 8years
2. Patients not willing to come for regular follow up
3. patients with diabetes
4. Patients with systemic diseases
5 Patients with HIV infection
6 Patients who refuse to give consent.

The product will be dispensed to the patient and shown how to apply the same
The effect of UG Formic acid based product will be studied in 72 cases

The callus area will be cleaned with a spirit –moistened cotton swab. Then the area will be dried. Formic acid will be applied with the pen with adequate precaution, on the callus area and a hydrocolloid plaster will be applied when area is dried. The formulation and plaster will be applied every second day for 2 weeks (7 applications).

Treatment will be continued for the maximum period specified above or till the disappearance of the lesions whichever is early and it will be considered as a failure if there are no desirable results after the maximum no of treatments has been finalized. Success of the treatment will be judged by the disappearance of the callus without any serious side effects.

- All the patients will be followed up immediately after 2 weeks treatment period. The response to therapy the appearance of the callus area and the presence of infection will be noted. The patient will be meet at the clinic day (0) and Day (14).

Pateints not showing up day 14 will be actively contacted to ensure that all patient results will be obtained. No-show patients will actively be contacted and as to report back to the clinic. In case where it is not possible to convience the patient to show up at the clinic, the clinic will visit the patient at their home address, or as a last resort a telephone interview will be conducted.

In patients who have side effects, treatment will be discontinued and considered as failures . Patients in whom there are recurrence or failure of treatment within the 3months after completion of treatment will be subjected to treatment with salicylic acid

Stastical analysis – Data will be analysed by a independent statistician

Article 1: UG agrees to entrust the *clinical evaluation: "Test of efficacy and safety of Unigroups callus product (* Formic Acid and carrier based callus product) *to Fr. Muller Medical College (RB)*

Article 2: Responsibility of RB:

- Obtain all permissions for the trial (this cost is included in article 4 below)
- Clinical trial in accordance with the guidelines for medical devices, council directive 93/43/EEC with changes induced by directive 2007/47EC and amending council directive 90/385EEC and including GCP and EN ISO/IEC 17025, EN ISO 14155-1; ISO 10993-10:2010, EN ISO 14155-2 and all other relevant standards
- Reporting according to ISO/EN 14155 and all other relevant standards

Article 3: Responsibility of UG:

- Supply samples.
- Settle for Research Expenses according to the contract.

Article 4: Payment Condition and time schedule:

Payment

payment: USD 9,000 when study is finalized and approved by Unigroup ApS

The payment will be made in the name of Fr Muller Research fund

First payment of 3,000 $s to give TA/DA to patients.

Second payment of 6,000 $s at the end of the study

Payment of 200$s at the time of submission to Ethics committee.

Invoices shall be issued by The Fuller Institute in USD. Payments shall be made in USD by bank transfer to a bank account stated on the original invoice.

Payment Details

Clinical Study charges(includes PI, Co-ordinator, Sub Investigator fee, Patient TA,Da, Institution Charges)---------- 72 patientsX100 $ =7,200$s

Miscellaneous charges---------- 1,800$s

Total-------9,000$s

Article 5

Public access and publication

All rights for the protocol content and clinical results, including all elements related to the study, belong to Unigroup ApS and will be kept confidential to 3rd parties unless otherwise decided by Unigroup ApS. Possible publication is part of the agreement and if decided by UG, RB shall apply for publication in a well respected publication decided by the parties.

Nothing in this Agreement shall constitute any right of RB to represent Unigroup in any way whatsoever and vice versa. Neither party shall have authority whatsoever to enter into any obligations on behalf of the other.

Information provided by Unigroup to RB is confidential and shall not be available for third parties. RB will ensure that 3rd parties involved in the clinical testing will be covered by a secrecy agreement.

Article 11: Miscellaneous

11.1 The parties agree that this Agreement shall be interpreted according to the laws of Denmark and the parties further agree that any court proceeding regarding this Agreement shall be subject to exclusive jurisdiction in the court of Sø og Handelsretten, Copenhagen.

11.2 The contractual language is English.

11.3 This Agreement with annexes contains the entire Agreement between the parties with respect to the subject matter hereof and supersedes all prior or contemporaneous agreements and understandings, whether oral or written relating to the subject matter hereof. No Amendment to this Agreement shall be effective unless the same shall be in writing and signed by the Parties.

11.4 The parties to this Agreement remain independent contractors. This Agreement does not create any partnership, joint venture, employment or agency relationship between them and does not give rise to any fiduciary obligation between the parties other than those defined herein. Neither party shall have the authority to bind the other party.

11.5 If any term or condition of this Agreement is null and void or will become null and void during its course, then the validity and effectiveness of all other terms and conditions shall not be impaired thereby. All terms and conditions of this Agreement are separable.

Unigroup ApS

Dr. RAMESH BHAT M (RB)
MD.,DVD.,DNB.,MNAMS.
PROFESSOR & H.O.D
Dept. of Dermatology, Venereology &Leprosy
Fr. Muller Medical College

Mr. Flemming Licht
CEO

DIRECTOR
Father Muller Charitable Institutions
FR. MULLER ROAD
MANGALORE-575 002

FATHER MULLER INSTITUTIONAL ETHICS COMMITTEE

Father Muller Road, Kankanady, Mangalore - 575 002
Karnataka, India

Tel : 2238399
e-mail: frmulleriec@gmail.com

REG. NO. ECR/540/Inst/KA/2014

CHAIRPERSON
Dr. Arun Rao
Prof. of Obstetrics & Gynaecology
Kasturba Medical College
Mangalore - 575 001
Phone : 9845677507

SECRETARY
Dr. B. Sanjeev Rai
Chief of Medical Services,
Father Muller Charitable Institutions,
Kankanady, Mangalore - 575 002
Phone : 9448133494
e-mail: raibs11@gmail.com

Ref. No : FMMC/FMIEC/1774/2014 *Date :* 28.06.2014

To,
Dr. Ramesh Bhat,
Principal Investigator
Prof and HOD, Department Of Dermatology
Father Muller Medical College Hospital
(Unit of Father Muller Charitable Institutions)
Father Muller Road, Kankanady, Mangalore – 575002, India.

Subject: Ethics Committee Approval of the Study

Ref: WAT/CMBP/2013 : A multicenter, double blind, randomized, parallel group, placebo controlled bioequivalence study with clinical endpoint to evaluate the bioequivalence of clindamycin 1% and Benzoyl Peroxide 5% gel of Watson Pvt. Ltd and the reference listed BenzaClin® (Clindamycin 1% and Benzoyl Peroxide 5%) gel of Dermik Laboratories, business of Sanofi Aventis US LIc, in treatment of subjects with acne vulgaris.

Dear Dr. Bhat,

The Father Muller Institutional Ethics Committee, Father Muller Medical College had reviewed and discussed your application dated 26/May/2014 to conduct the clinical trial for the protocol WAT/CMBP/2013.

The Ethics Committee meeting was held on 21-June-2014 at 3.00pm and the following documents were reviewed:

No.	Document Reviewed	Qty.
1	Study protocol Version 2, Amendment 1 dated 06 May 2014	14
2	Investigators brochure Version dated 7 Jan 2014	14
3	Informed consent document (English) Version 2, Amendment 1 dated 8 May 2014	14
4	Informed consent document (Hindi) Version 2, Amendment 1 dated 8 May 2014	14
5	Informed consent document (Kannada) Version 2, Amendment 1 dated 8 May 2014	14

6	Back translation from Hindi to English Version 2, Amendment 1 dated 16 May 2014	14
7	Back translation from Kannada to English Version 2, Amendment 1 dated 16 May 2014	14
8	Patient dairy (English)Version 2, Amendment 1 dated 8 May 2014	14
9	Patient dairy (Hindi) Version 2, Amendment 1 dated 8 May 2014	14
10	Patient dairy (Kannada) Version 2, Amendment 1 dated 8 May 2014	14
11	Back translation from Hindi to English Version 2, Amendment 1 dated 16 May 2014	14
12	Back translation from Kannada to English Version 2, Amendment 1 dated 16 May 2014	14
13	Patient instruction sheet (English) Version 2, Amendment 1 dated 8 May 2014	14
14	Patient instruction sheet (Hindi) Version 2, Amendment 1 dated 8 May 2014	14
15	Patient instruction sheet (Kannada) Version 2, Amendment 1 dated 8 May 2014	14
16	Back translation from Hindi to English Version 2, Amendment 1 dated 16 May 2014	14
17	Back translation from Kannada to English Version 2, Amendment 1 dated 16 May 2014	14
18	Translation certificates	14

The following members of the Ethics Committee were present at the meeting held on 21st June 2014 at 3:00pm in the Seminar Hall.

Sl No.	Name	Qualification	Designation/ Title	Affiliations as to the Institution
1.	Dr. Arun Rao	MD, DGO	Chairperson (Clinician)	No
2.	Dr. B. Sanjeev Rai	MD, DCH, MBA	Secretary (Clinician)	Yes
3.	Dr. Shiva Shanker	Ph.D	Joint Secretary (Scientist)	Yes
4.	Mr. Eric Sequeira	BABL	Vice Chairperson (Advocate)	No
5.	Prof. Irene T.R. Alvares	M. Sc	Member (Nursing)	Yes
6.	Dr. Prasanna Kumar	MD	Member (Homoeopathic)	Yes
7.	Dr. Ashok Shenoy	MD	Member (Pharmacologist)	No
8.	Dr. Jayaram Shetty	BVSc, MVSc	Member (Veterinion)	No
9.	Mr Nikesh Shetty	BABL	Member (Advocate)	No

The following are the members who could not present for the EC meeting due to unavoidable circumstances are:

Sl No	Name	Qualification	Designation/ Title	Affiliations as to the Institution
10.	Rev. Dr. Leo D' Souza	M. Sc, Ph.D	Member(Theologian)	No
11.	Mrs. Rameela Shekar	MSW, M. Phil, (PSW), PGDHRM, Ph.D	Member (Sociology)	No
12.	Dr. John Mathai	MD	Member (Clinician)	Yes
13.	Dr. Narasimman. S	MPT	Member (Physiotherapist)	Yes
14.	Ms. Bindiya Shetty	MSW	Member (Counsellor)	No
15.	Mrs. Veena Manoj	MA, B.Ed	Member (Lay person)	No

Neither you nor any of your study team members were present during the decision making procedure of the Ethics Committee Meeting.

We approve the trial to be conducted in its presented form.

The Father Muller Institutional Ethics Committee, Father Muller Medical College expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and a copy of the final report.

Yours truly,

Dr B. Sanjeev Rai
Member Secretary/Chairman,
Father Muller Institutional Ethics Committee,
Father Muller Medical College Hospital,
Kankanady, Mangalore - 575002,
Karnataka, India.

Secretary
Father Muller Institutional Ethics Committee
Father Muller Medical College
Mangalore-575002

Dr. Reddy's Laboratories Ltd.
8-2-337, Road No. 3, Banjara Hills,
Hyderabad - 500 034, Telangana,
India.
CIN : L85195TG1984PLC004507

Tel :+91 40 4900 2900
Fax :+91 40 4900 2999
Email : mail@drreddys.com
www.drreddys.com

AGREEMENT FOR CLINICAL TRIALS BY SITE

THIS MASTER AGREEMENT FOR CLINICAL TRIALS BY SITE (hereinafter referred to as this "**Agreement**") is made on this 12th day of the month of September in the year 2017 ("**Effective Date**"), by and between

Dr. Reddy's Laboratories Limited, a company registered under the Companies Act, 1956 and having its registered office at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana – 500034, India (hereinafter referred to as "**SPONSOR**", which expression shall unless contrary the meaning and context thereof mean and include its successors, representative and permitted assigns) of One Part;

And

Father Muller Medical College Hospital, a unit of Father Muller Charitable Institution registered under laws of India and located at Kankanady, Mangalore. Karnataka-575002(hereinafter referred to as "**INSTITUTION**" which expression shall unless contrary the meaning and context thereof mean and include its successors, representatives and permitted assigns) of the Second Part;

And

Dr. Jacintha Martis an individual, having an address at Father Muller Medical college Hospital, Kankanady, Mangalore. Karnataka-575002will serve as the principal investigator ("**Principal Investigator**")

Collectively Principal Investigator and Institution (with its personnel, officers, board members, affiliates, Site Management Organization, and agents) shall be referred to as the "**SITE**".

Within this Agreement, SPONSOR and SITE are individually referred to as the "**Party**" and jointly as "**Parties**"

RECITALS

A. **WHEREAS**SPONSOR researches, develops, manufactures and distribute a range of pharmaceutical products in a variety of therapeutic use;

B. **WHEREAS**, SITE, acting as an independent contractor, desires to conduct clinical research studies("**the Study**"), according to SPONSOR's Clinical Trial Protocol ("**Protocol**")and as agreed to by all the Parties;

C. **WHEREAS**, SPONSOR requires a clinical trial to be performed in relation to an investigational product ("**Investigational Product**");

D. **WHEREAS**, SITE has established and maintains a clinical trial study service, and has acquired expertise in conducting research evaluations, clinical trials, and laboratory test evaluations;

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E. **WHEREAS**, SPONSOR wishes to engage the SITE to carry out the Study;

F. **WHEREAS**, SITEhas sufficient authority, competence and experience in conducting clinical trials and, having reviewed the Protocol, the investigator brochure, and sufficient information regarding the Investigational Product related to the Study, desires to so participate in the Study as more particularly described in this Agreement. For the purposes of clarity, SITE has acquired the necessary clearances as per applicable laws for initiating or conducting any studies;

G. **WHEREAS**, SITE is willing to undertake the Study for SPONSOR according to the terms, conditions and covenants hereinafter set forth; and

H. **WHEREAS**SITE has agreed to provide the services to SPONSOR on the terms of this Agreement.

NOW THEREFORE THIS AGREEMENT WITNESSETH, that in consideration of the mutual covenants herein contained and other good and valuable consideration exchanged between the Parties, the receipt and sufficiency whereof is hereby acknowledged by the Parties hereto, the parties covenant and agree as follows:

ARTICLE 1: Study

1.1 SITE will perform the Study as detailed in Annexure 1 of this Agreement in compliance with the terms of this Agreement. .

ARTICLE 2: Period of Performance

2.1 The performance of this Agreement shall be from the Effective Date through completion of the Study, unless terminated earlier in accordance with Article 12 of this Agreement. This Agreement may be extended by the written agreement of the Parties.

ARTICLE 3: Conduct of the Study

3.1 The SITE agrees to perform the Study detailed in Annexure 1 heretoin strict accordance with the Protocol, the terms and conditions of this Agreement and any amendments thereto, and all federal, state and local laws and regulations applicable to the performance of the Study and this Agreement in the territory where the Study is performed, including but not limited to (a) Good Laboratory Practice, the revised and applicable versions of the Declaration of Helsinki Directive 95/46/EC; and (b) the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Topic E6: Guidelines on Good Clinical Practice and Directive 75/318/EEC, as amended from time to time ("**ICH/GCP**");(collectively, "**Applicable Law**").

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3.2. The Study will be supervised by the Principal Investigator, who will be employed/engaged, as applicable, by Institution, and who will personally be responsible for the direction of the research and the conduct of the Study in accordance with the applicable policies of the Institution, which the Principal Investigator represent and warrant are not inconsistent with (1) the terms of this Agreement, (2) the Protocol, (3) generally accepted standards of good clinical practice, and (4) Applicable Law. Principal Investigator shall conduct the Study and use his/her best efforts to complete the Study in a professional manner in accordance with the highest standards in the industry and in strict adherence to sub-parts (1) – (4) of this Article 3.2. If the Study is conducted by a team of individuals including Sub-investigator(s), the Principal Investigator shall be responsible for all Sub-investigators and Study team members utilized in any manner, in connection with the Study, and SITE shall instruct each Sub-investigator and team member to follow the direction of the SITE and otherwise adhere strictly to the Protocol. Institution shall ensure that Principal Investigator shall not delegate his/her responsibility to personally supervise the Study without Institution's prior written approval. Institution further agrees to ensure that Principal Investigator and/or any sub-investigators: (i) are fully informed of the Protocol, the Investigational Product; and (ii) participates in all investigator meetings and telephone conferences as required for the conduct of the Study. Institution will further ensure that Principal Investigator, sub-investigator, and any other personnel involved with the Study, participate in training sessions as necessary for the performance of the Study.

3.3 Institution/Principal Investigator will notify SPONSOR immediately if Principal Investigator is unable to continue as principal investigator for the Study. SITE further agrees that no other investigator may be substituted for the Principal Investigator without the prior written approval of SPONSOR and the ethics committee. If for any reason, Principal Investigator is unable to serve as principal investigator, and a successor acceptable to SPONSOR is not available, the SPONSOR may terminate this Agreement.

3.4 SITE shall ensure that Study subjects have agreed to participate in the Study as defined by the Protocol and in compliance with Applicable Law. SITE shall further ensure that the Study subjects are adequately informed of the aims, methods, anticipated benefits and potential hazards of the Study and the circumstances under which their personal data might be disclosed to relevant third parties including, but not limited to, SITE, SPONSOR and/or its affiliates, competent authorities, and/or ethics committees, in accordance with the requirements for such information as set forth in the Protocol prior to including any subject in the Study. SITE shall obtain the informed consent of subjects to participate in the Study prior to said participation, and shall document the Study subjects' informed consent by securing from each patient, his or her signature upon an informed consent form, that complies with Applicable Law, a copy of which shall be retained by the SITE. The Study subject shall also receive a signed copy of the informed consent. Further, the name, medical history, and any and all information relating to a Study patient obtained as a result of or in connection with his or her participation in the Study shall be held in strictest confidence and trust, and shall not be disclosed or transferred to third parties except as expressly permitted by this Agreement or the Protocol.

3.5 Adverse Events. SITE shall report to SPONSOR, any death, life threatening, or serious adverse event, or other event as specified by the Protocol. Such notification shall be given promptly, and in no instance later than twenty-four (24) hours of becoming aware of such an event and shall be made in accordance with the procedures outlined in the Protocol concerning the reporting of adverse events and serious adverse events.

3.6 No changes or revisions in the Protocol shall be made unless first mutually agreed upon in writing by SPONSOR and SITE, and reviewed and approved by the Applicable Authority in accordance with Applicable Law or where deemed necessary to protect the safety, rights or welfare of any subjects entered into the Study, in which case SPONSOR will be immediately notified in writing of such action and necessity for deviation from the Protocol. If any changes in the Protocol affect the charge for research conducted in the Study, SITE shall submit a written estimate of the charges for SPONSOR'S prior written approval.

ARTICLE 4: Payment

4.1 Fees

4.1.1 Fees mentioned in Annexure 1 are exclusive of GST, VAT, sales or similar withholding taxes. The SITE will provide its reasonable co-operation to SPONSOR to ensure that SPONSOR is only required to pay GST, VAT, sales or similar withholding taxes once, in accordance with Applicable Laws and where permitted, to minimise duplication of such taxes. All other taxes are the SITE's responsibility;

4.1.2 If any payments made by the Parties under this Agreement become subject to withholding taxes under Applicable Law of any state, central or foreign government, each Party shall be authorised to withhold such taxes as are required under Applicable Law, pay such taxes to the appropriate government authority, remit the balance due to the other Party net of such taxes, and provide a certificate as provided by the appropriate government authority towards this effect to the other Party. The Parties agree to cooperate in good faith to qualify the transactions for any exemptions or reductions in the amount of otherwise applicable withholding tax provided under Applicable Law (including the provisions of any relevant tax treaty) and to complete such forms as necessary for such purpose.

4.1.3 The quotation provided by SITE for a Study shall be optimal and on a fixed cost basis for both administrative cost and pass through costs except when mutually agreed upon by both parties. Parties acknowledge and agree that the Fees along with expenses quoted by SITE will be an upper limit of the estimated quote and has been arrived at, on the basis of the Study scope, requirements and allocation of resources for conducting the Study.

In the event that, the Parties believe that due to change in the Study scope, or resource re-allocation requirements, there is a need for upward or downward revision of the Study quote, SITE shall inform SPONSOR in writing and Parties shall mutually agree to modify the Agreement accordingly.

4.1.4 the Fees are fixed and will not be varied without SPONSOR' prior written consent;

4.1.5 the Fees include all performance requirements of this Agreement; and

4.1.6 The timelines provided by SITE for the completion of a Study shall be optimal and explain the best case scenarios for achievement of timelines.

4.2 Invoicing and Payment

4.2.1 The SITE will invoice SPONSOR in accordance with the terms mentioned herein or as per the milestones set in the agreement. Each invoice will specify the SPONSOR Study Code / Purchase Order provided by SPONSOR.

4.2.2 The SITE must provide appropriate supporting documentation to substantiate the amount charged, on request by SPONSOR.

4.2.3 SPONSOR will pay the Fees within forty-five (45)days of the receipt of a correct and valid invoice or as per the milestones set in the agreement, subject to the satisfactory completion of associated Deliverables.

4.2.4 SPONSOR will pay the undisputed portion of an invoice and may withhold payment on the disputed portion until resolved.

4.2.5 The SITE agrees that the Fees:

i. represent fair-market value for the Services or for conducting the Study;

ii. do not create any obligation to prescribe, supply, administer, recommend or buy SPONSOR' products or constitute any reward for past or future business; and

iii. do not represent any inducement to influence the SITE to push for or prescribe, supply, administer, recommend or buy SPONSOR' products.

ARTICLE 5: Record Keeping and Access

5.1 SITE shall ensure that:

5.1.1 It prepares, maintains and retains complete, current, organized, and legible Study documents relating to its performance of the Study which are required to be retained under Applicable Law, and any other records pertaining to the Study subjects who have participated in any way, in the Study including, without limitation, source documents monitoring Study subjects' progress, medical and clinical records and complete case report forms ("**CRFs**") (collectively, "**Study Records**") for each Study patient no later than three (3) days after a visit or as per protocol. SITE shall respond to all data queries within three (3) days from the date of such request. SITE will ensure that all personnel take appropriate measures to prevent unauthorized access to the electronic data capture system including maintaining confidentiality of their passwords. Study Records will be retained by the SITE for five (5) years following the date a marketing application is approved for the Investigational Product for the indication under investigation in the Study, or if no application is to be filed, or if the application is not approved for such indication, until five (5) years after the investigation is discontinued and the applicable regulatory authority is notified, or any longer retention period mandated by Applicable Law.

5.1.2 SITE maintains written adequate records of the disposition of the Investigational Product, including dates, quantity and use by Study subjects according to Applicable Law, as amended from time to time, and any successor regulations), the Protocol, or as otherwise established by written notice from SPONSOR, showing the receipt, administration, or other disposition of the Investigational Product.

5.1.3 SITE prepares and maintains adequate and accurate subjects case histories recording all observations and other data pertinent to the clinical Study of each patient enrolled as a subject in the clinical investigation of the Investigational Product.

5.1.4 SITE retains the records and reports required by Applicable Law as amended from time to time, and any successor regulations, and the Protocol, and shall deliver copies of the same to SPONSOR as required by the Protocol.

5.2 Authorized representative(s) of SPONSOR, shall be allowed during regular business hours, and at reasonable intervals, to examine and inspect SITE facilities utilized in the performance of the Study, and to inspect and copy all Study data, records, and work products related to the Study, for purposes of assuring compliance with Applicable Laws, the Protocol, and the terms of this Agreement. Audits shall be at no additional cost to SPONSOR provided such audits are at mutually agreed intervals and do not significantly alter Institution's ability to meet any deadlines delineated in this Agreement.

ARTICLE 6: Publications

6.1 SPONSOR shall be solely responsible for determination whether to submit the Study for listing in a publicly accessible clinical trial registry or any equivalent registry SPONSOR deems appropriate, prior to initiation of any Study patient enrolment. For greater certainty, SITE, shall not register the Study or Study results on any publicly accessible clinical trial registry. Where applicable, SITE shall ensure that a non-promotional summary of the results of the Study or a citation or link to a peer-reviewed article in a medical journal where one exists, will be posted on a free publicly accessible clinical trial results database within one (1) year after the Investigational Product is first approved and made commercially available in any country or, if the Study is under review by a peer-review journal that prohibits disclosure of results pre-publication, as soon as practicable after publication.

6.2 SITE hereby acknowledge and agrees that the SPONSOR has the right to use the Study results in any manner deemed appropriate to SPONSOR's business interests, both during, and following termination of this Agreement and/or the Study.

6.3 In the event Study is not part of a multi-centre study or where no multi-site publication has occurred within twelve (12) months after completion and close out of the Study, SITE may freely publish and disseminate the site-specific results of the Study, or otherwise publish or submit for publication an article, manuscript, abstract, report, poster, presentation, or other material containing or dealing with the site specific results of the Study (a "**Publication**") in accordance with the terms of this Agreement provided that, SITE shall: (i) obtain written consent of SPONSOR prior to any such Publication; (ii) provide SPONSOR with a copy of any proposed Publication sixty (60) days prior to submission for Publication. If SPONSOR determines that the proposed Publication contains patentable subject matter which requires

protection. SPONSOR may require the delay of publication for a further period of time not to exceed one hundred eighty (180) days for the purpose of filing patent applications.

6.4 Notwithstanding any other provision of this Section 6, and prior to any Publication, SITE shall preserve the right of SPONSOR to comment on the results and conclusions set forth in any proposed Publication upon SPONSOR's written request prior to the submission of any Publication. SITE agrees that all comments made by the SPONSOR in relation to a proposed Publication or presentation will be incorporated into the Publication or presentation. Reasonable comments for the purposes of this clause 6.4 shall mean such comments and suggestions that, with a view to the scientific interest or the treatment of Study subjects, will clarify or improve the proposed Publication or presentation of the results of the Study or the conclusions drawn therefrom, or any other such comments that aim to avoid a Publication or presentation that will misrepresent the results. SITE shall delete any SPONSOR's confidential information in the proposed Publication where reasonably requested by SPONSOR.

6.6 The obligations described in this Section shall survive the expiration or termination of the Agreement.

ARTICLE 7: Confidentiality and Use Restrictions

7.1 SPONSOR will disclose to SITE including its employees, agents, directors, and representatives, certain information furnished in any form, including written, verbal, visual, electronic or in any other media or manner, any information that a party would reasonably consider to be confidential or proprietary including, but not limited to, information concerning the Investigational Product, this Agreement, the Protocol, Study results, processes, know-how, discoveries, inventions, compilations, business or technical information, other materials prepared by either Party or their respective affiliates and representatives, containing or based in whole or in part, on any information furnished by the SPONSOR, and the procedures for carrying out the Study, (collectively, "**Confidential Information**"). SITE will keep, such Confidential Information in confidence and shall not use it for the benefit of nor disclose it to others, except as required by the Study or as defined in the Protocol and will at all times, refrain from any other acts or omissions that would reduce the value of SPONSOR's Confidential Information. SITE agrees to ensure that its employees, agents, contractors, representatives, or affiliates (including members of the Study team), who have access to Confidential Information are bound by an obligation of non-disclosure and shall procure non-disclosure agreements with such parties with the same breadth of coverage as provided for in this Section 7. SITE's obligations of confidentiality shall not apply to that part of the Confidential Information that SITE is able to demonstrate by documentary evidence: (i) already in the public domain prior to receipt of such information by SITE, or (ii) that becomes lawfully part of the public domain through no act on the part of the SITE, and/or its employees, agents, and representatives; or (iii) is obtained from a third party without an express obligation of confidence; or (iv) where required by applicable law, regulation, legal process, or other applicable judicial or governmental order to disclose, provided that, should the SITE be required to make such disclosure, where legally permissible, SITE shall provide the SPONSOR with prompt written notice of such request or requirement so that SPONSOR may, at its sole expense, seek an appropriate protective order prior to such disclosure; and where SITE is compelled to disclose, SITE

shall only disclose that portion of the Confidential Information that SITE is compelled to disclose and will exercise reasonable efforts to obtain assurance that confidential treatment will be accorded to that portion of the Confidential Information disclosed; or (v) is approved by SPONSOR with written authorization for disclosure by SITE.

7.2 SITE shall return all Confidential Information to SPONSOR, except where retention of same is required by Applicable Law, at the earlier of: (i) the time at which SITE ends its participation in the Study; (ii) as defined by the Protocol; or (iii) immediately upon request of SPONSOR.

ARTICLE 8: Intellectual Property (IP)

8.1 Intellectual Property that either Party owned prior to execution of this Agreement, or develops independently of the Study (without the use of SPONSOR IP and/or Confidential Information), is that Party's separate property and is therefore, not affected by this Agreement. Neither Party has any claims to, or rights in such intellectual property of the other Party.

8.2 The Parties agree that the SPONSOR owns the proprietary rights (whether or not protectable by patent, copyright or other intellectual property rights) to the Study and/or Study data or materials and other reports required to be generated and submitted to the SPONSOR pursuant to the Protocol, and any data compiled therein, or any discovery, concept, or idea arising out of the Study, including but not limited to any/all intellectual property and Confidential Information provided to SITE relating to the Study, or any inventions, mechanisms, substances, works, trade secrets, know-how, methods, or techniques (including improvements), tangible research products, any intellectual property conceived and reduced to practice, made or developed, the Investigational Product, formulation of the Investigational Product, device, or biologic, including its administration or use, alone or in combination with any other drug or device and any related assay or biomarker, or any improvements or methods of using such Investigational Product, existing or pending patents and patent applications, records or compilations of information (excluding records/compilations set forth in Section 8.3 herein), Study data produced by as a result of the Study, including records produced by Institution and/or Investigator, innovations of any kind made in performance or carrying out of the Study, and the Protocol, and the like, either of which, in whole or in part, relating to the Study, derived from the use or access to SPONSOR's Confidential Information, or developed conceived or reduced to practice during the course of conducting the Study (collectively, **"SPONSOR IP"**). The Parties agree that title, interest and rights to any SPONSOR IP shall remain the sole property of the SPONSOR. The Parties further agree that neither Party will have any proprietary or other ownership rights in any such SPONSOR IP, but that such rights in and to the following will remain with SPONSOR, subject only to the right of SITE, to use such information for: (i) Institution's own internal, non-commercial research and for educational purposes provided such use does not violate SPONSOR's confidentiality rights or impede commercialization; and (ii) if required during the Study, for the provision of standard of care medical treatment for a Study patient, without jeopardizing the SPONSOR's Intellectual Property Rights on such subject matter. This Agreement shall not be deemed or construed to convey or transfer any of such intellectual property rights to SITE except insofar as necessary to permit SITE to conduct the Study which is the subject of this Agreement. SPONSOR and SITE

acknowledge that the SPONSOR, owns the proprietary rights to the formulation of the Investigational Product, existing or pending patents and patent applications, trade secrets, know-how, and confidential information related to the Investigational Product and that these and all other proprietary rights shall remain the sole property of the SPONSOR.

8.3 Subject to the entirety of Section 7, and the provisions of this Section 8.1 and 8.2, Institution shall own all original hospital records, clinical and office charts, laboratory notes, evaluation checklists developed by Institution, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories involved in the Study (collectively, "**Source Documents**") provided that such does not utilize any Sponsor IP and/or contain any Confidential Information of Sponsor. Institution may utilize any Source Documents in any manner deemed appropriate by Institution without jeopardizing SPONSOR's Intellectual Property Rights derived out of such documents. Sponsor shall have the right to access such Source Documents in accords with Applicable Law.

8.4 Regulatory Filings. Any and all findings obtained as a result of the Study shall be communicated to SPONSOR, who shall be free to incorporate such findings in any regulatory filing concerning the Study. SITE understands and agrees that it shall have no ownership, license or access rights in, or to, such regulatory filings solely based upon the inclusion of such findings therein, nor shall they acquire any interest whatsoever in the findings as a result of performing the Study.

8.5 SITE shall promptly and fully disclose to SPONSOR, all discoveries and inventions (whether patentable or not) arising out of the performance of the Study or involving SPONSOR's IP ("**Study Inventions**"). SITE, each hereby assigns, all rights, title and interest in and to any Study Inventions and/or SPONSOR IP to SPONSOR. SITE hereby further agrees to refrain from taking any actions that would prejudice the intellectual property rights of SPONSOR in any way. Moreover, SITE agrees to inform the SPONSOR of any known infringement of its intellectual property rights, and to assist SPONSOR, at SPONSOR's sole expense, in actions intended to protect the SPONSOR's intellectual property rights.

8.6 Without SPONSOR's prior written approval, SITE, will not knowingly use in the Study, any of its own or any third-party intellectual property that may interfere with SPONSOR's rights to any SPONSOR IP and/or Study Inventions. Except as stated elsewhere in the Agreement, the Parties expressly authorize the use and grant a royalty-free license to their respective intellectual property to SPONSOR, to the extent necessary to accomplish the purposes of the Study.

8.7 SITE, agrees to use the Investigational Product only for a clinical Study under a regulatory authority Notice of Claimed Exemption for a New Drug as contemplated by this Agreement. SITE acknowledges that this Agreement constitutes a non-exclusive and non-transferrable or sub-licensable license to the SITE, by the SPONSOR to use the Investigational Product and the SPONSOR'S confidential and proprietary information relating to the Investigational Product solely for the research contemplated by this Agreement in accordance with the SPONSOR'S Protocol, and in accordance with regulatory authority regulations defining the

procedures, conditions and requirements applicable to investigational studies for new drugs under Applicable Law as amended from time to time, and any successor regulations. Furthermore, the SITEwill not transfer the Investigational Product or related information to any third party, or otherwise make the Investigational Product or related information available to any investigator other than those listed in the SPONSOR'S Protocol, nor to any clinic or medical facility for use with subjects not properly enrolled in the investigational Study, and hereby acknowledges that the SITEshall not use or exploit the results of the Study for any purpose other than that contemplated by this Agreement.

8.8 **License.** If for any reason it is subsequently determined that SPONSOR is not the sole owner of any such SPONSOR IP or, with respect to any inventions and discoveries arising from research conducted under this Agreement, other than as expressly provided for herein ("**Other Inventions**"), SITE shall promptly disclose to SPONSOR on a confidential basis any Other Invention arising under this Agreement. SITE each individually, hereby grants SPONSOR an exclusive option, without fee, exercisable within ninety (90) calendar days following written notice of any Other Invention, to obtain an exclusive or nonexclusive, worldwide, royalty-bearing commercialization license, upon reasonable commercial terms and conditions (including measurable provisions for due diligence in development, commercialization and marketing), to all rights, title and interest that SITE, may have or obtain in any such Other Invention. This license will include the right to sublicense, make, have made, use, and sell the Other Invention or products incorporating the Other Invention. Upon SPONSOR's exercise of its option with regard to any Other Invention, Institution and SPONSOR will negotiate in good faith for up to eight (8) months ("**Negotiation Period**") in an attempt to reach a license agreement satisfactory to both parties. If an agreement is not reached by the end of the Negotiation Period, SPONSOR's rights to that Other Invention will expire, and Institution may license the Other Invention to third-parties without obligation to SPONSOR. If negotiations between SPONSOR and SITE terminate and SITE thereafter negotiates a license agreement with a third party on substantially better terms than those last offered to SPONSOR, SPONSOR shall be given the first right to refuse such terms for a period of one-hundred, eighty (180) days from the date of SPONSOR's receipt of a draft of such license agreement from Institution or Principal Investigator as the case may be. SITE, , each individually grants SPONSOR, for the term of the Negotiation Period, a non-exclusive, worldwide, royalty-free license on SITE's rights to the Other Invention for SPONSOR's internal research purposes

8.9 The obligations described in this Section shall survive the expiration or termination of the Agreement.

ARTICLE 9: Use of Names

9.1 Neither Party shall be permitted to use the name, trademark, trade name, logo, or any adaptation thereof, of the Sponsor and/or either Party hereto, in any news or publicity release, policy recommendation, advertisement, promotional material, promotional activity, or in any other commercial fashion, without the prior written consent of the other Party or where applicable, of SPONSOR subject, however, to the following:

9.1.1 Sponsor may, without prior consent, identify Principal Investigator as the person conducting the Study;

9.1.2 SPONSOR may disclose the Principal Investigator to investors or potential investors or as required by federal, state or local laws or security exchange regulations.

9.1.3 SITE may, without prior consent, disclose their participation in the Study (but only with respect to the indication, treatment period, and number of Study subjects enrolled) and may disclose SPONSOR as the source of funding for the Study as well as the Protocol title as necessary to comply with regulatory, academic, and governmental reporting requirements. SITE, will not issue and will ensure the Study staff will not issue, any information or statement to the press or public, including but not limited to advertisements for the enrolment of Study subjects, without, where appropriate, the review and prior written consent of SPONSOR.

9.2 Nothing in this Article 9 shall be construed as prohibiting SPONSOR from submitting reports with respect to the Study to a governmental agency as required by law.

ARTICLE 10: Data Protection and Privacy

10.1 SITE, shall undertake to insure:

10.1.1 that data obtained from the Study subjects in connection with the Study is utilized for no purposes other than as outlined in the Protocol and that SITE shall cause such data to be managed in accordance with Applicable Law;

10.1.2 compliance with Applicable Law on the protection of individuals with regard to the processing and free movement of personal data;

10.1.3 that all Study subjects are properly informed that the data collected from them may be considered personal data and to obtain from such Study subjects written consent to the processing, disclosure, and transfer of this data by SITE and SPONSOR;

10.1.4 to provide information as requested by SPONSOR, to authorize the processing and storage of certain personal identifying information and data concerning a Study patient and other site personnel involved in the Study for the purpose of fulfilling legitimate business requirements relating to the Study, meeting regulatory requirements, as well as for the purpose of evaluating SITE for inclusion in future studies; and

10.1.5 to obtain the consent of Study team members and all other personnel involved in the Study for the processing of their personal data as required by Applicable Law.

ARTICLE 11: Subject Injury Reimbursement

11.1 In accordance with Applicable laws, as amended from time to time, SPONSOR shall reimburse Institution for all reasonable and necessary medical expenses for the diagnosis, care and treatment of any injury to a Study patient directly resulting from Study patient's participating in the Study ("**Subject Injury**"); provided, however, that: (i) the Subject Injury or illness was not caused by Investigator/Institution's deviation from the Protocol, Applicable Law, or other written instructions provided by SPONSOR (except for medically necessary deviations); (ii) the Subject injury or illness was not caused by the negligence or misconduct of the SITE and/or SITE staff; (iii) the Subject injury or illness is not attributable to the natural progression of any underlying illness, any pre-existing abnormal medical

condition or underlying disease of the Study patient, or treatment that would have been provided to the Study patient in the ordinary course of treatment notwithstanding participation in the Study; (iv) the injury or illness was not covered by the Study patient's medical or hospital insurance, or any similar third-party payer providing such medical or hospital coverage; (v) the Subject injury or illness was not directly attributable to a failure of the SITE any of its personnel conducting the Study to adhere to the terms of the Protocol, directions of the SPONSOR, or Applicable Law pertaining to the administration of the Study; (vi) the injury or illness is not attributable to the Study patient's deviation from the reasonable direction of SITE, Study personnel or the Study patient's physician.

11.2 This provision shall survive the expiration of termination of this Agreement.

ARTICLE 12: Termination

12.1 Performance under this Agreement may be terminated by SPONSOR for any reason or no reason upon thirty (30) days written notice to SITE. Performance may be terminated upon thirty (30) days prior written notice by SITE if circumstances beyond its control preclude continuation of the Study. However, termination of this Agreement shall not relieve SITE of its obligations under Articles 5, 6, 7, 8 and 9 of this Agreement. Other than in cases of termination for breach of this Agreement by SPONSOR, SPONSOR shall make all payments due hereunder to SITE for actual costs, non-cancellable commitments incurred in the performance of the research, which have accrued up to the date of such termination, or, in case of a termination of this Agreement up to the date of receipt of such final rejection. Should Institution have received higher payments than the payments due according to the work already performed, Institution shall reimburse the balance to SPONSOR.

12.2 Performance under this Agreement may be terminated by SPONSOR or SITE immediately upon written notice without any further action or notice by either Parties, in the event (a) SITE ceases operations, is insolvent or unable to pay its debts when they become due; (b) of negligence or wilful misconduct by SITE or its employees, contractors or agents which impacts or reasonably may impact the Study; (c) SITE's breach of this Agreement, or obligation and/or warranty hereof; (d) for reasons related to Study patient safety as determined by SPONSOR; (e) the Principal Investigator ceases or is unable to serve and a successor acceptable to SPONSOR cannot assume his/her duties within a reasonable period of time; (f) in case any regulatory or legal authorization necessary for the conduct of the Study is finally rejected; (h) in the event that Principal Investigator becomes debarred, threatened with debarment or any similar proceeding, is excluded from being able to participate in any such Study, and/or utilizes the services of a third party directly or indirectly in order to perform obligations related to the activities under this Agreement that has been debarred, threatened with debarment or any similar like proceeding.

12.3 Except as otherwise provided above, where either Party fails to perform any of its material non-monetary obligations under this Agreement, and does not cure such breach within thirty (30) days of receipt of written notice of such default, then the non-defaulting Party, at its option, may terminate this Agreement by giving written notice of termination to the defaulting Party. In such event, this Agreement shall terminate on the date specified in such notice.

12.4 Upon completion, termination (early or otherwise), suspension or discontinuation of the Study or upon the request of SPONSOR; SITE will immediately stop screening and enrolling Study subjects, and subject to the protection of the safety and welfare of Study subjects, cease Study activities and complete its normal Study completion responsibilities in an orderly and safe manner, of which shall include but is not limited to: (i) cooperate promptly and diligently in an orderly and safe manner, in the wind down of the Study, including, without limitation, discontinuing the Investigational Product as soon as medically appropriate, allowing SPONSOR access to records and facilities for Study close-out procedures, requiring Investigator to complete any actions required by the role of Investigator, and transferring to SPONSOR all Study data and, if applicable, the administration and conduct of the Study; (ii) allowing SPONSOR access to records and facilities for Study close-out procedures, and requiring Investigator to complete any actions required by the role of Investigator; (iii) returning all unused supplies associated with the Study to SPONSOR or the appropriate facility with the exception of Investigational Product which shall be returned to SPONSOR; and (iv) Immediately delivering to the SPONSOR, all Confidential Information, except for copies to be retained in order to comply with Institution's archiving obligations or for evidential purposes.

ARTICLE 13: Liability/Indemnification/Insurance

13.1 **SPONSOR**.SPONSOR shall be liable for and agrees to indemnify and hold SITE harmless from and against, any and all any/all claims, damages, liabilities and losses (including reasonable attorney's fees and expenses) (collectively, "**Losses**") arising out of SPONSOR's negligent act, omission or wilful misconduct.

13.2 **Institution**. Institution shall be liable for, and agrees to indemnify and hold the SPONSOR harmless from and against, any and all Losses caused by or attributable to SITE's (including principal Investigator), and/or any of its affiliates, subsidiaries, employees (including sub-investigators), officers, directors, contractors, sub-contractors, consultants or agents (collectively, "**Representative(s)**"): (i) negligent acts, omissions, wilful or intentional and/or professional malfeasance or misconduct of any Representative(s) involved in the Study; (ii) actions by the any Representative that is contrary to this Agreement, the Protocol, or other written instructions provided to an Institution Representative(s) by SITE; (iii) any unauthorized warranties relayed by any such Representative(s) to a third party concerning the Study Drug; and/or (iv) the failure of Institution Representative(s) to obtain the appropriate informed consent.

EXCEPT WITH RESPECT TO A PARTY'S INDEMNIFICATION OBLIGATIONS IN SECTIONS 13.1 AND 13.2, NEITHER PARTY SHALL BE LIABLE FOR ANY SPECIAL, INCIDENTAL, PUNITIVE, INDIRECT OR CONSEQUENTIAL DAMAGES OF ANY KIND, INCLUDING LOST PROFITS, WHETHER OR NOT A PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS OR DAMAGE.

13.3 **Insurance**. Institution represents that it will maintain general and professional liability insurance (malpractice) and if applicable, workers' compensation insurance, covering SITE's liability and the liability of its employees (including, Investigator and sub-investigator(s)) and its trustees, officers, agents, or directors, in amounts sufficient to adequately cover its obligations hereunder. Institution shall maintain such coverage for the duration of this Agreement and if the policy is claims-made, for two (2) years thereafter. Institution will provide evidence of all such coverage upon request. Institution will notify SPONSOR within twenty (20) days of any notice of cancellation, non-renewal, or material change in its insurance coverage.

13.4 The obligations described in this Section 13 shall survive the expiration or termination of the Agreement.

ARTICLE 14: Miscellaneous

14.1 **Assignment and Succession**

This Agreement and the rights and obligations hereunder granted to and undertaken by SPONSOR may be assigned by SPONSOR without prior written approval of SITE. Neither this Agreement, the obligations hereunder nor the rights granted to the SITE under this Agreement shall be assignable or otherwise transferable by the SITE without the prior written consent of SPONSOR. Any such assignee of the SITE shall be bound by the terms hereof as if such assignee were the original party hereto. Any assignment in violation of this provision shall be deemed null and void and of no effect.

This Agreement shall be binding upon and inure to the benefit of the Parties hereto, SPONSOR's assigns, successors, trustee(s) or receiver(s) in bankruptcy, and legal representatives and SITE'S permitted assigns, personal representatives, successors and trustee(s), or receiver(s) in bankruptcy. No assignment shall relieve either Party of the performance of any accrued obligation that such Party may then have under this Agreement.

14.2 **Independent Contractor Status**

In the performance of this Agreement the Principal Investigator and Institution shall be independent contractors with respect to SPONSOR. SITE is authorized to act as the agent for SPONSOR. SPONSOR shall not be bound by the acts of the SITE

14.3 **Notices**

Any notices concerning the administration of this contract which are required or permitted by this contract shall be delivered by hand, sent by mail, or by facsimile to the following Party:

To INSTITUTION at:
Rev. Fr. Richard Aloysius Coelho
Address: Father Muller Charitable Institutions, Fr. Muller Road, Kankanady,
Mangalore -575002, Karnataka.
Telephone: 0824-2238464
Attention : Director

To PRINCIPAL INVESTIGATOR at:
Dr. Jacintha Martis
Address : Professor, Department of Dermatology, Venereology and Leprosy, Father Muller Medical College Hospital, Fr. Muller Road, Kankanady,
Mangalore -575002, Karnataka.
Telephone: 0824- 2238261

To SPONSOR at:
Clinical & Medical Operations, Clinical Management
Dr. Reddy's Laboratories Limited,
IPDO, New Admin Block, Bachupally
Telephone:
Attention: Head Clinical & Medical Operations

With a copy to:

Dr. Reddy's Laboratories, Limited
8-2-337, Road No. 3, Banjara Hills
Hyderabad, Telangana 500034 (INDIA)
Fax: +91 40 4900 2999
Attention: The General Counsel

Or to such other address for either Party as is subsequently specified in writing.

14.4 **Applicable Law and Dispute Resolution**

This Agreement shall be governed in accordance with the laws of India. In the event the Parties are unable to mediate their dispute to a satisfactory resolution, the Parties agree that the dispute shall be exclusively settled by in accordance with the rules of arbitration under the Arbitration and Conciliation Act, 1996 as in effect on the Effective Date of this Agreement (the "**Arbitration Rules**"). The seat of arbitration will be Hyderabad, India. The language of the arbitration will be English. Each party will bear its own expenses in the arbitration and will share equally the costs of the arbitration; provided, however, that the arbitrators may, in their discretion, award costs and fees to the prevailing Party. Judgment upon the award may be entered in any court having jurisdiction over the award or over the applicable party or its assets.

14.5 **Impossibility and Waiver**

In the event that any further lawful performance of this Agreement or any part thereof by any Party hereto shall be rendered impossible by or as a consequence of any law or administrative ruling of any government, or political sub-division thereof, having jurisdiction over such Party, such Party shall not be considered in default hereunder by reason of any failure to perform occasioned thereby.

No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or of any other term, provision or condition of this Agreement.

14.6 **Amendment**

14.6.1 New or additional Services, or amendments to the Services, must be agreed by the parties in writing and documented in writing ("**Change Order**").

14.6.2 SPONSOR may remove any existing agreed Services with at least30days' written notice to the SITE. Once notice has been properly given, the Agreement is deemed to be amended in accordance with that notice. If SPONSOR removes Services under this Article, SPONSOR will pay for reasonable substantiated costs actually incurred and/or that are non-cancellable at the date of removal, up to a maximum of the Fees that would otherwise have been payable.

14.6.3 The SITE acknowledges that, where the Study is part of a multi-site Study, SPONSOR' objective is to recruit a set number of Study Subjects across all Study sites. SPONSOR may, at its discretion, amend the number of Study Subjects required to be enrolled for participation in the Study, in order to achieve this objective. This may be reflected in a removal of or amendment to the Services.

14.6.4 Where the Services are amended in any way, the parties will agree on the changes, if any, to the Fees related to those Services which are required.

14.7 **Force Majeure**

Any delays in or failure by either Party in performance of any obligations hereunder shall be excused if and to the extent caused by such occurrences beyond such party's reasonable control, including but not limited to acts of God, strikes, or other labour disturbances, war, whether declared or not, sabotage, and other causes, whether similar or dissimilar to those specified which cannot reasonably be controlled by the party who failed to perform.

14.8 **Conflict between Agreement and Protocol**

If the event provision of this Agreement conflicts with a provision of the Protocol relating to the conduct of the Study, the Protocol shall take precedence on matters of medicine, science and Study conduct. This Agreement takes precedence in any other conflicts.

14.9 **Third Party Beneficiaries**

Notwithstanding any other provision in this Agreement to the contrary, the Parties agree that the SPONSOR is an intended third-party beneficiary of any Agreement(s) between the SITEand third parties and shall have the full right to enforce any and all obligations owned to it as through it were a party to those Agreements.

14.10 **Severability**

The provisions of this Agreement shall be deemed severable. Therefore, if any part of this Agreement is rendered void, invalid or unenforceable; such rendering shall not affect the validity and enforceability of the remainder of this Agreement unless the part or parts which are void, invalid or unenforceable as aforesaid shall substantially impair the value of the whole agreement to either Party.

14.11 **Integration and Amendment**

This Agreement sets forth the entire agreement between the Parties and merges all prior communications relating to the subject matter contained herein and may not be modified, amended or discharged except as expressly stated in this Agreement or by a written agreement signed by the Parties hereto.

14.12 **Warranties**

SITE, for itself and its officers and directors, warrant and represent that they: (a) possess the necessary resources, skills, expertise, equipment and infrastructure, and training to perform the Study professionally and competently; (b) are familiar with current Applicable Law and regulations related to the Study, and maintain a program for regularly updating their familiarity and compliance with such Applicable Law and regulations; (c) are licensed and in good standing with all necessary and appropriate government agencies; (d) have never been disciplined or debarred by any government agency; (e) have never been convicted of an offence which prohibits them from performing the Study; (f) are not currently the subject of any regulatory, civil or criminal investigation; and (g) shall maintain and provide evidence upon request comprehensive general liability insurance, professional liability insurance and worker's compensation insurance.

14.13 **Third Party Beneficiary**

The Parties acknowledge and agree that SPONSOR is an express, intended third party beneficiary of any Agreements SITE will enter for the purpose of this Agreement.

14.14 **Counterparts**

This Agreement may be executed in any number of counterparts, each of which counterparts, when so executed and delivered, shall be deemed to be an original, and all of which counterparts, taken together, shall constitute one and the same instrument. Facsimile and PDF signatures shall be treated as original signatures.

14.15 **Headings**

Headings are used in this Agreement for convenience only and shall not affect any construction or interpretation of this Agreement.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed in duplicate as of the date and year first above written.

For DR. REDDY'S LABORATORIES LIMITED,	**For FATHER MULLER CHARITABLE INSTITUTIONS**	**For PRINCIPAL INVESTIGATOR,**
Authorised Signatory	**Authorised Signatory**	**Authorised Signatory**
Name: Dr Ramesh Jagannathan	Name: Rev. Fr. Richard Aloysius Coelho	Name: Dr. Jacintha Martis
Designation: Director & Head	Designation: Director	Designation: Professor
Place: Hyderabad	Place: Mangalore	Place: Mangalore
Department: Clinical Development	Institution: Father Muller Charitable Institutions, Fr. Muller Road, Kankanady, Mangalore - 575002	Department: Dermatology, Venereology and Leprosy, Father Muller Medical College Hospital, Fr. Muller Road, Kankanady, Mangalore - 575002
Witness		
Name:		
Designation:		
Finance		
Name:		
Designation:		
Legal		

Dr.Reddy's

ANNEXURE –1
STUDY

1. Title :A Clinical Trial Study to evaluate "**A Phase 2, Multicenter, Randomized, Double blind, Comparative Study to evaluate the reduction in incidence of scarring in acne vulgaris subjects treated with combination of Benzoyl peroxide (2.5%/5%), Zinc oxide and Polysiloxanes compared to Benzoyl Peroxide (2.5%/ 5%)".**

2. **Key information about the Study**

Primary & Secondary Objective: To evaluate the safety and efficacy of Lorcaserin in comparison to placebo in the treatment of Obesity.

Study Name: Benzoyl peroxide (2.5%/5%), Zinc oxide and Polysiloxanes
*Protocol Number:*DRL-INDG04-BPO/2016

3. **Study Fees**

PAYMENT TERMS AND SCHEDULE

1. **Estimated Expenses for 20# completed patients***

Sr. No	Particulars	Unit Costs (In INR)	No. of patients	No. of visit/months	Total Amount (in INR)
1	Investigator Consultancy Charges	Rs 1500	20	8	240000
2	Research Assistant Charges	Rs 12000	-	10 months	120000
3	Photographic Evaluation	Rs 300	20	8	48000
4	Patient Conveyance	Rs 500	20	8	80000
5	Screening Failure Charges (Assuming SF@ 05 patients) Consultation Charges	Rs 1500	05	-	7500
6	Fax, Telephone, Stationery, Courier	Rs 1000		10 months	10000
9	Institutional overhead charge (15 % from Sr. No 1& 2)				54000
10	**Total Cost of the Project for the 20*** completed Patients**				**559500**

2. **Payment Schedule:**

The agreed payment schedule is as follows.

Instalment	Milestone of Payment
1st	15% of estimated total as Advance payment
2nd	15% of estimated total after 5 patients are enrolled.
3rd	15% of estimated total after 10 patients are enrolled.
4th	15% of estimated total after 20 patients are enrolled.
Balance amount	On receipt of last completed case record form.

The final balance amount payable will be calculated on the basis of the actual number of patients who complete the Clinical trial

*The dropouts will be paid at actuals for Investigator Consultation charges, Patient Conveyance and Photographic charges upto the point of dropout.

** Research Assistant will be paid a fixed amount, whereas the investigators will be paid compensation per patient/per visit

*** If there are less number of patients enrolled in the study, payment will be made paid according to prorata basis.

In case extra patients (more than 20 patients) are recruited in this clinical trial at the request of sponsor, additional payment will be made on pro rata basis for Investigator Consultation charges, Photographic charges and Patient Conveyance (as applicable).

@ Screening failures will be paid at actuals for one time consultation charges.

3.	If Any amendment in the protocol or any other documents which require Responsible Ethics Committee approval it will be charged as additional cost;
4.	In the event of pre-termination/closeout of the project, professional fees will be paid based on the milestone achieved up to the termination with pro-rata adjustment;
5.	Services tax and VAT will be charged additionally as per the prevailing rates;
6.	Any government approvals/Notification required for the study other than EC approvals shall be obtained by the Dr. Reddy's Laboratories Ltd. Limited.;

Please provide the following details for future payments:

1. Cheques should be issued in favour of **"Father Muller Research Centre"**
2. Name of the bank: Syndicate Bank
3. Branch: Father Muller Charitable Institution Branch, Mangalore
4. Bank Account No.:02392160000136

Statutory Details:

PAN No.AAATF0345D(Scan/ Xerox copy of Pan Card to be enclosed)

MEMORANDUM OF AGREEMENT

BETWEEN

INTI INTERNATIONAL EDUCATION SDN. BHD.
(Co No: 328838-A)
("INTI")

AND

FATHER MULLER MEDICAL COLLEGE AND HOSPITAL
(HOSPITAL)

Dated on the 26th of NOVEMBER 2015

IN WITNESS WHEREOF the parties hereto have hereunto set their hands the day and year first above written.

SIGNED by

on behalf of **INTI INTERNATIONAL EDUCATION SDN. BHD.** (Co No: 328838-A)

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)
)

Rohit Sharma
Chief Executive Officer
INTI Universal Holdings Sdn Bhd

In the presence of

.....

Puvan Balachandran
Senior Vice President
Products & Partnership Management

SIGNED by

on behalf of **Father Muller Medical College Mangalore**, India.

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)
)

REV. FR PATRICK RODRIGUES
Director
FATHER MULLER CHARITABLE INSTITUTIONS
Fr Muller Road, Kankanady
Mangalore-575 002

In the presence of

.....

Name:
Designation:

Schedule

ITEM	MATTER	PARTICULARS
1.	Name and Particulars of HOSPITAL	FATHER MULLER MEDICAL COLLEGE AND HOSPITAL, Kankanady, Mangalore, Karnataka, India.
2.	Expiry Date	Five (5) years from the Commencement Date.

ગુજરાત गुजरात GUJARAT

AW 144838

નંબર : ૮૦૧૦ રૂ. ૧૦૦
તારીખ: ૧૬ માહે ૦૫ ૨૦૧૬
નામ : TORRENT PHARMACEUTICALS LIMITED
ઠેકાણું : (RESEARCH & DEVELOPMENT CENTRE)
AIRPORT GANDHINAGAR HIGHWAY,
VILLAGE : BHAT
આઈ.ડી. પ્રુફ નં. DIST. GANDHINAGAR-382 428. (GUJ.)
ચિરાગ લક્ષ્મણભાઈ સ્વાદીયા
લા. નં. એસ.બી. /૩૦૦/૩૦૧/૧૯૯૬
અમદાવાદ નારણપુરા વિસ્તાર નાં સહિંદી
લેનારની સહી

CLINICAL TRIAL AGREEMENT

This **CLINICAL STUDY AGREEMENT** (hereinafter "Agreement") shall be effective as of 21st Day of May, 2016 (the "Effective Date"), and is made by and between

TORRENT PHARMACEUTICALS LIMITED, a company incorporated under the Companies Act, 1956 and having its registered office at Torrent House, Off Ashram Road, Ahmedabad-380 009, Gujarat, India and also having its Research Centre at Village Bhat, Gandhinagar-380 428, Gujarat, India (hereinafter referred to as the **"SPONSOR"** and whose expression shall unless revoked be deemed to include its successors, legal representatives, executors, administrators, assigns, subsidiaries, affiliates and related entities) And

Rev. Fr. Patrick Rodrigues, Director, Father Muller Charitable Institution through its unit Father Muller College and Hospital, Kankanady, Mangalore – 575 002, Karnataka (hereinafter referred as **"Institution"**) And

TORRENT PHARMACEUTICALS LTD. Torrent PHARMA AHMEDABAD

ગુજરાત ગુજરાત GUJARAT

AW 144839

નંબર : 1019 રૂ. 900

તારીખ: 13 માહે 07 ૨૦૧૬

નામ : TORRENT PHARMACEUTICALS LIMITED

ઠેકાણું : (RESEARCH & DEVELOPMENT CENTRE)
AIRPORT GANDHINAGAR HIGHWAY,
VILLAGE : BHAT
DIST. GANDHINAGAR-382 428. (GUJ.)

આઈ.ડી. પુફ નં.

ચિરાગ લક્ષ્મણભાઈ સ્વાદીયા

લા. નં. એસ.બી./300/301/૧૯૯૬

અમદાવાદ નારણપુરા વિસ્તાર નાં સબંદી

લેનારની સહીઃ

Dr. Ramesh Bhat, DVD, MD, DNB having principal place of work at Father Muller College and Hospital, Kankanady, Mangalore – 575 002, Karnataka (hereinafter referred to as **"Investigator"**)

SPONSOR, Investigator and Institution are hereinafter individually referred to as the "Party" or collectively as the "Parties", as the case may foresee.

NOW

WHEREAS, the SPONSOR is a pharmaceutical company involved in the research, development, manufacture and sale of medicines for use in humans;

WHEREAS, the Investigator has the requisite expertise and resources for providing clinical trial services and research services, and other services for the pharmaceutical industry;

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WHEREAS, the Institution has the necessary infrastructure and resources to carry out clinical trial services.

WHEREAS the SPONSOR wishes to engage the Investigator for clinical trials and other related services to have researched and developed its compound/ drugs (IMP as defined here under) and the SPONSOR wishes to engage the Institution so that its infrastructure can be utilized with respect to the clinical trials and other related services.

DEFINITIONS

When used in this Agreement the terms set forth below shall have the meanings as indicated below:

Adverse Event
All such medical occurrences in a Subject, as has been specified in the Protocol, resulting directly from usage of the IMP (as defined hereunder).

Affiliate(s)
Any other entity, whether de jure or de facto, which directly or indirectly controls, is controlled by, or is under common control with, such Party. A business entity or Party shall be regarded as in control of another business entity if it owns, or directly or indirectly controls, at least fifty percent (50%) (or such lesser percentage which is the maximum allowed to be owned by a foreign entity in a particular jurisdiction) of the voting stock or other ownership interest of the other entity, or if it directly or indirectly possesses the power to direct or cause the direction of the management and policies of the other entity by any lawful means whatsoever.

Agent/Representative
"Agent/Representative" shall mean any individual who is officially authorized by SPONSOR to do work on behalf of SPONSOR.

Applicable Law
"Applicable Law" shall mean all applicable laws, rules, and regulations and any applicable policies of any relevant authority, including, but not limited to, any Regulatory Authority, that maybe in effect from time to time, including but not limited to, guidance, guidelines, regulations, directives, rules and standards relating to the conduct of clinical studies, the use of investigational drugs in humans, and good clinical, good laboratory and good medical practice, ethical principles acceptable to the world community for the conduct of clinical trials, and the mandates of any relevant review board.

Budget
"Budget" shall mean an estimate of the agreed costs for Services and as provided in Annexure-2 to the Agreement.

Clinical Trial
"Clinical Trial" shall mean the investigation of the IMP (as defined hereunder) conducted on the Subject at the Trial Site/s in accordance with the specific Protocol and for the study code: CT/CLOB/PSO/16 and titled "A multicentric, open label, randomized, active controlled, parallel design study comparing -efficacy and safety of clobetasol foam vs. clobetasol lotion in patients with mild to moderate plaque type psoriasis. ."

CRF
"CRF" shall mean the document designed in consonance with the Protocol to record data and other information of each Subject. The CRF is required to be filled by the Investigator for each Subject, the format of which is attached as Annexure - 5 to this Agreement that shall include all the latest amendments to the CRF, unless otherwise specified.

DCGI
"DCGI" shall mean the Drugs Controller General of India

Disclosing Party
For the purpose of this Agreement the Party disclosing the Confidential Information will be referred to as the "Disclosing Party".

TORRENT PHARMACEUTICALS LTD.

Ethics Committee
"Ethics Committee" shall mean the independent review board or Institutional Ethics committee comprising of medical / scientific and non-medical / non-scientific members, whose responsibility, amongst others, is to approve the conduct of Clinical Trial including Protocol, verify the protection of the rights, safety and well-being of Subjects involved in the Clinical Trial which is being carried out by the Investigator, etc.

GCP
"GCP" shall mean the regulations and guidelines established by the Declaration of Helsinki, the International Conferences on Harmonization (ICH) and the regulating bodies of countries and economic affiliations world wide that set the standards of good clinical practice for trials of medicinal products in human beings.

Informed Consent
"Informed Consent" shall mean consent obtained from a Subject that complies with guidelines established by the Declaration of Helsinki, International Conference of Harmonization (ICH), and all the applicable laws, guidelines, or standards, governing the participation of Subject in trials.

Intellectual Property Rights
"Intellectual Property Rights" shall mean patents, trademarks, copyrights, rights to extract information from a database, design rights and all rights or forms of protection of a similar nature or having equivalent or similar effect to any of them which may subsists anywhere in the world, whether or not any of them are registered and including applications for registration of any of them.

Interim Report
"Interim Report" shall mean those summaries of data developed during the Clinical Trial in order to make the in-process described in the Protocol.

Investigational Medicinal Product (IMP)
"Investigational Medicinal Products" shall mean the Drugs being tested/ developed and for this Clinical Trial is Test Product : Clobetasol propionate Foam 0.05% & Comparator Product : Clobetasol propionate lotion 0.05%.

Key Clinical Trial Personnel
"Key Clinical Trial Personnel" shall mean any personnel or employee or staff of the Investigator responsible for the implementation of the Clinical Trial and Services including, but not limited to, the sub-investigator, operational contract/ project or Trial Site manager, clinical research co-ordinators, phlebotomist, nurse and medical writer or other similar titles.

Know How
"Know How" shall mean all technical and other information which is not in the public domain, including but not limited to information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, invention, methods, models, procedures, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, clinical data, manufacturing data and information contained in submissions to regulatory authorities.

Monitor
"Monitor" shall mean one or more persons appointed by the SPONSOR to monitor compliance of the Clinical Trial with ICH GCP as well as Protocol and to conduct source data verification.

Protocol
"Protocol" shall mean the description of the Clinical Trial as provided under Annexure - 4 and shall include, unless otherwise specified, all the latest amendments to the Protocol which have been intimated/ notified to or permitted by DCGI, as required under Applicable Law.

Receiving Party
For the purpose of this Agreement the Party receiving confidential information shall be referred to as the "Receiving Party".

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Regulatory Agency (ies)
"Regulatory Agency (ies)" shall mean all agencies, including DCGI or an office nominated by him, having jurisdiction to regulate, audit or otherwise review the research process, administration or facilities used in the conduct of the Clinical Trial and/or its results.

Service(s)
Services are any and all drug investigation, conceptual, consultancy, analytical, pharmaceutical, clinical & non-clinical and regulatory activities and their related sub-activities relating to the research and development of the SPONSOR's IMP as entrusted to the Investigator and as provided under the Agreement. The details of Services are provided under Annexure-1 to this Agreement.

Start Up Meeting
"Start Up Meeting" shall mean a meeting to train the Investigator(s) and their Staff(s) on the conduct of the Clinical Trial.

Subcontractor(s)
"Subcontractor" shall mean any and all entity selected by Investigator to perform specific Services, or contributions to the provision of Services as contracted to Investigator by SPONSOR under this Agreement.

Subjects
"Subjects" shall mean the volunteers (healthy or patient) who participate in the Clinical Trial.

Third Parties
"Third Parties" shall mean any person/s or legal entity (ies) other than the SPONSOR, Institution and the Investigator, their respective personnel and consultants.

Timelines
"Timelines" shall mean the dates set out in the Annexure - 3 and as amended from time to time under mutual agreement by the Parties and Timeline shall mean any one of such dates.

Trial Site(s)
"Trial Site(s)" shall mean the premises of the Institution having the address as set out above, where the Clinical Trial is being conducted.

Work Product
"Work Product" shall mean collectively all documentation, reports, records, data, or specimens generated in connection with the Services by Investigator under this Agreement for the SPONSOR.

1. Scope of the Agreement

1.1 Pursuant to this Agreement, the SPONSOR appoints the Investigator to provide the Services subject to the terms and conditions set forth herein. The SPONSOR grants to the Investigator the non-exclusive, free of charge, non-transferable and non-sublicenseable, if not agreed otherwise, right to use the IMP, for the purpose of the Services.

1.2 The Annexures to the Agreement, includes as appropriate and amongst others, specific details of the Services agreed between the Investigator and the SPONSOR are provided under Annexure the Protocol, Timeline, Budget and payment schedule and CRF format.

1.3 The Services covered by this Agreement may include, without limitation, expert consultation, clinical trial services, project management, laboratory services, and other research and development services requested by SPONSOR and agreed to by Investigator as set forth in the Annexure - 1. The Parties agree that the Institution shall be responsible for providing necessary infrastructure facilities and resources for carrying out Services in relation to Clinical Trial by the Investigator under this Agreement.

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2. Investigator

The Investigator warrants and represents as follows:

a) He (for the purpose of this Agreement, the term 'he' & 'his/him' shall include 'she' & 'her' respectively) has the necessary qualification, expertise and resources to perform the Clinical Trial and Services mentioned hereunder.

b) He is free to participate in the Clinical Trial and there are no rights which may be exercised by or obligations owed to any Third Party which might prevent or restrict his performance of the obligations detailed in this Agreement.

c) He is not involved in any regulatory or misconduct litigation or investigation by the food and drug authorities, the medicines and healthcare products regulatory agency, or other regulatory authorities in India or outside India which can affect the validity or any other way adversely affect the Services provided under this Agreement. No report/ study produced by him in any previous clinical study has been rejected because of concerns as to its accuracy or because it was generated by fraud.

d) He has considered and is satisfied that facilities to the Clinical Trial are available to him at the Trial Site and that he is supported, and will continue to be supported, by medical and other staff of sufficient number and experience to enable him to perform the Clinical Trial efficiently and in accordance with its obligations under the Agreement.

e) He shall comply with the Drug Controller General (India) / Govt of India order dated 03.07.2014, as amended from time to time and accordingly he shall not be conducting more than two (2) Clinical Trials on the date of initiation of the Study and undertakes not to conduct more than (2) trials during the term of this Agreement,excluding the Study being conducted under this Agreement. Additionally, he shall submit a self-declaration for such representation/ warranty to the Sponsor before initiation of the Study under this Agreement.

3. Clinical Trial Governance

3.1 The SPONSOR shall inform the Investigator of the name and telephone number of the Monitor and the name of the person who will be available as a point of contact. The SPONSOR shall also provide the Investigator with an emergency number to enable Adverse Event reporting at any time.

3.2 The Investigator as well as the Institution shall comply with all laws and statues applicable to the performance of the Services including, but not limited to the Human Rights Act, the Data protection Act, Indian Drugs and Cosmetics Act 1940 and the Indian Drugs and Cosmetics Rules 1945, and the Code of Ethics Regulations, 2002 framed under The Indian Medical Council Act, 1956 and with all relevant guidance relating to medicines and clinical trials from time to time in force including, but not limited to, the ICH GCP, the World Medical Association Declaration of Helsinki entitled 'Ethical Principles for Medical Research involving Human subjects'(2008 version and any further updation thereof from time to time) and the Ethics Committee. The Investigator shall comply with all guidelines from time to time in force. The SPONSOR shall be responsible for obtaining such approvals as are required in India under the provisions of the Indian Drugs and Cosmetics Act 1940 and the Indian Drugs and Cosmetics Rules 1945 including DCGI approval and other applicable law in connection with the manufacture of IMP and the Clinical Trial.

4. Obligations of the Parties

4.1 The Investigator shall be responsible for obtaining and maintaining all approvals from the Ethics Committee for the conduct of the Clinical Trial including approval for Protocol and the Investigator shall keep the SPONSOR fully apprised of the progress of Ethics Committee submissions and shall upon request provide the SPONSOR with all correspondence relating to such submissions. The SPONSOR shall provide the Investigator with such information and documents as may be required by the Ethics Committee in connection with the grant of their consent or otherwise in connection with the Clinical Trial. The Investigator shall not consent to any change in the Protocol requested by the Ethics Committee without the prior written consent of the SPONSOR.

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4.2 On obtaining consent from the Ethics Committee, the SPONSOR shall organize a Start up Meeting with the Investigator before the Clinical Trial is initiated.

4.3 The Investigator shall conduct the Clinical Trial in accordance with:

(i) The Protocol provided under Annexure-4;

(ii) The terms and conditions of the approval of the Ethics Committee and further the Investigator shall ensure that neither administration of the IMP to any Subject nor any other clinical intervention mandated by the Protocol takes place in relation to any such Subject until it is satisfied that all relevant regulatory and Ethics Committee approvals have been obtained; and

(iii)Applicable Law and regulating guidelines and other acceptable ethical and medical considerations.

4.4 SPONSOR shall provide the Investigator with sufficient quantities of the IMP and all the materials and information which the Protocol specifies or which SPONSOR deems necessary or which is desirable to enable the Investigator to conduct the Clinical Trial (including but not limited to information relating to the IMP and possible side/adverse affects, precautions for handling, handling instructions, etc., if any).

4.5 The Investigator and the Institution shall not use or permit use of the IMP or other materials provided by the SPONSOR for any purpose other than the conduct of the Clinical Trial.

4.6 The Investigator shall obtain the Informed Consents from the Subjects who enter this Clinical Trial in the format provided by the SPONSOR and same shall be maintained by the Investigator for record. The process of Informed Consent shall be applicable as per prevailing Rules under Drugs and Cosmetics Act, 1940.

4.7 The Investigator shall recruit Subjects as provided under Annexure-3 in accordance with the Timeline to participate in the Clinical Trial but the enrolment of Subjects shall be on competitive basis. The SPONSOR may amend the number of Subjects to be recruited at its sole discretion as follows:-

(i) SPONSOR may by notice to the Investigator require the recruitment at any Trial Site to cease and the terms of Agreement shall relate thereafter to the number of Subjects who have been accepted for treatment on the date of such notice; or

(ii) SPONSOR may by notice to the Investigator increase the number of Subjects to be recruited by the Investigator.

4.8 In the event, that the Investigator is unable to complete Clinical Trials on account of the fact that the adequate number of Subjects were not available for the conduct of the Clinical Trial in terms of the Agreement within the stipulated TimeLines then, the SPONSOR may, solely at its own discretion, extend the TimeLines for completion of Clinical Trials so as to recruit further Subjects.

4.9 In case, the Investigator is not able to complete the Clinical Trials even on SPONSOR or Investigator exercising the above mentioned options, or the Investigator does not wish to comply with the directions of SPONSOR provided in such Clauses, then, SPONSOR shall be entitled to recover from the Investigator the entire cost/ fees paid/ payable under the Agreement with respect to such Clinical Trial.

4.10 The Investigator shall monitor the Subjects to ensure timely reporting to SPONSOR of all Adverse Events in accordance with applicable regulations and as described in the Protocol. The Investigator shall be responsible for collating Adverse Events and including such data in the study database.

4.11 The Investigator and the Institution shall permit the Monitor access to the records of Subjects for monitoring and source data verification, such access to be arranged at mutually convenient times. The SPONSOR will alert the Investigator promptly to significant issues (in the opinion of the Monitor) relating to the conduct of the Clinical Trial. In the event the SPONSOR reasonably believes there has been any research

misconduct in relation to the Clinical Trial, the Investigator shall provide all reasonable assistance to any investigation into any alleged research misconduct undertaken by or on behalf of the SPONSOR. At its conclusion, the SPONSOR and the Investigator shall review the conduct of the Clinical Trial at the Trial Site.

4.12 The Investigator shall ensure that the clinical samples required to be tested during the course of the Services are tested in accordance with the Protocol and at a laboratory approved by the SPONSOR.

4.13 The Investigator shall:

a) Complete an eCRF for each Patient in accordance with the procedure set out in the Protocol.

b) Review eCRF entries to confirm that they accurately depict the data collected during the Clinical Trial.

c) Promptly submit the eCRF data within 7 working days after actual visit to the Sponsor in accordance with the procedure prescribed in the Protocol.

d) Obtain and maintain record of signed informed consent of individual patients. The process of Informed Consent shall be applicable as per prevailing Rules under Drugs and Cosmetics Act, 1940.

4.14 The SPONSOR shall carry out medical liability insurance for Subjects as required by the relevant rules and regulations applying for the performance of clinical studies and details and evidence of the coverage shall be provided on the Investigator's request, to the Ethics Committee before commencement of the Clinical Trial.

5 Response to Regulatory Actions, Audits & Data Protection

5.1 Notification of Regulatory Actions: Investigator shall notify SPONSOR immediately if any Regulatory Agency (i) contacts Investigator or the Institution with respect to any IMP, (ii) conducts, or gives notice of its intent to conduct, an inspection at Trial Site or (iii) takes, or gives notice of its intent to take, any other regulatory action alleging improper or inadequate research practices with respect to any activity of Investigator, Institution or Ethics Committee, whether or not in connection with the Services. The Investigator or the Institution, as the case may be, shall provide SPONSOR with copies of such notice(s) and related correspondence within three (3) business days of receipt (or sooner if necessary to permit SPONSOR to be present at such visit) and permit SPONSOR representatives to be present at, or otherwise participate in, such inspections or regulatory actions with respect to a Clinical Trial, and the Investigator shall supply SPONSOR with all documentation and information pertinent thereto and provide to SPONSOR any proposed response. All submission required to be made by the Investigator or the Institution shall be with prior approval of the SPONSOR. No submission made by the Investigator or the Institution to any Regulatory Agency shall include any false or misleading information relating to any Clinical Trial, IMP or SPONSOR.

5.2 Under certain circumstances, the Investigator or the Institution may be required by Applicable Law to report unusual adverse findings to appropriate Regulatory Authorities. In the event such a reporting requirement arises in connection with or relating to this Agreement or any matters contemplated thereby, the Investigator as well as the Institution shall (i) comply with its obligation under Applicable Law, (ii) immediately inform SPONSOR of the substance of any such finding, in any event with in twenty-four (24) hours of his first becoming aware of any such finding (iii) should, for any report to be submitted to Regulatory Authority, provide sponsor with a copy of report simultaneously with submission to Regulatory Authority (iv) furnish SPONSOR to comply with its reporting and other disclosure obligations under Applicable law.

5.3 The SPONSOR or his authorized representatives shall have the right, with reasonable advance notice, at SPONSOR's cost, and during regular business hours, to (a) visit the Institution' facilities which is used in the performance of the Services to observe and verify Investigator's compliance with this Agreement and to monitor the conduct of the Clinical Trial under the Agreement, (b) inspect relevant facilities, including, but not limited to, facilities used to store or use an IMP, (c) inspect Work Product relating to the

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Clinical Trial or the Ethics Committee, and all required licenses, certificates and accreditation of Investigator, including but not limited to, training records for personnel assigned to perform the services,(d) interview any and all Investigator personnel, including, but not limited to, any Key Clinical Trial Personnel, and (e) audit any recordkeeping, data collection and processing, information and other systems and business processes used by Investigator in the performance of the Services under the Agreement. In the event the security requirement of Investigator's or the Institution's other clients' conflict with the visits of SPONSOR's representatives, a compatible visitation schedule shall be promptly negotiated in good faith by SPONSOR and Investigator or the Institution, as the case may be. The Investigator and the Institution shall cause its employees to, cooperate with any and all activities contemplated by this clause and shall ensure timely access to requested facilities and documentation.

5.4 The Investigator as well as the Institution confirms and undertakes that it will act in accordance with data protection legislation and that all data in its possession being the subject of this Agreement will be securely stored and will also be kept confidential under the terms of clause 11 of this Agreement. The Investigator shall keep full, accurate and up to date records on all the Subjects and shall maintain all records of Work Product unless provided otherwise. The Investigator and Institution further confirms that it will only act on instructions given by SPONSOR relating to such data. The Investigator shall obtain the consent from the Subjects who enter this Clinical Trial to take part in the study, to process their personal data and for their personal data to be processed by SPONSOR or any other SPONSOR group company or company working for or with SPONSOR. The Investigator shall indemnify SPONSOR against any claims arising from any breach by the Investigator or the Institution of this Clause.

6. Subcontracting

In the pursuance of this present Agreement, the Investigator may be required to seek the assistance of specialised entities to assist the Investigator in the performance or procurement of a Service, or part of a Service. If Investigator wishes to engage Third Parties to become Subcontractors he shall disclose such intention to the SPONSOR and shall only engage any Third Party after written consent of the SPONSOR, which consent shall not be unreasonably withheld. Investigator shall be entitled to grant a sub-licence under the Intellectual Property of the SPONSOR - only to the extent necessary - to the Subcontractor for such Subcontractor to be able to perform or procure the Service(s), or any part of such Service and Investigator to share any Confidential Information or other Clinical Trial related information with such Subcontractor provided that the Investigator shall not be entitled to grant to Subcontractor the right to grant any sub-licence under the SPONSOR's Intellectual Property. The Investigator represents and warrants that Subcontractors shall follow and observe all responsibilities which are afforded to the Investigator under this Agreement, including but not limited to, confidentiality and ownership rights of data and information and inventions. The Investigator shall be wholly responsible for the acts and omissions of a Subcontractor.

7. **Insurance:** For the duration of this Agreement each Party will maintain, where necessary, insurance in an amount reasonably adequate to cover its obligations hereunder, and, upon request, each Party will provide to the other Party a certificate of insurance showing that such insurance is in place.

8. Indemnity

8.1 SPONSOR shall indemnify Investigator, its personnel and staff (hereinafter collectively "Investigator Representatives") for any and all damages, costs, expenses and other liabilities, including reasonable attorney's fees and court costs, incurred cost by or attributed to the IMP dispensed or administered or data submitted in accordance with the provisions of this Agreement, provided, however, SPONSOR shall have no indemnification obligation hereunder with respect to any claim, action or proceeding arising from:

a) a negligence, misconduct, malpractice, or improper statement or act of the Investigator, and Investigator Representatives;

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b) breach by Investigator of any of its obligations under this Agreement including deviation from the Protocol, non adherence to Applicable Laws by the Investigator with respect to the conduct of the Services as envisaged hereunder;

c) any unauthorized use of the IMP by the Investigator and Investigator Representatives.

Provided further that the SPONSOR's obligations for indemnification shall be subject to the Investigator and Investigator Representatives having strictly adhere to and comply with the Agreement and all recommendations furnished by the SPONSOR for the use and administration of the IMP and Applicable Laws.

8.2 The Investigator shall indemnify SPONSOR, its directors, officers, and employees (hereinafter collectively "SPONSOR Representatives") for any and all damages, costs, expenses and other liabilities, including reasonable attorney's fees and court costs, incurred in connection with any Third Party (including the relevant Regulatory/Statutory Authority and Government/Semi-Government bodies) claim, action or proceeding or otherwise arising from the following:-

(i) Investigator's negligence, malpractice, misconduct, improper acts or omissions of the Investigator and/or the Investigator Representatives or non-compliance in accordance with the Agreement or deviation from the Protocol or unauthorized use of IMP, in the performance of Investigator's obligations hereunder or the instructions of the SPONSOR or

(ii) Non compliance or non adherence of Applicable Law or non-compliance in accordance with the Agreement or

(iii)deviation from the Protocol or

(iv)unauthorized use of IMP,

provided, however, Investigator shall have no indemnification obligation hereunder with respect to any claim, action or proceeding arising from:

a) a negligence or willful misconduct of SPONSOR and SPONSOR representatives.

b) breach of SPONSOR of any of its obligations under this Agreement

8.3 The Institution shall indemnify SPONSOR Representatives for any and all damages, costs, expenses and other liabilities, including reasonable attorney's fees and court costs, incurred in connection with any Third Party (including the relevant Regulatory/Statutory Authority and Government/Semi-Government bodies) claim, action or proceeding arising or otherwise from the Institution's negligence, malpractice, misconduct, improper acts or omissions of the Institution and/or the staff/ representatives of the Institution in the performance of Institution's obligations hereunder or the instructions of the SPONSOR.

8.4 Where a Party is required to provide an indemnity under Clause 8.1, 8.2 or Clause 8.3, that Party shall have the right to take over full care and control of the defence to any claim, action or proceeding by a Third Party, said defence to be at the sole expense of the indemnifying Party. The indemnifying Party shall be entitled to use legal counsel of its choice. The indemnified Party shall keep the other Party fully informed of the progress of any such claim, action or proceeding, will consult fully with indemnifying Party on the nature of any defence to be advanced, and will not compromise or settle any such claim, action or proceeding (whether by admission, statement or payment) nor will it conduct itself in such a way as could prejudice the defence of any such claim, action or proceeding without the written approval of the other Party, such approval not to be unreasonably withheld. Each Party will give the other written notice of any claim, action or proceeding brought against it with respect to any matter to which it may be entitled to indemnification hereunder and each Party will also use its best endeavors to inform the other Party promptly of any circumstances thought likely to give rise to any such claim, action or proceeding. Each Party will give to the other Party such help as may reasonably be required for the conduct and prompt handling of any such claim or proceeding.

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8.5 The SPONSOR, Investigator and the Institution warrant appropriate insurance cover and will provide evidence to the satisfaction of the Party of self-insurance and/or adequate coverage in respect of its potential liability (ies) under clause 8.1, 8.2 or 8.3 above.

8.6 The Ethics Committee shall investigate all indemnification claims arising under this Agreement.

9. Liability

9.1 The Parties agree that a non-defaulting Party may suffer immediate, material, and irreparable damage and harm in the event of any material breach of this Agreement and the remedies at law in respect of such breach may be inadequate (each Party hereby waives the claim or defense that an adequate remedy at law is available) and that such non-defaulting Party shall be entitled to seek specific performance against the defaulting Party for performance of its obligations under this Agreement in addition to any and all other legal or equitable remedies available to it. Any sums payable hereunder by SPONSOR shall be limited to the Agreement value.

9.2 In no circumstances shall either Party be liable to the other in contract, tort (including negligence or breach of statutory duty) or otherwise howsoever arising or whatever the cause thereof, for any loss of profit, business, reputation, contracts, revenues, or anticipated savings for any special, indirect or consequential damages of any nature, which arises directly or indirectly from any default on the part of either Party. Nothing in this clause shall affect the responsibility of either Party in relation to death or personal injury caused by the negligence of that Party or its servants, agents, sub-contractors or employees.

9.3 For the purpose of the indemnity provided in Clause 9.2 above, the expression "agents" shall include, but shall not be limited to, any person providing services to the Institution, Investigator or the SPONSOR under a contract for services or otherwise provided such 'agents' have been mutually agreed upon by the Parties.

10. Medical Confidentiality

The Parties agree to adhere to the principles of medical confidentiality in relation to Subjects involved in the Clinical Trial. The Investigator shall disclose the data required directly or indirectly to satisfy the requirements of the Protocol or for the purpose of monitoring or adverse event reporting. The SPONSOR shall not disclose the identity of Subjects to Third Parties without prior written consent of the Subject, in accordance with the requirement of laws applicable to the protection of individuals' personal data, a copy of which the Investigator shall supply to the SPONSOR on request.

11. Confidential Information & Reporting

11.1 The Receiving Party undertakes to treat in strict confidence any and all information (henceforth "Confidential Information") received from the Disclosing Party, under this Agreement and to use it only for the purpose of this Agreement. This includes any and all information relating to the respective Parties' business, personnel and other scientific information that the Receiving Party may have become aware of. The Receiving Party represents and warrants that it shall protect the Confidential Information received with utmost care and diligence and shall use such degree of care expected to use to protect such Information and which shall not be less than the degree of care used to protect its own Confidential Information from unauthorised use or disclosure .

11.2 The Investigator, Institution and the SPONSOR shall ensure that only those of its officers and employees and/or Subcontractor directly concerned with the carrying out with the subject matter of this present Agreement have access to the Confidential Information on a need to know basis and each Party undertakes to treat as strictly confidential and not to disclose to any Third Party any Confidential Information save where disclosure is required by a regulatory authority or by law or else permitted and not to make use of any Confidential Information other than in accordance with this Agreement without the prior written consent of the other Party.

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11.3 In the event of a Party visiting the establishment of the other Party, the visiting Party undertakes that any further information relating to Investigator's or SPONSOR's operations which may come to the visiting Party's knowledge as a result of any such visit, shall be kept strictly confidential and that any such information will not be disclosed to any Third Party or made use of in any way by the visiting Party without prior written permission of the other Party.

11.4 The obligations of confidentiality set out in the above clauses 11.2 and 11.3 shall not apply to Confidential Information which is (i) published or generally available to the public through no fault of the Receiving Party, (ii) in the possession of the Receiving Party prior to the date of this Agreement and is not subject to a duty of confidentiality, (iii) independently developed/discovered by the receiving Party and is not subject to a duty of confidentiality, (iv) obtained by the Receiving Party from a Third Party not subject to a duty of confidentiality.

11.5 The Investigator will regularly and promptly share with and/or disclose to and/or make available to the SPONSOR all relevant information that has been obtained and/or generated as a result of a Service offered in accordance with the Agreement. The SPONSOR may at any time request such information or up-to-date information. The general procedure anticipates that at latest when the final stage of the Agreement as per the Annexure is reached, the Investigator shall provide to the SPONSOR all the Work Product in the agreed format.

12. Final Result Reports

The SPONSOR shall prepare a report of the data generated as a result of the Clinical Trial conducted at the Trial Site. On the basis of the statistical and clinical evaluation, the SPONSOR in collaboration with the Investigator will prepare a final consolidated report which will be reviewed and signed by the Investigator. The report prepared by the SPONSOR shall be submitted to the DCGI. The Investigator shall sign the report within 48 hours of receipt of the same from SPONSOR. The result of the Clinical Trial and the final deliverables including the CRFs and Work Product submitted by the Investigator to the SPONSOR shall be in accordance with the standards set out in the Protocol.

13. Publicity

The SPONSOR will not use the name of the Investigator, or of any member of the Investigator's staff, or of any of the Subcontractors, in any publicity, advertising or news release without the prior written approval of the Investigator or of the respective Subcontractor, such approval not to be unreasonably withheld. The Investigator or the Institution will not use the name of the SPONSOR nor of any of its employees, in any publicity or reproduce SPONSOR's logo in any form or medium without the prior written approval of the SPONSOR.

14. Publication

The Investigator acknowledges that the IMP under investigation may not have been licensed for the indication described in this Clinical Trial and, accordingly, the information obtained from the Clinical Trial may be of a commercially sensitive nature. The Investigator as well as the Institution shall have no right, therefore, to publish any paper or make any presentation which utilizes data generated under this Agreement without the prior written consent of SPONSOR. At least 30 days before submission for publication (or presentation), all proposed articles and abstracts must be sent to SPONSOR for review and any differences of opinion between Investigator and SPONSOR must be satisfactorily resolved before submission. The Investigator as well as the Institution shall not issue a press release that references any Protocol or Clinical Trial conducted by SPONSOR, or that uses SPONSOR's name or trademarks without the prior written permission of SPONSOR.

15. Intellectual Property and Know How

15.1 All Intellectual Property Rights and Know How:

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(i) owned by the Investigator prior to and after the date of this Agreement, not being the Intellectual Property Rights and Know How in respect hereof other than any intellectual property Rights and Know How arising from, in connection with or as a result of the Clinical Trial is and shall remain the property of the Investigator;

(ii) licensed to the Investigator prior to and after the date of this Agreement, not being the Intellectual Property Rights and Know How in respect hereof other than any intellectual property Rights and Know How arising from, in connection with or as a result of the Clinical Trial is and shall remain the property of the Investigator.

15.2 All Intellectual Property Rights and Know How Owned by or licensed to SPONSOR prior to and after the date of this Agreement other than any Intellectual property Rights and Know How arising out of the Clinical Trial is and shall remain the property of the SPONSOR.

15.3 All Intellectual Property Rights and Know How arising from the Clinical Trial shall vest in or be exclusively licensed to the SPONSOR in accordance with clauses 15.4 and 15.5 below.

15.4 The Investigator hereby assigns its Intellectual Property Rights and to the extent possible all Know How, arising out of the Clinical Trial directly or indirectly, to the SPONSOR and at the request and expense of the SPONSOR, the Investigator shall execute all such documents and do all such other acts and things as the SPONSOR may reasonably require in order to vest fully and effectively all such Intellectual Property Rights and Know How in the SPONSOR or its nominee. The ownership of Intellectual Property Rights other than as resulting directly or indirectly from a Clinical Trial shall be mutually and amicably agreed between the Parties.

15.5 The Investigator shall promptly disclose to the SPONSOR any and all Know How generated pursuant to this Agreement. The Investigator hereby grants to the SPONSOR an exclusive, worldwide, irrevocable, fully paid up, royalty free licence under such Know How to exploit the same, if relating to the IMP.

16. Remuneration

16.1 SPONSOR shall remunerate Institution in accordance with Budget and Payment Schedule attached herewith as Annexure-2. The payment made to the Institution under this Agreement shall be subject to Tax Deducted at Source.

The following shall apply:

a) All payments shall only be made to the Institution by the SPONSOR under this Agreement and shall be made in the name of Father Muller Research Centre wherein Investigator is employed as Senior Consultant Diabetalogist The payment shall be made in the aforementioned name, in lieu of the Services provided by the Investigator and Institution under the Agreement and the same is being made as per the directions of the Investigator.

b) SPONSOR shall pay to the Institution all dues (i.e. all milestones, agreed fees and other costs) as detailed in the Annexure.

c) The Institution shall raise an invoice for each payment due;

d) In no event shall SPONSOR be required to pay any amount exceeding to that specified in Annexure unless otherwise agreed by all Parties in writing. Unless otherwise specified, all fees shall be inclusive of all applicable taxes.

e) The Institution will return to SPONSOR any excess fund received but unearned by return transfer, if not counterbalanced against other dues of SPONSOR.

16.2 If any portion of any invoice is disputed, then SPONSOR shall pay the undisputed amount(s) and the Parties shall use good faith efforts to reconcile the disputed amount as soon as practicable.

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17. Term of the Agreement

This Agreement shall commence on the Effective Date and shall continue till submission of Final Result Report as provided under Clause 12 unless prematurely terminated by either Party in accordance with Clause 18 below. The Parties may agree to extend the term of this Agreement by mutual consent in writing.

18. Premature Termination

18.1 The SPONSOR hereto may forthwith by notice in writing to the Investigator or the Institution, as the case may be, prematurely terminate this Agreement, if an important reason exists, in particular, if:

(i) The Investigator or the Institution, as the case may be, commits any material breach of any of its obligations herein and does not within thirty (30) calendar days from the notice of such breach by SPONSOR remedy the same if capable of remedy;

(ii) The Investigator or the Institution, as the case may be, commits any material breach of its obligations herein which cannot be remedied;

(iii) The recruitment of the Subjects in the Clinical Trial is too slow to meet the agreed TimeLines;

(iv) Adherence to the Protocol is poor or data recording is chronically inaccurate or incomplete

Provided that the SPONSOR may terminate the Agreement in accordance with this clause if the data available indicates that it is not safe to continue to administer IMP on the Subjects.

18.2 The SPONSOR may at any time prematurely terminate this Agreement at its sole discretion in case approval of the competent Ethics Committee and/ or other authorities with respect to the Clinical Trial is not received within a reasonable time. The SPONSOR may also at any time prematurely terminate this Agreement at its sole discretion by serving notice for any reason the SPONSOR deems fit, including but not limited to, reason of the Clinical Trial not being commercially viable, reasons relating to any Adverse Events that may be caused to Subjects based on the IMP, Clause 19 applies.

19. Consequences of Termination

In the event this Agreement is prematurely or orderly terminated, the following consequences shall follow: -

i. The Investigator shall provide the SPONSOR with all the data including Work Product, Final Result Report and CRF in relation to the Clinical Trial relating to the period till the termination of the Agreement. The Investigator reserves a right to retain one copy of all the material provided to SPONSOR as the result of Services performed, which will remain subject to the confidentiality provisions herein, and to be used only if a dispute arises regarding the Services performed by the Investigator hereunder;

ii. All Confidential Information, unused IMP or any other material provided by the SPONSOR shall, at the SPONSOR's option, either be returned to the SPONSOR or disposed of in accordance with the Protocol. Alternatively, at SPONSOR's written request, such materials and Confidential Information may be retained by the Investigator on behalf of SPONSOR for an agreed-upon time period;

iii. In case of a premature termination of this Agreement (except as stated otherwise), save not caused by a contractual violation of the Investigator or the Institution, the Investigator as well as the Institutuion shall be entitled for remuneration corresponding to the part of the Services being already performed and/or for costs which have already been incurred for such completed part of Services. In case of premature termination caused due to contractual violation of the Investigator and/ or the Institution, the Investigator and/or the Institution, as the case may be, shall refund the total amount paid by Sponsor to Investigator and/or the Institution under this Agreement;

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iv. Any termination of the present Agreement will be without prejudice to the accrued rights and liabilities of the Parties under these agreements/contracts;

v. The respective Parties hereby agree to cooperate on orderly operational, administrative and financial wind up of operations.

20. Relationship between the Parties

20.1 The Party may not assign its rights under this Agreement or any part thereof without the prior written consent of the other Party and neither Party may subcontract the performance of all or any of its obligations under this Agreement without the prior written consent of the other Party.

20.2 Nothing shall be construed as creating a partnership, contract of employment or relationship of principal and agent between the Parties.

20.3 Any act or failure to act on part of the Institution, or any of the Institution's employees, Institution's representatives, or any other person working for or on behalf of the Institution shall be deemed to be an act or failure to act on part of the Investigator and the Investigator shall be liable to the SPONSOR for every act or failure to act on part of the Institution, or any of the Institution's employees, Institution's representatives, or any other person working for or on behalf of the Institution.

21. Agreement and Modifications

21.1 Any change in the terms of this Agreement shall be valid only if the changes are made in writing, agreed and signed by the Parties.

21.2 The Annexure shall be considered an integral part of the Agreement. To the extent that any terms or provisions of the Annexure conflict with the terms and provisions of this Agreement, the terms and provisions of this Agreement shall prevail, except to the extent that the applicable Annexure expressly and specifically states intent to supersede this Agreement on a specific matter.

21.3 This Agreement including the Annexures contains the entire understanding between the Parties and supersedes all other negotiations representations and undertakings whether written or oral of prior date between the Parties relating to the Purpose of this Agreement.

22. Force Majeure: Neither Party shall be liable to the other Party or shall be in default of its obligations hereunder if such default is the result of war, hostilities, revolution, civil commotion, strike, epidemic, accident, fire, wind, flood or because of any act of God or other cause beyond the reasonable control of the Party affected. The Party affected by such circumstances shall promptly notify the other Party in writing when such circumstances causing a delay or failure in performance ("a Delay") and where they cease to do so. In the event of a Delay lasting for 8 weeks or more the non-affected Party shall have the right to terminate this Agreement immediately by notice in writing to the other Party. In case of such termination SPONSOR shall pay to the Institution fees for achieved milestone and also pay a pro rata portion of fees for any partially achieved milestone.

23. Notices: Any notice required or permitted to be given hereunder by either Party shall be in writing and shall be deemed given on the date received if delivered personally or by a reputable overnight delivery service, or seven (7) days after the date postmarked if sent by registered or certified mail, return receipt requested, postage prepaid, or the next day if sent by facsimile transmission (confirmed by registered or certified mail above) to the following addresses, if not updated from time to time:

If to Institution: Rev. Fr. Patrick Rodrigues
Director
Father Muller Charitable Institutions
Kankanady, Mangalore – 575 002,
Karnataka

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If to Investigator: Dr. Ramesh Bhat M
Principal Investigator
Father Muller College and Hospital,
Kankanady, Mangalore – 575 002,
Karnataka

If to SPONSOR:

Vice President (Product development & projects)
Torrent Research Centre
Ahmedabad Airport-Gandhinagar Highway,
Near Indira Bridge,
Village Bhat-382428,
Tal & Dist. Gandhinagar
Telephone: 91-079-23969135

With a copy to:

Director (R&D)
Torrent Research Centre
Ahmedabad Airport- Gandhinagar Highway,
Near Indira Bridge,
Village Bhat-382428
Tal& Dist. Gandhinagar
Telephone: 91-079-23969100
Fax: 91-079-23969135

24. **Waiver:** No failure, delay, relaxation or indulgence by any Party in exercising any right conferred on such Party by this Agreement shall operate as a waiver of such right, nor shall any single or partial exercise of any such right nor any single failure to do so, preclude any other or future exercise of it, or the exercise of any other right under this agreement.

25. **Governing Law & Dispute Resolution:** This agreement shall be governed by the laws of India. Any dispute arising out of or in connection with this Agreement will be finally settled through arbitration by a sole arbitrator mutually appointed by the Parties, as per the provisions of the Arbitration and conciliation Act, 1996, as amended from time to time. The arbitration proceedings shall be conducted in English language and held at Ahmedabad, India.

26. **Statutory Provision:** Any reference to a statutory provision shall be deemed to include reference to any statutory modification or re-enactment of it.

27. **Limit of Authority:** It is hereby agreed that neither Party has the right to bind the other Party to any obligation other than set out in this Agreement.

28. **Ineffective Clauses:** The invalidity or unenforceability of one provision of this Agreement shall not affect any other provision of this Agreement. Should any Clause of this Agreement prove invalid and/or un-implementable, the Parties will, on request of either Party, begin negotiations about effective and implementable provisions, which will, as far as possible, lead to the same economical and legally permissible results as the invalid or un-implementable Clause or provision would have led to.

29. **Survival:** The provisions of Clause 8, 9, 11, 13, 14, 15, 19, 25 and 29 and the rights and obligations contained thereunder shall not terminate on termination of this Agreement.

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AHMEDABAD

IN WITNESS WHEREOF, the Parties hereto have authorized their officers or representatives to execute this Agreement to be effective as of the Effective Date. This Agreement is signed in duplicate and each Party shall retain one copy.

Signed on behalf of the SPONSOR: Torrent Pharmaceuticals Ltd.	**Signed on behalf of the Investigator**
Name: Vinod Pillai	**Name:** Dr. Ramesh Bhat
Designation: Vice President (Product development & projects)	**Designation:** Dermatologist
Date: 25/5/2016	**Date:**
	Signed on behalf of the Institution:
Name: Ashok Modi	**Name:** Rev. Fr. Patrick Rodrigues
Designation: Executive Director (Finance)	**Designation :** Director, FMCI
Date: 7/6/16	**Date:**

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REV. FR PATRICK RODRIGUES Director PATRICK MULLER CHARITABLE INSTITUTIONS Fr Muller Road, Kankanady Mangalore-575 002

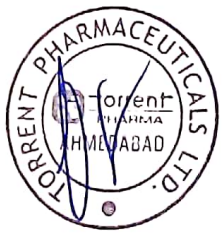
ANNEXURE I

DETAILS OF THE SERVICES

The Investigator shall provide following Services for the Clinical Trial:

- Review the clinical trial protocol and provide undertaking to carry out the study
- Recruit the volunteers as per the clinical trial protocol
- Arrangement to carry out laboratory investigations & ECG as per the need of protocol
- Obtaining the informed consent from individual patients, by explaining study related information to the patients and confirming his/her understanding on such consent and maintain the same for record.
- An audio video / audio recording of the informed consent process of individual patients, including the procedure of providing information to the patients and his/her understanding on such consent shall be recorded and maintained as per prevailing Rules under Drugs and Cosmetics Act, 1940 as applicable. Arrangement to carry out study procedures as per the need of protocol
- Arrangement to carry out any additional clinical investigations/test if required
- Capturing study related data in electronic case record form within 7 working days of actual visit of the patient.
- Provide medical treatment to patient upon untoward medical occurrence
- Review the clinical trial report
- Support to sponsor monitor during monitoring visit
- Regulatory requirements compliance

Apart from the aforementioned, the Investigator shall upon the request of the Sponsor, provide any other Services that the Sponsor may require for the purpose of successful completion of the Clinical Trial.



ANNEXURE - 2

BUDGET AND PAYMENT SCHEDULE

Payment Terms:

1. The total charges per visit for each Subject shall be as follows:

Items	Amt Per Visits (A) (In Rs.)	Visit	Total Amt (Sub Total A) (In Rs.)
Investigator charges	2500	Screening Visits	13000
Investigator charges	2500	Visit 2	
Investigator charges	2500	Visit 3	
Investigator charges	3000	Visit 4	
Investigator charges	2500	Visit 5	
*Clinical Assessor Charges	1000	Screening Visits	5000
*Clinical Assessor Charges	1000	Visit 2	
*Clinical Assessor Charges	1000	Visit 3	
*Clinical Assessor Charges	1000	Visit 4	
*Clinical Assessor Charges	1000	Visit 5	
Co-ordinator Charges	600	Screening Visits	3000
Co-ordinator Charges	600	Visit 2	
Co-ordinator Charges	600	Visit 3	
Co-ordinator Charges	600	Visit 4	
Co-ordinator Charges	600	Visit 5	
Total payment for each completed Subject			**21000**

***Clinical Assessor will evaluate only few clinical efficacy parameters as per protocol and will remain blind to the treatment.**

The payment shall be released pursuant to an invoice raised by the Institution based on inputs received from Investigator on monthly basis for activities completed by a cheque in favour of Father Muller Research Centre. In case invoice not received for particular month on time, payment dues shall be carried forward for the next month.

2. For drop outs or discontinued Subjects payment shall be made to the Institution in accordance with the table in Clause 1 on pro rata basis.

3. The charges shall be inclusive of all taxes and will be subject to Tax Deducted at Source (TDS). Service Tax will be paid by SPONSOR, if applicable and required by law as charged in invoice. To receive the payment is the responsibility of the Institution.

4.

a) In the event any laboratory examination or tests are to be conducted on the Subjects during the visits as per the Protocol in accordance with Clause 4.12, the actual charges incurred by the Institution for such examination or tests shall be reimbursed to the Institution on submission of requisite supporting documents including adequate bills/invoices for such examination. In the event such charges are to be directly paid by the SPONSOR to the hospital or laboratory, the Investigator/Institution shall verify adequate bills/ invoices or other documents pertaining such examination or test before submitting such bills/ invoices for payment to SPONSOR.

b) The investigation charges including laboratory investigations for AE or SAE if any shall be paid on an actual basis on submission of supportive documents for such investigation charges incurred to the SPONSOR.

c) In case of Adverse Event, laboratory investigation shall be made at any laboratory identified by the Investigator and payment for the same shall be made on the basis of actual laboratory charges on being supported by necessary vouchers provided eCRF entries has been completed.

5. In case of unscheduled visit required for the Trial, the SPONSOR shall pay a sum of Rs. 700/- (Rupees Seven hundred only) per visit per Subject based on documentation and eCRF entries

6. The SPONSOR shall pay a fixed amount of Rs. 500/- per completed Subject (will be paid on pro rata basis for dropouts or discontinued subjects) towards administrative charges (i.e., stationery, courier, fax, telephone charges etc.).

7. The SPONSOR shall pay a fixed amount of Rs.200/- per screened failure patient (i.e., documentation of screened failure patient)

8. In the event of any Serious Adverse Event (SAE) in accordance with protocol is reported, the SPONSOR shall pay a sum of Rs. 2000/- (Rupees Two thousand only) to institution for submission of each SAE report (initial and follow up reports) to regulatory authority.

9. For obtaining necessary approvals from Ethics Committee in connection with the Study, advance payment shall be paid to the Institution or to the Ethics Committee directly, as the case may be, upon receipt of necessary invoice(s) from the Institution or the Ethics Committee.

10. Conveyance charges per visit shall be reimbursed to the Subjects on actual basis by Institution. Such charges paid by the Institution will be reimbursed by the Sponsor based on invoice raise by Institution provided such invoice/reimbursement receipt has been countersigned by the Subject to whom such conveyance charges have been paid by the said Institution. In the event, conveyance charges per Subject per visit exceeds Rs. 500/-, such amount shall be reimbursed subject to requisite supporting documents (eg, tickets) pertaining to such conveyance charges paid are provided to Sponsor for each of such visit.

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ANNEXURE - 3

TIMELINES

- Total duration of the study would be approximately 5-7 months from the date of initiation of Study
- It includes expected recruitment of 1-2 subjects per week in each participating centre.
- Overall recruitment period of 14-18 weeks and a total number of 232 Subjects from all Sites

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Government of India
Department of Atomic Energy (DAE)
Board of Research in Nuclear Sciences (BRNS)

Shri D. K. Dalal
Programme Officer (ATC)

BRNS Secretariat, 1st Floor, CC,
BARC, Trombay, Mumbai-400085
Phone: 25594683 FAX: 022-25505151
e-mail: dkdalal@barc.gov.in

No. 34/14/18/2014-BRNS/ 0310-[redacted] Date: 16 MAY 2014

OFFICE MEMORANDUM

Sub: R/P entitled "Identification of specific variability parameters and pulse patterns for disease characterization using peripheral pulse analyzer" under Dr. J. P. Alva, Professor of Medicine, Father Muller Medical College, Kankanady, Mangalore 575 002 bearing sanction **No.34/14/18/2014-BRNS** with **ATC**, BRNS.

On the recommendations of the Board of Research in Nuclear Sciences (BRNS), I am pleased to convey the administrative approval and sanction of the President of India for the captioned project for two years beginning from financial year **2014-15** with a total grant of **₹14,23,100/- (Rupees fourteen lakh twenty three thousand one hundred only)** for the project as under:

	Item of expenditure	I Year (2014-2015)	II Year (2015-2016)
*	Equipment	4,10,000	--
#	Staff JRF (1)	1,92,000	1,92,000
~	Technical Assistance	1,00,000	2,00,000
	Consumables	25,000	25,000
	Travel (PI)	25,000	25,000
	Contingency	25,000	25,000
$	Overheads	56,400	33,150
	Total:	8,33,400	5,00,150

* (i) Peripheral Pulse Analyzer, (ii) Anu-photo Rheograph, (iii) Standard Accessories PC, Printer (4 Nos).

\# JRF salary @16,000/- in 1st and 2nd year.

~ Technical Assistance includes Equipment Hire Charges, Computer Charges and Charges for Hiring Services.

$ Overheads calculated @ 7.5% of the other heads except contingency. The remaining 7.5% towards overheads (**₹89,550/-**) shall be released only on meeting the requirements specified **(See Annex-B)**.

2. I am also pleased to convey the sanction of the President of India to incur an expenditure of **₹8,33,400/- (Rupees eight lakh thirty three thousand four hundred only)** towards grant for the year **2014-15**.

3. The expenditure involved is debitable to:

Grant No.	-	04	Atomic Energy
Major Head	-	3401	Atomic Energy Research
Minor Head	-	00 004	Research & Development
Sub Head	-	08 02	Board of Research in Nuclear Sciences (BRNS)
Detailed Head	-	08 02 31	Grant-in-aid

4. This issues with the concurrence of Scientific Secretary, BRNS and IFA, DAE.

Sd/-
(D. K. Dalal)

Pay & Accounts Officer,
Department of Atomic Energy,
Anushakti Bhavan,
CSM Marg, Mumbai - 400 001.

No.34/14/18/2014-BRNS/ Date:

Copy forwarded to:

1. Director of Audit, Scientific Department, AEAP, OYC, CSM Marg, Mumbai - 400 001.
2. Joint Secretary (R&D), DAE, Anushakti Bhavan, CSM Marg, Mumbai-400 001.
3. Dean, Father Muller Medical College, Kankanady, Mangalore 575 002.
4. ** Principal Investigator (PI): Dr. J. P. Alva, Professor of Medicine, Father Muller Medical College, Kankanady, Mangalore 575 002.

A. First year grant is being released in full through Pay & Accounts Officer, Department of Atomic Energy, Anushakti Bhavan, CSM Marg, Mumbai-400 001 directly. You may await a DD/ MT, accordingly.

i) Receipt of this sanction letter and the DD/ MT for the amount sanctioned for the first financial year may please be acknowledged **(Form-I)**.

ii) THIS SANCTION IS FURTHER SUBJECT TO THE CONDITIONS STIPULATED IN ANNEX-A AND ANNEX-B **(ENCLOSED)**, WHICH MAY BE GONE THROUGH CAREFULLY.

B. Second year Sanction Letter will be issued automatically in the month of April/May of the 2nd financial year, however, the grant will be released after the PI submits the following documents to the Programme Officer, BRNS:

a) Claim in Form-II **(enclosed)** quoting the reference of the sanction issued for the first year.

b) Utilisation Certificate (UC) as on **31st March** of the preceding financial year in Form-III **(enclosed)** duly audited by the Internal Auditor of the University/ Institution or a Chartered Accountant.

c) Statement of Accounts (SA) as on **31st March** of the preceding financial year in Form-IV **(enclosed)** duly audited by the Internal Auditor of the University/ Institution or a Chartered Accountant. **Interest earned in previous year should be reflected in the Statement of Accounts.**

d) Copy of appointment order and joining report of the staff appointed for the project along with minutes of the Selection Committee.

e) An inventory of equipment in Form-V **(enclosed)**.

f) A One Page reports on the progress of work during first year.

C. Grant for the third year and subsequent years (if any), will be released only after the Principal Investigator (PI) fulfills the following requirement:

i) The Department will issue a fresh sanction for the third and subsequent years after receiving the recommendation of the BRNS after scrutiny of the Renewal Application in Form PRA.
Hence, Principal Investigator (PI) is required to submit a renewal/extension application in the prescribed **Form - PRA** by email to Member Secretary (ATC) (**pvananth@barc.gov.in**) by **January 1** of the second and subsequent years of the project as the case may be alongwith the progress report giving year wise details of the progress made. Form-PRA is also available on http://barc.gov.in/brns/index.html A printed copy of the application duly signed and forwarded by head of the institution should also be submitted to the Member Secretary (ATC) as well as Programme Officer (ATC), BRNS, 1st Floor, Central Complex, BARC, Mumbai-400 085 by **January 15**.

ii) Sanction Letter: If the progress is found to be satisfactory the renewal sanction for the year will be issued in the beginning of that financial year in April/May.

iii) Claim: On receipt of the renewal sanction, the PI shall claim the funds sanctioned by submitting the following documents to **Shri D. K. Dalal, Programme Officer (ATC), BRNS Secretariat, First Floor, Central Complex, BARC, Trombay, Mumbai-400 085**:

a) Claim in **Form-II** (enclosed) quoting reference of the renewal sanction.

b) Utilisation Certificate (UC) as on **31st March** of the preceding financial year in **Form-III** (enclosed) duly audited by the Internal Auditor of the University/ Institution or a Chartered Accountant.

c) Statement of Accounts (SA) as on **31st March** of the preceding financial year in **Form-IV** (enclosed) duly audited by the Internal Auditor of the University/ Institution or a Chartered Accountant. **Interest earned in previous year should be reflected in the Statement of Accounts.**

d) Copy of appointment order and joining report of the staff appointed for the project along with minutes of the Selection Committee.

e) An inventory of equipment **in Form-V** (enclosed).

These forms are enclosed with the sanction letter (first year) also.

D. At the end of Terminal Year the final Settlement Grant will be released on fulfillment of the following requirements:

a) Claim Form-II,

b) The final Consolidated Statement of Accounts (SA) and Consolidated Utilization Certificate (UC) **duly audited by a Chartered Accountant or a Statutory (Govt.) Auditor.**

c) Final Consolidated Progress Report **in Form-VII** (enclosed).

5. AAO (Bills II), DAE, Anushakti Bhavan, CSM Marg, Mumbai - 400 001 – With a request that the amount granted for the first year of the project may be released immediately.

6. Member Secretary (ATC): Dr. P.V.A. Padmanabhan, L&PTD, BARC, Mumbai-400 085.

7. Co-Investigator (CI): Dr. B. Sanjeev Rai, Professor of Pediatrics, Father Muller Medical College, Kankanady, Mangalore 575 002.

8. Principal Collaborator (PC): Mr. R. K. Jain & Mr. Vineet Sinha, Electronics Division, BARC, Trombay, Mumbai-400 085.

You or your nominee may please be the DAE representative for selection of Research Fellow/ Research Associate for the project.

Dalal

(D. K. Dalal)

** **Note:**

1. All documents as applicable be sent in time to avoid delays & unnecessary correspondence.
2. Please quote Sanction No. **34/14/18/2014-BRNS** in all your correspondence with BRNS.
3. If you do not receive the money please contact AAO (Bills II), DAE **on 022-22862709.**

FATHER MULLER INSTITUTIONAL ETHICS COMMITTEE

Father Muller Road, Kankanady, Mangalore - 575 002
Karnataka, India

Tel : 0824-2238399
e-mail: fmiethicscommittee@gmail.com

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Professor of Pharmacology
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Phone : +919880530703
E-mail: ashok.shenoy@manipal.edu

SECRETARY
Dr. Shivashankara A.R.,
Associate Professor of Biochemistry,
Father Muller Medical College
Mangalore - 575 002
Phone : +919880146133
E-mail: arshiva72@gmail.com

Ref. No : .....FMMC/FMIEC/2997/2016 *Date :* 12.09.2016

To,

Dr.Sukumar D
Principal Investigator
Prof and HOD, Department Of Dermatology,
Father Muller Meducal College Hospital
(Unit of Father Muller Charitable Institutions)
Father Muller Road, Kankanady,
Mangalore – 575002, India.

Ref:Protocol GPL/CT/2014/022/III: "A Randomized, Double-Blind, Placebo-Controlled, Comparative, Prospective, Multicentre Trial to Assess Efficacy and Safety of Apremilast Tablets in Subjects with Moderate to Severe Plaque Psoriasis who are Candidates for Phototherapy or Systemic Therapy"Subject: Ethics Committee Approval of the Essential documents for the above mentioned Clinical trial.

Dear Dr.Sukumar D,

The Father Muller Institutional Ethics Committee, Father Muller Medical College reviewed and discussed your application to conduct the clinical trial Protocol GPL/CT/2014/022/III: "A Randomized, Double-Blind, Placebo-Controlled, Comparative, Prospective, Multicentre Trial to Assess Efficacy and Safety of Apremilast Tablets in Subjects with Moderate to Severe Plaque Psoriasis who are Candidates for Phototherapy or Systemic Therapy" on 10 Sep 2016 at 3:00 PM

We have rechecked for following documents:

1. Protocol Version 3.0 dated 28-Sep-2015
2. Investigator's Brochure, Edition 1.0 dated 24-Mar-2015
3. Case Report Form (Version 1.0) dated 16-Jul-2015
4. Patient Information Sheet and Informed Consent Form in English, Core_3.0 dated 28-Sept-2015 customized for Dr. Sukumar D on27-Jun-2016
5. Patient Information Sheet and Informed Consent Form in Kannada, Core_3.0 Kannada _1.0 dated
   14-Oct-2015 customized for Dr. Sukumar D on28-Jun-2016
6. Patient Information Sheet and Informed Consent Form in Malayalam,Core_3.0 Malayalam _1.0 dated14-Oct-2015 customized for Dr. Sukumar D on28-Jun-2016
7. Patient Information Sheet and Informed Consent Form, Core_3.0 Kannada_1.0 dated 14-Oct-2015, Customized for Dr. Sukumar D on28-Jun-2016, Back translated from Kannada to English on 28-Jun-2016
8. Patient Information Sheet and Informed Consent Form, Core_3.0 Malayalam_1.0 dated 14-Oct-2015, Customized for Dr. Sukumar D on28-Jun-2016, Back translated from Malayalam to English on 28-Jun-2016
9. Subject Diaries in English Version 1.0 dated 3-Jun-2015 (for visit 2, Visit 3,Visit 4,Visit 5 and Visit 6)
10. Subject Diary version 1.0 dated 3-Jun-2015, Translated from English to Kannada on 4-Jun-2015
    (for visit 2, Visit 3,Visit 4,Visit 5 and Visit 6)
11. Subject Diary version 1.0 dated 3-Jun-2015, Translated from English to Malayalam on 4-Jun-2015 (for visit 2, Visit 3,Visit 4,Visit 5 and Visit 6)
12. Psoriasis Area and Severity Index (PASI) sheet and Psoriasis Global Assessment (PGA) Sheet
13. Insurance Endorsement: Endorsement No. 01-P0000433-CLT-R002 valid from 1 July 2015 to 30 June 2016
14. Investigator's undertaking - Dr. Sukumar D
15. Investigator's Curriculum Vitae& MRC - Dr. Sukumar D
16. DCGI Submission letter dated 12-Oct-2015
17. DCGI Approval Letter
18. Justification for the use of placebo

And also rechecked updated insurance certificate No: 4067-16-17-Glenmark-001, Policy No: 4067/119088310/00, Policy Period: From Friday Jul 01, 2016to Friday Jun 30, 2017for the above referenced study.

The following members of the Ethics Committee were present at the meeting held on 10 Sep 2016 at 3:00 PM.

Sl No.	Name	Qualification	Designation/ Title	Affiliations as to the Institution
1.	Dr. Ashok Shenoy	MD	Chairperson	No
2.	Mr. Eric Sequeira	BA, BL	Member – Legal Expert	No
3.	Dr. Shivashankara A.R.	M.Sc., Ph.D	Member Secretary	Yes
4.	Dr. Sudhir Prabhu	MD	Joint Secretary	Yes
5.	Dr. Varadaraj Shenoy	MD, DCH	Member-Clinician	Yes
6.	Dr. Safeek A.T.	DPM, DNB	Member-Clinician	Yes
7.	Dr. Kurian P.J.	MD	Member –Homeopathy Expert	Yes
8.	Mr. Sudeep Pais	MPT	Member –Physiotherapy Expert	Yes
9.	Fr. Dr. Leo D'Souza	M.Sc, Ph.D	Member-Ethicist /Philosopher	No
10.	Mrs.Veena Manoj	MA, B.Ed	Member – Lay Person	No
11.	Dr.Anuradha Shetty	MSW	Member - Social Scientist	No

The following are the members who could not present for the EC meeting due to unavoidable circumstances are:

Sl No	Name	Qualification	Designation/ Title	Affiliations as to the Institution
12.	Prof. Irene T.R. Alvares	M.Sc.	Member - Nursing	Yes

At the Ethics Committee meeting held on 10 SEP 2016, previous queries and sponsor justification letter along with supporting documents were examined and discussed. After due consideration, the committee has decided to approve the conduct of the study.

We approve the trial to be conducted in its presented form

Father Muller Institutional Ethics Committee, Father Muller Medical College expects to be informed about the progress of the study on a quarterly basis, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

We hereby confirm that the Father Muller Institutional Ethics Committee, Father Muller Medical College is organized and operates as per GCP and applicable regulations.

Yours Sincerely,

Dr. Shivashankara A.R.
Member Secretary/Chairman,
Father Muller Institutional Ethics Committee,
Father Muller Medical College,
Kankanady, Mangalore – 575002,
Karnataka, India.

Dr. Shivashankara A.R., PhD.
Secretary
Father Muller Institutional Ethics Committee

ANNEXURE 5

Payment Schedule

GPL/CT/2014/022/III Site Budget

Site Budget	
Visit Details	Cost
Visit 1 (Screening)	3,000
Visit 2 (Randomization- Day 1)	5,000
Visit 3 (Day 8)	3,000
Visit 4 (Day 29)	3,000
Visit 5 (Day 57)	3,000
Visit 6 (Day 85)	3,000
Visit 7 (Day 113)	5,000
Total Per Patient	25,000
CRC fees(per Month from SIV till 12 Months or Last DCF resolution whichever is earlier)	5,000
Travel Reimbursements per patient all visit (500*7)	3,500

Description of Payments	Cost(INR)	No. of patients projected a t site	Total
Investigator Fee Per Patient(per completed subjects)	25,000	15	375,000
CRC fees(per Month from SIV till 15 Months or Last DCF resolution whichever is earlier)	5,000	NA	75,000
Travel Reimbursements per patient all visits	3,500	15	52,500
Total			**502,500**

- Patient travel reimbursement is upto maximum INR 500/- per visit and as per actuals. The amount for patient travel reimbursement mentioned above would be paid on actuals based on invoice received

GLENMARK PHARMACEUTICALS LTD. MUMBAI 400099

IAN ASSOCIATION OF DERMATOLOGISTS, VENEREOLOGISTS & LEPROLOGISTS (IADV

2016

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To,

Dated on 10-09-2016

Dr Rochelle c Monteiro

Asst. Professor, Dept. of Dermatology

Fr Muller Medical College, Mangalore

Dear Dr. Rochelle,

Greetings from IADVL Headquarters!

It's my pleasure to inform you that IADVL Academy has approved your project titled ***"A study of the bacteriology of acne and in vitro antibiotic susceptibility patterns of oral and topical antibiotics in treatment of acne"*** and the Executive Committee, IADVL has sanctioned Rs 1,50,000/- (Rupees One Lakh Fifty Thousand Only) for the same project. As per the advice of Academy, IADVL an initial amount of Rs. 80,000/- (Rupees Eighty Thousand Only) was transferred to your institutional bank account on 27th May, 2016. (NEFT UTR NO: SBIN616148306458 dt 27.05.2016). The remaining amount will be transferred after the submission of the mid-term progress report on the same project. Kindly acknowledge the receipt of the same at your end.

Best regards,

Dr. Rajib Kumar Gogoi
Hony. Treasurer
IADVL

Dr. Rajib Kumar Gogoi

Hon. Treasurer, IADVL

Clinical Trial Agreement

Lambda Therapeutic Research Ltd.

Plot No. 38, Near Silver Oak Club,
S G Highway, Gota,
Ahmedabad 380061,
Gujarat, India.

(Hereinafter referred to as "LAMBDA" or "CRO")

Acting as agent for

Intas Pharmaceuticals Limited
2nd Floor, Chinubhai Centre,
Ashram Road,
Ahmedabad- 380009,
Gujarat, India.
(Hereinafter referred to as the "Sponsor")

AND:

Dr. Ramesh Bhat M.
Professor and HOD,
Department of Dermatology, Venereology and Leprosy,
Father Muller Medical College,
Kankanady,
Mangalore-575002

(Hereinafter referred to as the "Investigator")

AND:

The Director,
Father Muller Charitable Institutions,
Father Muller Medical College,
Kankanady,
Mangalore-575002

(Hereinafter referred to as the "Institute")

THIS AGREEMENT shall come into effect on the date of signature of all the parties.

BETWEEN:

Lambda Therapeutic Research Ltd.

Plot No. 38, Near Silver Oak Club,
S G Highway, Gota, Ahmedabad 380061, Gujarat, India.

(Hereinafter referred to as "LAMBDA" or "CRO")

Acting as agent for

Intas Pharmaceuticals Limited
2nd Floor, Chinubhai Centre,
Ashram Road,
Ahmedabad- 380009,
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AND:

Dr. Ramesh Bhat M.
Professor and HOD,
Department of Dermatology, Venereology and Leprosy,
Father Muller Medical College,
Kankanady,
Mangalore-575002

(Hereinafter referred to as the "Investigator")

AND:

The Director,
Father Muller Charitable Institutions,
Father Muller Medical College,
Kankanady
Mangalore-575002

(Hereinafter referred to as the "Institute")

WHEREAS:

LAMBDA is acting as a Contract/Clinical Research Organization (CRO) under a Service Agreement on behalf of Intas Pharmaceuticals Limited.

Intas Pharmaceuticals Limited.has asked LAMBDA to handle and negotiate site Agreements on its behalf;

LAMBDA on behalf of Sponsor wishes the Investigator and Institute to participate in a clinical trial entitled **"A Randomized, Double-Blind, Placebo-Controlled, Threearm, Parallel Group, Multi-Centric, Clinical Study To Evaluate The Therapeutic Bio-Equivalence Of Two Tacrolimus0.1% Topical Ointment Formulations In Adult Patients With Moderate To Severe Atopic Dermatitis"** ("Clinical Trial") to be conducted under the direction and supervision of the Investigatorusing the facilities of the Institution; and,

The Investigator and Institute is willing to participate in the Clinical Trial; and,

The Investigator is authorized to conduct the clinical trial at the Institution. The Investigator will review the Clinical Trial for patient safety, scientific validity, and utilization of hospital resources.

IN CONSIDERATION of the mutual promises and covenants herein, the parties agree as follows:

1 Definitions

1.1 In this Agreement, the following terms shall have the following meanings:

Term	Meaning
"Compound"	**Tacrolimus0.1% Ointment**(Test) Protopic® (tacrolimus) [Reference] **Manufactured by:**Intas Pharmaceuticals Limited **Manufactured for:**Intas Pharmaceuticals Limited
"CRF"	Case Report Form
"CRO"	Contract/Clinical Research Organization

"Declaration of Helsinki"	The 1996 version of the Helsinki Declaration of the World Medical Association and amendments.
"DCGI"	Drug Controller General of India.
"Ethics Committee"	The relevant properly constituted ethics committee as organized by the Hospital Authority or independent, which has reviewed or will review the application for conducting the Clinical Trial.
"ICH GCP"	ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) as may be amended from time to time.
"Site Investigator File"	The file maintained by the Investigator containing the documentation specified in section 8 of ICH GCP.
"Payment Agreement"	The payment agreement set out in Schedule "B".
"Protocol"	The protocol together with its amendments as agreed between the parties from time to time (Schedule "A").
"SAE"	Serious Adverse Event as defined by ICH GCP.
"Site"	The site at which the Clinical Trial is conducted.
"Study"	The study to be undertaken by the Investigator and the Institution in accordance with the Protocol, ICH-GCP and applicable regulatory requirements.

2 Investigator/Institution responsibilities

2.1 The Investigator in his personal capacity and as an authorized representative of the Institution and the Institution undertakes to adhere to the Protocol and general acceptable clinical practices for the conduct of the Clinical Trial.

2.2 The Investigator and the Institution will adhere to ICH GCP, Declaration of Helsinki, current Schedule Y of DCGI, and all applicable laws and regulations for the conduct of the Clinical Trial.

2.3 The Investigator and Institute is also responsible for supporting Sponsor and Lambda in resolving any technical issues encountered during the performance of the Clinical Trial and queries from national / international authorities in close coordination with Lambda in a timely manner. The provisions of this article shall remain in force for a period of 10 years even after expiry or termination of this agreement.

2.4 The Investigator is responsible for submitting to the Ethics Committee; the conduct of the Clinical Trial in accordance with the terms of the Protocol and for obtaining written approval from the Ethics Committee prior to the commencement of the Clinical Trial. The Investigator will deliver a copy of such approval to LAMBDA. Trial supplies to the Investigator or the Institution will not be delivered until LAMBDA has received a copy of such approval. The said approval must indicate the date of approval and contain the name and signature of the Chairperson/member secretary of the Ethics Committee.

2.5 The Investigator is responsible for training and supervision of sub-investigators and other site study team members on the procedures specified in the Protocol to ensure scientific, technical and ethical conduct of the Clinical Trial. In case of any personnel changes, the Investigator is responsible for notifying LAMBDA of such change in a timely manner.

2.6 The Investigator shall communicate all relevant aspects of the Clinical Trial to the patients intending to participate in the trial and their legally acceptable representatives and shall obtain voluntary signed written informed consent from all prospective patients and their legally acceptable representatives prior to start of any study related procedures.

2.7 During the performance of the Clinical Trial and for a period of 15 years after expiry/termination of the agreement, the Investigator and/or Institute is responsible for, but are not limited to, the following aspects:

a) Provision of required study documents (e.g. curriculum vitae(s), medical registration certificates and/or other relevant documents evidencing qualifications of investigator(s) and sub-investigator(s), confirmation of adequate site facilities, etc.);

b) Progress reporting (including recruitment figures) to ethics committee and LAMBDA on a regular basis;

c) Ensuring direct access by Lambda monitors, Lambda auditors, Sponsor representative and regulatory authority to original study documents, medical records, study materials, etc and providing appropriate working conditions for monitors, auditors and regulatory authority to perform study-related monitoring, audit and inspection respectively;

d) To allow any regulatory audit by DCGI or any applicable regulatory authority within 15 years of submission of report and ensure compliance of any regulatory deficiency raised by such authorities in reasonable period of time; If Investigator is to submit any information to such regulatory authorities agencies, such submissions shall not be made without Lambda's prior review and written approval, and any changes (other than entry of required information) also shall be subject to such prior written approval.

e) Safe handling, storage, transportation and disposal of infectious materials and wastes involved in the Clinical Trial;

f) Inform the Ethics Committee of study closure.

g) Maintenance of drug accountability records, study documents including study drug acknowledgement receipts, study supply receipts, payment receipts, EC approvals etc.;

h) Handling and storage of compound according to protocol.

i) Archival of study documents including source data/patient medical records in accordance with ICH-GCP for at least 15 years after completion of study as per the site archival fees which will be paid by sponsor on actual.

j) Retention of Investigational Medicinal Products at site after completion of study as per regulatory requirements

2.8 All SAEs has to be promptly reported by the Investigator to LAMBDA and/or Sponsor, Ethics Committee, Head of institution, DCGI and Expert Committee (In case of Death). The Investigator is responsible for reporting, and shall report, all such findings in the manner and within the time limits as set out in the applicable provisions of ICH GCP and the applicable legislation. LAMBDA and/or Sponsor confirms an effective system for centralized tracking and notification to investigators and to applicable regulatory authorities of all findings that could adversely affect the safety of Clinical Trial subject,

including, without limitation, all unexpected serious adverse drug reactions experienced by any subject taking part in the Clinical Trial at any site has been established. Notwithstanding anything in this Agreement to the contrary, the Investigator and the Institution shall have the right to disclose findings that could adversely affect the safety of Clinical Trial subjects to the Ethics Committees of participating sites, and appropriate regulatory authorities if they deemed necessary to protect the health of study participants, provided that Sponsor is copied on such reports.

2.9 The Investigator and the Institution shall indemnify, defend and hold harmless Lambda and the Sponsor against any and all claims arising out of or in connection with the performance of this agreement, allegedly arising from Investigator's and / or his team's negligence or reckless or intentional misconduct, breach or failure to perform its obligations and responsibilities under this agreement. Lambdaundertakes to provide timely written notice after such claim is served upon Lambda / Sponsor. The Investigator shall have the right to defend the same at his own expenses including selection of counsel, control of the proceedings and settlement of the claim. Lambda shall fully cooperate and aid in such defense. In the event that a claim or suit is or may be asserted, Lambda shall have the right to select and to obtain representation by separate counsel, at its own expense. Investigator may not settle or compromise a claim or suit without the express prior written approval of Lambda.

2.10 The Investigator is responsible for supporting LAMBDA in development of the Clinical Trial Report.

3 CRO responsibilities

3.1 LAMBDA will adhere to and confirms the Sponsor will adhere to ICH GCP, the Declaration of Helsinki, requirements of DCGI and all applicable guidelines, laws and regulations for the conduct of the Clinical Trial.

3.2 LAMBDA confirms that the Sponsor has committed to provide Lambda with the Compound and with guidelines and descriptions for the safe and proper handling regarding the use, storage and disposal of the Compound. Lambda will be responsible for shipment of drug supplies and investigational products to the PI or Site. The Compound is the property of Sponsor and is being provided only for the purposes of the performance of the Clinical Trial by the PI or by individuals working under his direct supervision at the Institution. The Compound shall not be used for any other research or study activities other than outlined in this Agreement.

3.3 LAMBDA and/or Sponsor is responsible for obtaining and maintaining all applicable government or regulatory approvals for the Clinical Trial in India, and warrants that

these will be obtained before the Clinical Trial begins at the Institution. Development and improvement of the Protocol is the responsibility of LAMBDA and Sponsor.

3.4 LAMBDA on behalf of the Sponsor will provide the study-specific documents, e.g. Investigator Site File, Electronic Case Report Form, etc. to the Investigator before commencement of the Clinical Trial.

3.5 LAMBDA on behalf of the Sponsor will provide the Investigator with documentation, which describes the Compound being tested in the Clinical Trial and its known effects and safety information (e.g. Prescribing Information / Summary of Product Characteristics, an Investigator Brochure equivalent document). LAMBDA on behalf of Sponsor will, to the best of its knowledge; answer any questions the Investigator or the Institution may have regarding the Protocol or the Compound being tested, whether such questions are asked before the commencement of the Clinical Trial or during its conduct. Sponsor is responsible for reporting of relevant new information regarding the investigational Compound.

3.6 LAMBDA will transfer on behalf of Sponsor the financial support to the Institution or Investigator according to the budget agreed by Sponsor, Investigator and the Institution as set out in Schedule B subject to the terms of this Agreement.

4 Performance standards of the work to be conducted by the Investigator

4.1 The Investigator and/or the Institution shall use all reasonable endeavors to enroll at least **03 patient** within **1** months; minimum expected recruitment rate from the site is **05 patients per month** on an average. The parties may agree in writing to extend the time for recruitment of eligible patients if so desired. Recruitment period will be of **6** months; however recruitment will be competitive among participating sites hence the site may have recruitment period even less or more than specified.

"Eligible Patients" is defined as those who fulfill inclusion and exclusion criteria specified in the Protocol which is verifiable from source documents.

4.2 In the event that the study is part of a multi-center trial, Sponsor may amend the number of Eligible Patients to be recruited as follows:

a) If in the reasonable opinion of LAMBDA or Sponsor recruitment of Eligible Patients is proceeding at a rate below that required for the relevant timelines to be met, LAMBDA may by notice to the Investigator or the Institution require recruitment at the Site to cease and the terms of this Agreement shall relate to the

number of patients that have been accepted for entry into the Study at the date of such notice; or

b) If recruitment of Eligible Patients is proceeding at a rate above that required meeting the relevant timelines, LAMBDA may, with the agreement of the Investigator or the Institution increase the number of cases to be recruited.

4.3 The Investigator or the Institution shall use all reasonable endeavors to comply with the time frames as agreed with LAMBDA.

4.4 The Investigator shall enter the data into the eCRF within **3**working days after completion of each visit.

4.5 The Investigator shall participate in teleconference and meeting as required by LAMBDA or Sponsor to update the Compound information and to resolve issues, if any.

4.6 The Investigator shall strictly adhere to the SAE reporting timelines in accordance with requirement of ICH GCP, current Schedule Y and standard operating procedure ("SOP") of LAMBDA, whichever is tightest.

5 Payment terms

LAMBDA confirms the Sponsor agrees to support the Clinical Trial as outlined in the Protocol and as described in and in accordance with the provisions of this Agreement and the Payment Agreement as set out in Schedule B.Lambda will have oversight on patient reimbursement records maintain at the site.

6 Period of validity of the Agreement

6.1 This Agreement shall be effective as of the date executed by all the parties and shall continue in full force and effect until the site is closed, Clinical Trial and Clinical Trial Report are completed unless otherwise extended, renewed, or amended by mutual written consent or unless terminated earlier in accordance with Section 14 of this Agreement. In any event, the terms of this Agreement shall not be longer than fifteen (15) years from the date of commencement.

6.2 However following matters shall survive even after expiry/termination of the agreement:

- Archival of study documents including source data as referred to in para 2.7 and 14.3
- Reasonable access by monitors, auditors and regulatory authority to original study documents and source data and providing appropriate working conditions for monitors, auditors and regulatory authority to perform study-related monitoring, audit and inspection;
- Confidentiality as per para 11

7 Data ownership / Intellectual property rights

7.1 LAMBDA, the Institution and the Investigator undertake to be bound by applicable laws and regulations on the protection of personal data.

7.2 The Investigator undertakes to transfer data to Sponsor, LAMBDA, Ethics Committee, and the regulatory authority. In the event of an audit/inspection, LAMBDA, the Sponsor, Ethics Committee, and regulatory authority may obtain information that includes patient identification.

7.3 All data and results derived from the Study and any inventions or discoveries made as a result of the Clinical Trial will be the property of Sponsor. Disclosure to LAMBDA, Ethics Committee, or regulatory authority does not transfer the ownership thereof.

7.4 All intellectual property rights owned by, or licensed to, the Investigator / Institute prior to and after the date of this Agreement, other than intellectual property rights arising from the Clinical Trial is and shall remain the property of the Investigator / Institution.

7.5 All intellectual property rights owned by, or licensed to, Sponsor prior to and after the date of this Agreement, other than intellectual property rights arising from the Clinical Trial is and shall remain the property of Sponsor.

7.6 All intellectual property rights in the data and results derived from the Clinical Trial shall be the property of Sponsor and shall be assigned to Sponsor.

7.7 The Investigator/Institute is obliged to report any inventions or discoveries promptly to Sponsor and/or LAMBDA.

7.8 Investigator and Institute agree that Sponsor may utilize the data at its own discretion in compliance with the applicable data protection rules, including but not be limited to, submission to government regulatory authorities.

7.9 The Investigator and the Institution shall assist Sponsor in making any patent applications and shall execute, complete, deliver and perform any and all instruments necessary to make all such applications.

8 Publication

8.1 Study results are Sponsor's property and as a result of this, no publication can be performed without the written approval by the sponsor.

9 Indemnity / Liability

9.1 In no event, shall LAMBDA, Sponsor, Investigator or Institution/Site be liable for any indirect, incidental, special, or consequential damages or lost profits arising under or as a result of this agreement (or the termination hereof).

9.2 In the event of a material error by Investigator/Institute in the performance of the Services, which renders the Services invalid, Investigator/Institute shall repeat the Services at no additional expense to LAMBDA, if Lambda requests or Investigator/ Institute should reimburse the payment already made by Lambda. Lambda has the right to terminate the services of Investigator due to any breach of this agreement.

9.3 Sponsor will indemnify the Investigator and/or Institution from any claims due to acts of omission or wrong by Sponsor.

9.4 Sponsor will indemnify liability arising from design or manufacture of the Compound, sale and use of the Compound following the Clinical Trial and injury to study subject directly attributable to Compound, which is jointly identified by a medical monitor/ Sponsor's medical expert and the Investigator.

9.5 The Investigator and/or the Institution will indemnify LAMBDA and Sponsor from any claims due to acts of negligence, omission or wrong by the Investigator or Institution.

9.6 The Investigator and/or the Institution are responsible and liable for conduct of the Clinical Trial at the Institution according to the Protocol and the Agreement.

9.7 Each party will notify other parties of any claim related to the Clinical Trial.

9.8 Sponsor will cover medical expenses for the treatment of any SAE as identified by the Investigator, which arise from using the Compound and study procedures in accordance

with the Protocol, to the extent not covered by any other insurance by patient and provided the patient did nothing to cause or contribute to the injury.

10 Compensation / Insurance

10.1 Sponsor/LAMBDA shall maintain appropriate insurance coverage for the Study subjects against financial losses caused by personal injury, which are study and/or Compound related.

11 Confidentiality

11.1 For a period of 10 (ten) years from the effective date of this Agreement, Recipient shall not disclose the Discloser's Confidential Information to any third party. Recipient shall use the Confidential Information solely for purpose of the terms of the agreement, unless otherwise mutually agreed in writing. Upon request, Recipient shall return or destroy, at the Discloser's option, all Confidential Information, including any copies and extracts thereof, will immediately cease using such Confidential Information and shall deliver to the disclosing party all such Confidential Information including all copies, reproduction, facsimiles and any other tangible records of such information.

11.2 Notwithstanding the performance, or the discharge for whatever reason including breach of this Agreement, the provisions of this article shall remain in force for a period of 10 years from the date of execution of this Agreement but shall, thereafter, cease to apply provided that the expiry of such period shall not entitle Investigator or Institution to sell or otherwise dispose of, or otherwise turn to use for its own or another's advantage, any confidential information received during the conduct of projects covered by this Agreement.

11.3 The Investigator may only to the extent is, as far as necessary for the performance of its obligations under this Agreement, but not further or otherwise, disclose confidential information to study staff or to any relevant committee, that need to know the same to undertake and/or participate in this study. Investigator shall ensure that all persons shall be made aware of the relevant terms and conditions of this Agreement and shall agree to be bound by them.

11.4 The Investigator/institution shall not disclose or use any confidential information, which is provided by Sponsor or LAMBDA or generated by Investigator as a result of the Study, for any purpose other than the conduct of the Clinical Trial as outlined in the Protocol and this Agreement.

11.5 Confidential information shall remain the confidential and proprietary property of Sponsor, and shall only be disclosed to those who have a need to know the same. Where it is necessary to disclose any confidential information to any third party for the performance of this Agreement, a confidentiality agreement with the same terms and conditions as this Agreement shall be entered into with such third party.

11.6 Each party will keep an updated list of all individuals who have received the other parties' confidential information, together with their contact information and job title, and will provide the list if it is legally requested. All confidential information must be identified as confidential at the time of disclosure, preferably provided in writing. If the disclosure is verbally, visually, or otherwise (e.g. an X-ray, a visit to a site or lab), then the information must be summarized in writing within thirty (30) days after the disclosure and provided to the receiving party.

11.7 Confidential information shall not include any information which:

a) Is already in the public domain at the time of disclosure

b) Becomes part of the public domain after receipt of the information through no fault of the Institution or the Investigator

c) Was previously known to the Institution or the Investigator as evidenced by written documents

d) Is disclosed to the Institution/Investigator by a third party who has the right to disclose and who is not under a direct or indirect obligation of confidentiality to Sponsor.

e) Has been permitted to be disclosed by Sponsor.

11.8 All Confidential Information disclosed to a party under this Agreement will remain the property of the disclosing party (or the Sponsor, if such information was disclosed through LAMBDA) and may be re-called and withdrawn by the disclosing party at any time. Upon receipt of a written request from the disclosing party for return or destroy of such Confidential Information, the receiving party will immediately cease using such Confidential Information and shall deliver to the disclosing party all such Confidential Information including all copies, reproduction, facsimiles and any other tangible records of such information.

11.9 Any previous Confidentiality Agreement between Sponsor and/or LAMBDA and the Investigator or the Institution shall be superseded by the confidentiality obligations in this Agreement.

12 Privacy

12.1 Sponsor, LAMBDA, the Investigator and the Institution will adhere to applicable privacy laws, regulations, and other standards.

12.2 The Investigator and Institute/Institution consents to LAMBDA and Sponsor and its affiliates collecting and/or otherwise processing personal data provided by or relating to the Investigator for purposes of any necessary sharing with regulatory authorities and for any use by Sponsor and its affiliates and their agents.

12.3 The Investigator and Institute consents to Sponsor or LAMBDA transferring such personal data to Sponsor's facilities, Sponsor's affiliated companies, regulatory authorities, and third party vendors that may be utilized in other countries. For such purposes, the Investigator and Institute acknowledge that such other countries may not provide the same level of data protection as the laws in India.

12.4 The Investigator and Institution will inform each study subject of the potential for disclosure of their personal or health information to Sponsor, Sponsor's affiliated companies, LAMBDA, the Ethics Committee, and the regulatory authorities and the measures being taken to ensure their privacy.

13 Independent Contractor

13.1 Investigator is an independent contractor engaged by LAMBDA to perform the Services in accordance with the provisions of this Agreement, and the relationship hereby created is specifically governed by, limited to, and subject to all of the terms and conditions contained in this Agreement. The parties further agree that LAMBDA does not have the authority to hire or fire employees of the Investigator / Institution, nor does LAMBDA determine the rate or method of pay of such employees. Additionally, nothing contained in this Agreement shall entitle Investigator/Institute to the right or authority to make any representation on behalf of LAMBDA or the Sponsor, bind LAMBDA or Sponsor to others in any manner, or use LAMBDA's / Sponsor's name or trademarks in any public disclosure, without LAMBDA's / Sponsor's prior written permission.

14 Termination

LAMBDA on behalf of Sponsor retains the right to terminate this Agreement on Institution or Investigator's involvement in the Study for any reason with or without cause including but not limited to the following;

1. Investigator or Institution fails to recruit patients within **60** days of site initiation visit.

2. The incidence and/or severity of adverse drug reactions in this or other studies with the Compound indicate a potential health hazard.

3. Adherence to the Protocol is poor or data recording is inaccurate or seriously incomplete.

4. LAMBDA, the Principal Investigator and/or the Institution agree to terminate this Agreement.

5. The total number of patients required to be randomised is reached before the end of the recruitment period.

6. The Sponsor of the Study mandates the termination of the Study for any reason, with or without cause.

7. The appropriate Regulatory Agency mandates the termination of the Study.

In case of termination of the agreement without any default on the part of Investigator or Institution, except in the event of non-recruitment of patients by the Institution or Principal Investigator, LAMBDA shall reimburse the Institution or Principal Investigator on a pro rata basis of the number of visits completed by patients. Should the Institution or the Principal Investigator have already received payments in excess of the actual pro rated amounts due then that overpayment will be promptly remitted to LAMBDA by the Institution or Principal Investigator. Payments should be payable to LAMBDA.

15 Record retention

15.1 The Investigator and/or the Institution shall provide Sponsor through LAMBDA any and all records and data in relation to the Clinical Trial in time and in full according to requirements of ICH GCP, Schedule Y and the Declaration of Helsinki, and all applicable guideline, laws and regulations.

15.2 The Investigator and/or the Institution, LAMBDA/CRO and Sponsor shall comply with all regulatory requirements relating to the retention of records and shall maintain all such records, and make them available for inspection, and shall allow Sponsor and all applicable authorities in charge of the Clinical Trial to inspect such records. The Investigator and /or the Institution shall inform Sponsor in the event of relocation or transfer of archiving responsibilities.

15.3 The Site Investigator File containing the essential documents, case report forms, informed consent forms and any other source data/document (like patient medical records) must be archived for at least 15 (Fifteen) years following completion of the study at the Site or such other facilities as agreed between Sponsor and the Investigator. Sponsor shall also keep all clinical trial data and documents according to the relevant regulatory requirements.

15.4 In the event that the Institution and/or the Investigator is or are unable to maintain the Clinical Trial records due to any unforeseen event/s during the study or retention period, the Institution and/or the Investigator shall, no later than **30** days prior to the day when the Clinical Trial records were planned to be removed, notify Sponsor in writing of such occurrence to permit Sponsor to fulfill its record retention obligation in connection with the Clinical Trial.

15.5 In the event that Sponsor removes the Clinical Trial records, Institution and/or Investigator may nevertheless retain a copy of Clinical Trial records (1) as required by law, regulation, regulatory guidelines or ICH GCP and (2) in order to ascertain and fulfill their obligations of confidentiality under this Agreement.

15.6 In the event that the Investigator/Institute is to destroy the Site Investigator File or source data, the Investigator/Institute should inform LAMBDA prior to destruction to confirm it is acceptable for them to be destroyed.

16 Representation and Warranty

16.1 The Investigator and Institution represent and warrant that they have and will keep throughout the Clinical Trial study all such qualifications, approvals, permits, licenses and conditions as necessary for performance of the Clinical Trial hereunder as required by laws and regulations of India.

17 Laws and Jurisdiction

17.1 This Agreement shall be governed by and interpreted in accordance with the laws of India in Ahmedabad.

18 Notice

18.1 All notices shall be delivered to the following addresses:

CRO

Address:	Lambda Therapeutic Research Ltd Plot No. 38, Near Silver Oak Club, S G Highway, Gota Ahmedabad 380061, Gujarat, India.
Telephone:	+91 79 4020 2020
Fax:	+91 79 4020 2021
Contact person:	**Dr. Kiran Marthak**

Investigator:	**Dr. Ramesh Bhat M.**
Address:	Department of Dermatology, Venereology and Leprosy, Father Muller Medical College, Kankanady, Mangalore-575002
Telephone Number:	08242238261
Fax Numer:	---

Institution

Address :	**Father Muller Charitable Institutions,** Father Muller Medical College, Kankanady, Mangalore-575002
Contact Number:	---
Contact Person:	Mrs. PreethaLinet Pereira

18.2 Either party should inform the other party of any change of the said addresses in writing within forty-eight (48) hours of the change.

18.3 Any notice shall be deemed to be given: a) If sent by courier - on the day when the recipient signs for the notice; b) If sent by registered letter - at 9:00 am on the five (5) working day of dispatch; or c) If sent by telefacsimile - at 9:00 am on the second day of delivery.

18.4 Any notice one party delivered to other parties, which concerns important issues such as claims or amendments under this Agreement should be signed by the legal representative or the authorized representative of the delivering party.

19 Miscellaneous

19.1 Any unsettled issues of this Agreement shall be negotiated and agreed upon in separate supplementary agreement signed by all parties. The supplementary agreement and Schedules of this Agreement which form an integral part of this Agreement and have the same legal effect as this Agreement.

19.2 No party shall assign to any third party its rights and obligations hereunder without the prior written consent of the other parties except when Sponsor takes over some of the activities from Lambda. The Investigator and the Institution acknowledge that Lambda is acting as the agent of the Sponsor and hence in such case Sponsor will get into the shoes of Lambda for all rights and obligations contemplated under this agreement as between Lambda on one side and Investigator and the Institution on the other side.

19.3 This Agreement shall constitute the entire agreement among the parties and shall supersede all previous negotiations, discussions, understandings or agreements among the parties.

19.4 No amendment or modification to this Agreement shall be effective unless made in writing and signed by all the parties or their duly authorized representatives.

19.5 All infrastructures provided by Lambda on behalf of sponsor for the conduct of this clinical trial to the Institute/Investigator will be retrieved from the Institute/Investigator upon completion of the trial.

IN WITNESS hereof, the parties hereto have caused this Agreement to be executed by their respective duly authorized representatives and the Agreement shall come into effect on the date of signature of all the parties.

LAMBDA:

Sign: _____ **Date:** 11/JAN/2016

Mr. Raviraj Karia
Sr. GM, Finance,
Lambda Therapeutic Research Ltd

Witness:

Sign: _____ **Date:** 11 Jan 2016.

Witness Name : **Dr. Dharmesh Domadia**

Witness Address : Lambda Therapeutic Research Ltd.,
Plot No. 38, Near Silver Oak Club,
S. G. Highway, Gota,
Ahmedabad 380061, Gujarat

Institute:

Sign: _____ **Date:** 16/Jan/2016

Rev. Father. Patrick Rodrigues
Director,
Father Muller Charitable Institution,
Father Muller Medical College,
Kankanady,
Mangalore-575002

REV. FR PATRICK RODRIGUES
Director
FR. MULLER CHARITABLE INSTITUTIONS
Fr. Muller Road, Kankanady
Mangalore-575 002

Witness:

Sign: _____ **Date:** 16/Jan/2016.

Witness Name: **Mrs. PreethaLinet Pereira**

Designation: Secretary

Department/Work Unit: Department Of Dermatology

Institute Name: Father Muller Charitable Institutions,
Father Muller Medical College

Investigator: Dr. Ramesh Bhat M.

ACKNOWLEDGMENT: In signing below, I, the Investigator, acknowledge that there is no real or perceived conflict-of-interest in the execution of this clinical trial project (e.g. stock or equity in companies which manufacture products being tested in the clinical trial, or obligations or restrictions which will conflict with the performance of this Agreement). I hereby agree to act in accordance with all the terms and conditions of this Agreement and further agree to ensure that all participants in the clinical trial are informed of their obligations under such terms and conditions.

Principal Investigator:

Sign: _____ **Date:** 16/Jan/2016.

Dr. Ramesh Bhat
Professor and HOD,
Department of Dermatology, Venereology and Leprosy,
Father Muller Medical College,
Kankanady,
Mangalore-575002

Witness:

Sign: _____ **Date:** 16/Jan/2016

Witness Name: Laveena Rodrigues

Witness Address: 'Grecilia'
Prashanth Nagar
Vamanjoor Post
Mangalore-575028.

Schedule A

Study Protocol

Protocol No: 175-14

"A Randomized, Double-Blind, Placebo-Controlled, Threearm, Parallel Group, Multi-Centric, Clinical Study To Evaluate The Therapeutic Bio-Equivalence Of Two Tacrolimus0.1% Topical Ointment Formulations In Adult Patients With Moderate To Severe Atopic Dermatitis"

Schedule B
Budget and Payment Agreement:

(I) Budget

INVESTIGATOR GRANT BREAKUP							
Items	**Visit 01**	**Visit 02**	**Visit 03**	**Visit 04**	**Visit 05**	**Visit 06**	**Total**
Investigator Grant	5000	3000	3000	3000	4000	1000	19000
Co-ordinator Grant	1500	1000	1000	1000	1000	500	6000
ECG (12 Lead)	400				400		800
Administrative Charges	200	200	200	200	200	200	1200
Institute Overhead (15 %)	975	600	600	600	750	225	3750
PK Sample Charges			500				
Patient Compensation	500	500	1000	500	500		**3000**
Total Grant	8575	5300	6300	5300	6850	1925	34250
Unscheduled Visit : 1500/UV							

Note:

- Payment for the screen failure patients will be made on actual up to the maximum of 20% of total patients screened at site.
- Service tax will be applicable on payment done to site as per government regulations (i.e. 14.5 %) upon availability of service tax number and required documents to claim service tax

The above budget also includes the

a. Investigator (s), other team members fees
b. The cost which would be incurred for stationary, cupboard, courier, telephone, fax, internet and electricity bills etc.
c. Patient recruitment
d. e-Case Report Form completion
e. Data Clarification Form Resolution
f. Consultation charges

(II) Payment Schedule

The parties hereto agree as follow on the basis of the Clinical Trial Agreement:

a) LAMBDA will pay a sum for every complete and evaluable patient as defined in the payment schedule.

b) A complete and evaluable patient is defined as follows:
- all procedures must be performed according to the protocol
- a patient will only be included according to the inclusion/exclusion criteria
- all data are documented completely and accurately

c) All payments will be on a *pro rata*basis as mentioned in budget above. For patients who do not complete (early termination, drop-out, etc), the budget will be evaluated according to the number of days completed as per protocol. If any investigation is not performed during a visit then an equivalent amount mentioned in the above budget will be deducted.

d) Invoice will be generated/requested for payment on monthly basis according to the actual work performed (after source data verification and e-CRF review for completed visits). Invoice will be generated / requested according to days completed by patient as specified above.

e) Central Laboratory costs will be paid by Lambda on behalf of Sponsor.

f) If patient was randomized in the study deviating from protocol inclusion and exclusion criteria (without waiver, if applicable) then payment will not be made for such wrong randomization and subsequent visits, however screening visit can be paid, if performed according to protocol.

g) **Patient conveyance/compensation** will be paid by LAMBDA on behalf of the Sponsor, and is included in budget as mentioned. "TDS would not be deducted on Reimbursement only if original supporting are provided for full amount." **Service tax applicable as per union budget rules.**

h) The investigator grant includes payment of meals provided to patient and patient's relative (if applicable) during the study.

i) Payment mentioned under "Final Payment" will be released at the time of site close out. LAMBDA will release payment within 30 days from the receipt of invoice.

Should the trial terminate prematurely, any payments made by LAMBDA exceeding the amount actually earned will be promptly refunded to LAMBDA (minus Ethics Committee fees, and patient conveyance/compensation).

Method of payment

LAMBDA, on behalf of the Sponsor, shall pay the relevant cost and fee as set out in this Payment Agreement to following payee through A/c Payee Cheque as agreed by the Institution & PI. Details of Payee are:

Payee: Father Muller Research Centre

Payee Address : Father Muller Research Institute
Father Muller Medical College
Kankanady Mangalore 575002

PAN / TAN Number: AAATF0345D0

Note: All the payments made to the payee are subject to Tax Deducted at Source (TDS) as per the applicable existing tax laws in the country. LAMBDA will deduct the tax at the time of making payments unless a valid Certificate from tax authority is made available.

(III) Per Patient Fee, Payment Schedule and Terms

1. As consideration for performance under the terms of this Agreement, the Sponsor will provide financial support for the Trial that will be transferred by the LAMBDA on behalf

of the Sponsor to the Investigator / Institute at the rate specified above per patient grant, for each Subject completing all Protocol specified treatments.

The "Per patient grant" is a fixed fee per patient which includes all costs and honoraria, including, but not limited to:

- all study related activities such as conduct of visits and eCRF completion
- time and effort of investigators and other site staff
- study coordinator salary
- electricity expenses for use of equipment for study conduct
- procurement of any study related material
- all diagnostic tests and other investigations (like Hb level measurement etc)
- housing/hospital stay (if applicable) and meals during housing for patient and patient's relative
- Phlebotomy expenses for safety samples
- usage of internet while filling of eCRF
- Patient conveyance/compensation which will be on a pro rata basis
- miscellaneous (telephone, fax, courier, etc)
- All overhead costs.

Not included are (which are separate and in addition to per patient payment):

- EC submission fee

2. In the event that the LAMBDA requests that additional Subjects be enrolled in the Trial, the Trial Cost will be equal to the Per patient grant multiplied by the number of complete and evaluable Subjects.

3. All payments to be made by the LAMBDA under this Agreement will be done within 30 days following receipt of the corresponding invoice from the Investigator to LAMBDA, it being understood that such payment will only take place after the CRO (LAMBDA) has received the necessary funds for that purpose from the Sponsor. All such payments will be Any made by A/C Payee Cheques to the Institution/Investigator.

4. Payment mentioned under "safety follow up" will be released at the time of site close out. The Final Payment will be made by LAMBDA in accordance with the following paragraphs.

5. As regards tasks that are not specifically itemized in this Agreement, payments will not be made without prior written approval of the LAMBDA. These additional tasks will be submitted to LAMBDA in writing, with estimated completion dates and costs, if any. Any expenses not specified in this Agreement or any changes to the amounts mentioned in this

agreement, will be communicated to LAMBDA and are subject to prior written approval by LAMBDA, which, in its turn, must obtain prior written approval from Sponsor.

6. In the event that a randomized Subject is determined to be ineligible for the Trial, LAMBDA will decide, together with the Sponsor, if required, whether or not to pay to the Institution/Investigator the Per Subject Fee for such Trial Subjects. In the event that a Trial Subject withdraws voluntarily or is withdrawn from the Trial (a) by LAMBDA or (b) by the Investigator for any reason other than the Trial Subject failing to meet eligibility requirements for the Trial, then LAMBDA will pay the Institution/Investigator a prorated amount of the per patient grant through the date of such withdrawal. Further, if, at the completion of the Trial, LAMBDA has advanced sums under the terms of this Agreement that exceed the adjusted Trial Cost, the Investigator/Institute will reimburse to LAMBDA any amount by which amounts advanced by the CRO exceed the adjusted Trial Cost.

7. The CRO may withhold all or part of any amounts in the event of:
   (1) failure of the Investigator/Institute to complete the services according to the Protocol;
   (2) failure to provide LAMBDA with requested documentation:
   (3) Failure of the Investigator/Institute to comply with the terms of this Agreement.

8. Sponsor reserve right to verify study related payment records (e.g. invoices , patient reimbursement receipts) at SITE or at LAMBDA as applicable ; as a compliance measure .

9. All screen failure patients payments will be made post LPLV.

10. For any disputed payments from the invoices, site will communicate through proper channel of LAMBDA.

GENERAL MEMORANDUM OF UNDERSTANDING (MoU) FOR ACADEMIC AND RESEARCH COOPERATION

BETWEEN

FATHER MULLER MEDICAL COLLEGE

AND

NATIONAL INSTITUTE OF TECHNOLOGY KARNATAKA, SURATHKAL

MANGALORE, INDIA

Father Muller Medical College, Kankanady, Mangalore and The National Institute of Technology Karnataka, Surathkal, establish this General Agreement to foster mutual cooperation in education and research.

1. Both parties agree to encourage the following activities, to promote academic cooperation and exchange of domain knowledge;

a) Exchange of materials in education and research, publications and academic information;

b) Facility to the research scholars to exchange data, ideas and knowledge;

c) Joint research and meetings for education and research;

d) Technical assistance;

Both parties shall discuss the problems involved to the satisfaction of each party and enter into specific activity agreements based on the mutually agreed objectives and outcomes of the relationship.

2. This General Agreement shall be applicable to educational and research organizations attached to each party.

3. This Agreement constitutes the entire agreement between the parties and all prior discussions, agreements and understandings, whether verbal or in writing are assumed to be merged in this agreement.

4. This is not considered to be a contract creating legal and financial relationship between the parties. Rather, it is designed to facilitate and develop a genuine and mutually beneficial exchange process/research relationship, and so forth.

5. This General Agreement shall become effective as on the date of signature of both parties. The Agreement may be amended by the written consent of the parties.

6. This Agreement should be reviewed every five years to evaluate the progress and the quality of the mutual cooperation. The Agreement may be extended for additional five-year period upon the written consent of both parties. If the agreement is not renewed by mutual consent The Agreement will conclude at the end of the specified time period, or after activities in progress have concluded.

7. This Agreement may be terminated by either party with minimum of 120 days written notice. However, activities in progress at the time of termination of this agreement shall be permitted to conclude as planned unless otherwise agreed.

8. Both institutions subscribe to a policy of equal opportunity and do not discriminate on the basis of race, color, gender, age, height, weight, marital or familial status, ethnicity, religion, national origin, disability and on similar issues.

9. All disputes or difference arising between the parties as to the affect, validity or interpretation of this MoU or as to their rights, duties or liabilities shall be resolved by mutual discussion between representatives of National Institute of Technology Karnataka and Father Muller Medical College.

10. Neither National Institute of Technology Karnataka nor Father Muller Medical College will be held responsible for any liability to the other party, and neither party shall

be required to purchase any insurance against loss or damage to any property due to activities to which agreement relates.

Each party shall designate a person or office to serve as liaison for implementing this agreement. For Father Muller Medical College, Kankanady, Mangalore, the contact person will be- Dr Anil Shetty, Dept of Pediatrics, Father Muller Medical College, Kankanady, Mangalore -575003, Phone no +91-0824-2238000, Fax no +91-0824-2436352, email id: anilshettyk@hotmail.com. For National Institute of Technology Karnataka, Surathkal, the contact person will be Dr. Shashidhar G. Koolagudi, Dept. Of CSE, National Institute of Technology Karnataka, Surathkal, Mangalore, 575 025, India. Phone no.: +91-0824-2473413, Fax no.: +91-0824-2474060, email Id: koolagudi@nitk.ac.in.

Every collaboration will have its own agreement/ contract which addresses issues such as publications, IPR, funding pattern, disclosure of information etc. This has to be based on the mutual discussion and agreement finalized by the concerned people involved in it.

for **Father Muller Medical College, Kankanady, Mangalore:**

Rev Fr. Patrick Rodrigues

Director

for **National Institute of Technology Karnataka, Surathkal:**

Dr. Swapan Bhattacharya Feb 10, 2015

Director

Dr. Jaya Prakash Alva

Dean

Dr. M. B. Saidutta

Dean (Alumni Affairs & Institutional Relations)

Date-10/02/2015

GOVT. OF KARNATAKA
DEPT. OF STAMP & REGISTRATION
भारत 75107 192673 कर्नाटक FEB 09 2018
INDIA R 0000100 12:08 PB6948
STAMP DUTY KARNATAKA
Sub Registrar Jayanagar, Bangalore

INVESTIGATOR CLINICAL TRIAL AGREEMENT

THIS AGREEMENT FOR "CLINICAL TRIAL" is made and entered into this **08th day of February, 2018** by and between

Biocad India Pvt. Ltd. Registered office address: #163/C, 3rd Cross, 3rd Phase, JP Nagar, Bangalore-560078, Karnataka, India., duly represented by Mr. Krishnamurthy Rao, Managing Director **(herein after referred to as "Biocad")**

AND

Dr. Ramesh Bhat, Professor, Father Muller Medical College Hospital, Father Muller Road, Kankanady, Mangalore 575002, Karnataka, India
(hereinafter referred to as the "**Principal Investigator**" or "**PI**")

AND

Father Muller Medical College Hospital, a unit of Father Muller Charitable Institutions, Father Muller Road, Kankanady, Mangalore 575002, Karnataka,India .
Protocol No: BCD-057-2
(hereinafter referred to as the **"Institution."**)

in connection with conduct of clinical trial - "A Multicenter Comparative Randomized Double-blind Study of the Efficacy and Safety of BCD-057 (INN: Adalimumab, CJSC BIOCAD, Russia) and Humira® (INN: Adalimumab, Vetter Pharma) in Patients with Moderate to Severe Plaque Psoriasis" bearing the protocol/study ID: BCD-057-2 .

PI, Institution and Biocad hereinafter are individually referred to as "**the Party**" and are jointly referred to as "**the Parties**".

WHEREAS:

1. Sponsor is a pharmaceutical company responsible for execution of a clinical trial in **India.**

2. Biocad India is the Indian subsidiary of CJSC "BIOCAD" (Sponsor) which is a Russian biotechnology company, established in 2001. CJSC Biocad has both research and development and full cycle manufacturing facilities. Biocad India desires to engage the services of the PI to conduct/assist in this clinical trial ;

3. PI has the necessary qualification, training, skill and facilities to conduct the clinical trial and is desirous of rendering such services upon such terms and conditions as envisaged below.

1. Provision of Services

1.1 The services to be provided by the PI to Biocad are described in detail in the statement attached hereto and incorporated herein by references as **Exhibit A** (hereinafter referred to as "**the Proposal**").

1.2 The Study will be conducted at the Institution under the supervision and direction of the Investigator, wherein Investigator shall control any individual performing any portion of the Study at the Institution. Site will carry out Study-related laboratory services and investigations as may be required for the Study.

1.3 The PI will conduct various activities with respect to the Clinical Trial (hereinafter referred to as "**activities**") in accordance with the following:

- Responsibilities of PI (attached herewith as **Exhibit A**) and Protocol of Clinical trial as amended from time to time.
- Budget (attached herewith as **Exhibit B)**
- All applicable International Conference on Harmonisation (ICH) Good Clinical Practice (hereinafter referred to as **"GCP"**) guidelines.
- All relevant current Indian Regulations and guidelines implemented or advised by the Indian Laws.

1.4 Biocad will provide the PI with all the information, documents, and materials which, in Biocad's reasonable opinion, are required in order to carry out activities in a Clinical Trial.

1.5 Biocad transfers the obligations, explicitly detailed in **Exhibit A** to this Agreement, for this clinical study to the PI and the PI accepts the same and shall diligently carry them out along with other obligations under this Agreement. The PI will take all reasonable steps to ensure that personnel used to perform his/her obligations under this Agreement are appropriately trained and qualified.

1.6 Biocad will appoint a representative (hereinafter referred to as the "**Clinical Research Associate (CRA)/Clinical Research Monitor (CRM)**") to be authorised to monitor the activities of the Clinical Trial. The CRA/CRM will coordinate performance of Clinical Trial with the PI. All communications between Biocad and the PI regarding the conduct of Clinical Trial shall be addressed to or routed through the CRA/CRM. Biocad may, at its discretion, change the CRA/CRM during the course of Clinical Trial and inform the PI accordingly.

1.7 The PI will store copies of all data and records generated during the trial in accordance with local regulations, applicable GCP and as per the directions of Biocad.

2. Term

This Agreement shall commence on the date of execution and shall continue till the date of payment of the last sum due hereunder or till the date when the last services

required to be performed hereunder are performed, whichever date shall last occur, unless terminated earlier as provided herein.

3. Termination and Consequences of Termination

Termination:

3.1 Either Party may terminate this Agreement without any notice, only for subjects' safety or medical reasons.

3.2 Either Party may terminate this Agreement by written notice of **forty five (45) days** to the other Party without assigning any reason thereof and **with no penalty on either side**.

3.3 Either Party may terminate this Agreement by written notice of **thirty (30) days** in advance issued by means of communication ensuring evidence of the date of receipt in case of a substantial breach by the other Party of the obligations arising out of this Agreement, provided the Party receiving such notice has neither remedied nor sufficiently explained for the breach within the period specified in the notice.

3.4 Any failure by a Party to carry out all or part of its obligations under this Agreement resulting in such detriment to the other Party as to substantially deprive such other Party of what it is entitled to expect under this Agreement, shall be considered a substantial breach for the purpose of clause 3.3 above.

3.5 Upon receipt of a written termination notice, both the parties will work diligently, in good faith and in cooperation with each other, to conduct the orderly termination of the services set forth under this Agreement.

Consequences of Expiry or Termination:

3.6 Upon expiry or termination of this Agreement, Biocad shall, in accordance with the payment provisions of Clause 2, pay for all reasonable, verifiable and completed activities up to the date of actual termination. In no event will payments made by Biocad to the PI under this Agreement exceed the project costs as set forth in the study Budget.

3.7 Upon expiry or termination of this Agreement, the PI shall, at Biocad' option, either immediately transfer to Biocad or destroy any or all Confidential Information, including any copies thereof, except for those materials or copies that are required by law or regulation or for archival purposes.

4. Intellectual Property Ownership, Invention & Discoveries and Publication

4.1 The PI acknowledges that all the intellectual property rights in the Confidential Information of and belonging to Sponsor (Biocad) which is disclosed to the PI is and shall always remain the sole and exclusive property of Sponsor (Biocad).

4.2 The primary right in the data generated during and in connection with the conduct of the trial, including publication rights, rests with the Sponsor. However, the PI may publish data generated at their (own) site:

- only upon getting written approval from Sponsor and
- only after the first publication of such data by the Sponsor.

5. Representations; Indemnification

5.1 The PI hereby warrants and represents that the following are true and correct on the date of entering into this Agreement:

a. The PI is an individual and has the requisite qualification, legal power to enter into this Agreement and to perform his/her obligations hereunder. This Agreement, when duly executed, shall constitute the legal, valid and binding obligation on the PI and is enforceable against the PI in accordance with its terms;

b. All acts and conditions required by the laws in force at the date thereof to be done, fulfilled and performed in order (i) to enable him/her lawfully to enter into this Agreement and to exercise his/her rights and perform his/her obligations under this Agreement and (ii) to make this admissible in evidence have been done, fulfilled and performed in strict compliance with the applicable laws.

5.2 The PI will be covered by a professional indemnity of sufficient value as decided by Biocad, which shall be in force throughout the term of this trial. However, this indemnity coverage does not cover any indemnity, liability or consequence arising out of or attributable to the negligence or willful misconduct of the PI.

6. Conflict of Interests

Site warrants that neither Institution nor Investigator has any conflict of interest that would affect the conduct of the Study. PI shall notify Biocad promptly and within twenty four (24) hours, if a conflict of interest arises during the term of this Agreement

7. Payment

7.1 The total fees and expenses payable by Biocad to the PI for the services set forth herein shall not exceed the Budget as per **Exhibit B**.

7.2 This study is non-negotiable and includes all costs associated with the conduct of the study, including pharmacy fees, laboratory fees, dry ice, procedure cost, study coordinator/investigator fees, patient payments, all overhead charges and administrative fees.

7.3 Non Payment:

Unless and otherwise agreed in writing, Biocad India shall make no payment for patients whom the investigator entered into the study in violation of protocol (i.e, the patient is not a qualified participant)

7.4 Biocad shall pay the PI for same in accordance with the terms set forth herein after deducting there from any tax as applicable.

7.5 Payment shall be made by account payee Cheque / DD only.

8. Governing Law

This Agreement and the rights and obligations of the parties hereunder shall be governed by and construed in accordance with the laws of **India.**

9. Arbitration

9.1 Any dispute, controversy or claim arising out of or in connection with this agreement including any question regarding its existence, validity, interpretation or termination, shall be conclusively settled by referring the same to arbitration. The arbitration proceedings shall be conducted in the English language and be governed by the provisions of the Arbitration and Conciliation Act, 1996. The venue for arbitration proceedings shall be **Bangalore**.

10. Force Majeure (Act of God)

In the event either Party is delayed or hindered in or prevented from the performance of any act required hereunder by reasons of restrictive government or judicial orders or decrees, riots, burglary, insurrection, war, acts of God, inclement weather or other similar reasons or causes beyond such Party's control, and such Party has exerted all reasonable efforts to avoid or remedy such event, then performance of such act shall be excused for the period of such delay (which is reasonable and consented by the other Party in writing). Notice of the start and stop of any such force majeure shall be provided to the other Party.

11. Record Keeping

During the term of this Agreement, PI shall maintain all materials and all other data obtained or generated by PI in the course of providing the services in a secure area reasonably protected from fire, theft and destruction.

12. Review of Work, Audit

12.1 The PI shall agree and permit concerned Government Agency, Regulatory Body, Sponsor Representative to perform, during normal business hours, quality assurance audits of the work performed under this Agreement to determine that the services are being performed in accordance with the applicable study Protocol, Government Regulations and this Agreement. PI promptly shall correct any errors or deficiencies discovered during an audit, under intimation to Biocad.

13. Headings

The headings used in this Agreement are for the sake of convenience and the same are not to be construed to define, limit or affect the construction of interpretation of this Agreement.

14. Notices & Service of documents

The notice and documents required to be given under this Agreement shall be deemed to be sufficiently given if hand delivered by one Party to the other or sent by Registered Mail with acknowledgement due.

All the correspondence/ notices to be sent by the PI to Biocad shall be addressed to:

Biocad India Pvt. Ltd.
#163/C, 3rd Cross,
3rd Phase, JP Nagar,
Bangalore-560078
Phone No. 080-41699773
Fax No. 080-41699773

All the correspondence/ notices to be sent by Biocad to PI shall be addressed to:

Dr. Ramesh Bhat
Professor,
Department of Dermatology Venereology and Leprosy,
Father Muller College hospital,
Father Muller Road,
Kankanady,
Mangalore, Karnataka,
India

FOR BIOCAD INDIA PVT. LTD.

Mr Krishnamurthy Rao **Managing Director** **Biocad India Private Limited**	**Principal Investigator** **Dr. Ramesh Bhat M**	**Institute Head** **Rev .Fr. Richard Aloysius Coelho**
Seal: BIOCAD INDIA PVT. LTD. # 163/C, 3rd Cross, 3rd Phase, J.P. Nagar BANGALORE-78	**Seal** DEPT. OF DERMATOLOGY, VENEREOLOGY AND LEPROSY Fr. Muller's Medical College Kankanady, Mangalore-575 002.	**Seal:** REV. FR RICHARD ALOYSIUS COELHO Director Father Muller Charitable Institutions Fr Muller Road, Kankanady MANGALORE-575002
Witness	**Witness**	**Witness**

Exhibit A

RESPONSIBILITIES OF PI:

INVESTIGATOR'S AGREEMENT FOR THE CLINICAL TRIAL - "A Multicenter Comparative Randomized Double-blind Study of the Efficacy and Safety of BCD-057 (INN: Adalimumab, CJSC BIOCAD, Russia) and Humira® (INN: Adalimumab, Vetter Pharma) in Patients with Moderate to Severe Plaque Psoriasis" bearing the protocol/study ID: BCD-057-2

1. I have sufficient time, adequate staff, and appropriate facilities to conduct and complete the Clinical Study. I agree to make these resources available for the duration of the study and agree that other Studies will not divert essential subjects or facilities away from this trial.

   I assure Biocad India Pvt. Ltd., that no other Clinical Study conducted by me shall give rise to a conflict of interest or interfere with the Clinical Trial.

   I will endeavor to ensure an adequate recruitment rate during the clinical investigation.

2. Biocad India Pvt. Ltd. will furnish me with copies of the Investigator's Brochure and the Study Plan or Protocol and I agree:

   a) to become thoroughly familiar with the properties of the investigational product as described in the Investigator's Brochure, which provides full information concerning the pre-clinical investigations that justify clinical studies, together with informative material describing any prior investigations, side effects, and precautions to be taken into account in the course of the clinical investigation; and

   b) To become well acquainted with the Study Plan before signing it.

3. I agree to make the necessary arrangements, including provisions for emergency treatment, to ensure the proper conduct of the Study.

4. I understand that I shall have primary responsibility for the accuracy, legibility, and security of all Study data, documents, and subject records both during and after the Study. I will be responsible for signing the Case Report Forms (CRFs). Any alteration of the raw/source data shall be signed and dated, without obliterating the original entry.

   I agree to abide by the following conditions governing my handling of the data associated with this Study.

   a) I am required to maintain adequate records regarding all investigational product received and used by me including batch numbers, dates, and quantities. If the Study is terminated, suspended, discontinued, or completed, I shall return to Biocad India Pvt. Ltd., any unused supplies unless other arrangements are made by Biocad India Pvt. Ltd.

   b. I am required to prepare and maintain adequate and accurate subjects case histories, recording all observations and other data pertinent to the clinical investigation of each subject in the Clinical Study.

c. I understand I am to furnish my records of the Study to Biocad India Pvt.Ltd.

d. I will maintain records of the disposition of the investigational product and other records for the duration longer than the following periods: Archival will be done by Third Party

i. the period defined by national or local law and rules
ii. five years after the Study is terminated or computed, or
iii. five years after the records are no longer required for purposes of supporting the relevant United States, other national, European (EU), or other international regulatory applications.
iv. To avoid any possible errors I will contact Biocad India Pvt. Ltd. prior to the destruction of records or in the event of accidental loss or destruction of any Study records.

e. I agree to provide accurate information to the Ethics Committee upon request. I also agree to provide accurate information to the regulatory authorities upon their request and within the scope of the agencies' authorities and my ethical obligations, as set forth below:

1. Upon the request of a scientifically trained and specifically authorized employee of national or international regulatory agencies, I will make records related to the Clinical Study available for inspection and copying.

2. The subject's identity will not be released except under the following limited circumstances.

i) Where data verification procedures demand inspection of subject's personal identity or personal medical information, in which case this inspection may be performed only by a properly authorized person.

3. The subject's identity shall not be released to third parties without the Subject's or subject's legal representative's prior consent. Accordingly, the study subject's or subject's legal representative's consent to the potential release of patient identity information to regulatory bodies for data verification purposes will be obtained as part of the informed consent procedure.

5. I agree to be responsible for submitting the Investigational Protocol for opinion or approval, to an appropriate Ethics Committee and shall transmit the results to Biocad India Pvt. Ltd.

I shall not commence the Study without an approval or favorable opinion from the Ethics Committee of the Investigational Protocol, informed consent forms, subject recruitment procedures, and any written material to be provided to the subject or the Subject's legal representative.

I shall provide the Ethics Committee or Institutional Review Board with all required information.

6. I certify that the investigational products for clinical investigation will be provided only to subjects under my personal supervision or under the supervision of the following sub-investigators responsible to me (add any additional names on a separate sheet, if needed):

   Sub-Investigator 1:

   I further certify that the investigational products will not be supplied by me to any investigator, other than those listed above as sub-investigators, or to any clinic, medical facility, or study site for use.

7. No procedure will be performed until all personnel have been properly trained.

8. I agree to be responsible for the personal safety and well being of the subjects. To this end, I agree to abide by the Declaration of Helsinki and their subsequent amendments, national policy, and the following conditions governing the ethical treatment of subjects in this clinical investigation:

   Following national policy and the Declaration of Helsinki, informed consent shall be documented by the subject or subject's legal representative with dated signature.

   a) I will ensure that subject / subject's legal representative or their guardians receive adequate information to make informed consents. This information will be provided both in oral and in written form and shall be in a form easily understood by the subject / subject's legal representative.

      The informed consent information shall include the aims, expected benefits, risks and inconveniences of the clinical investigation, an explanation of any alternative methods or treatments available, and an explanation of possible consequences of any withdrawal from the clinical investigation.

   b) I will ensure that the subject / subject's legal representatives are given the opportunity to inquire about the details of the Clinical Study. The information given to the subject /subject's legal representatives shall make clear to them that they remain free to refuse to participate in and free to withdraw from the Clinical Study at any time without any sanction. I will make an effort to ascertain the reasons for any withdrawal while fully respecting the subject's and/ the subject's legal representative's rights.

   c) I will ensure that the subject / the subject's legal representatives are provided adequate time to decide whether or not they wish to participate / wish their ward to participate in this clinical investigation.

   d) I will ensure Audio-Visual recording of the complete informed consent process will be done.

9. I will ensure that complete Case Report Forms (CRF) provided by Biocad will be completed promptly and accurately within 5 working days after the visit occurs at site and also ensure that any queries arising will be resolved within 3 working days.

10. I will discuss with Biocad India Pvt. Ltd. any question of modification of the Study Plan and obtain Biocad India Pvt. Ltd. written agreement and also approval from the ethics committee prior to implementation of any modification. I will not precede with a non-emergency deviation from the Clinical Protocol without approval from Biocad India Pvt. Ltd. and as needed the Ethics Committee. It is my responsibility to inform the Ethics Committee about any protocol amendment or any significant change in the Investigational Plan or Protocol that has been approved by Biocad India Pvt. Ltd., including the reason for the change, and to obtain the Ethics Committee's approval or favorable opinion regarding the change.

11. I will report all adverse events to Biocad.

a. I will promptly report:
   - Deviations from or changes to the protocol to eliminate immediate hazards to the study subjects.
   - Changes increasing the risk to subjects and/or affecting significantly the conduct of the study.
   - All adverse drug reactions (ADRs) and Adverse Events (AEs) that is both serious and unexpected.
   - New information that may affect adversely the safety of the subjects or the conduct of the study.

b. All staff in contact with the subject should be aware of their responsibility to note and report all adverse events reported by the Subjects / subjects legally acceptable representative.

c. The Investigator or designate should assess the patient at each visit for adverse event or serious adverse event that may have occurred since the previous visit.

d. All serious adverse events (SAEs) should be reported to Biocad within 24 hours.

e. The immediate reports should be followed promptly by detailed written reports including the completed Adverse Event Forms.

f. The immediate and follow-up reports should identify subjects by unique code numbers assigned to the study subjects rather than by the subjects' names, personal identification numbers and/or addresses.

g. Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations should be reported to Biocad according to the reporting requirements and within the time periods specified by Sponsor in the Protocol.

h. I will personally be responsible for, or I will appoint a sub-investigator (who has signed an Investigator Agreement and has been added to the Institution's, Biocad India Pvt. Ltd. and the Study Monitor's Investigator List) to be responsible for all Study related medical decisions.

i. I agree to personally conduct and/or supervise the clinical trial at my site. I may delegate some of the activities to the study staff, However all delegated activities will be my responsibility.

12. I will report all deviations from the protocol to Biocad India Pvt. Ltd. and the study monitor.

13. I will notify Biocad India Pvt. Ltd., immediately, but in no event in more **than five working days**, about withdrawal of approval by the reviewing Ethics Committee of my part of the Clinical Study.

14. I will comply with any request by Biocad India Pvt. Ltd. to return or dispose off, investigational product (IP) upon termination or completion of the clinical study. I understand that Biocad India Pvt. Ltd. is required by law to discontinue shipments of investigational product to me if I fail to comply with the Study Protocol or with any applicable laws or regulatory requirements applicable to the investigation, including national guidelines.

15. I agree to permit personnel from Biocad India Pvt. Ltd. and/or the Study Monitor/auditor to visit me and/or the Study Site to monitor my compliance with the protocol and/or audit the investigational records. To facilitate Biocad India Pvt. Ltd., or the Study Monitor's audit, I further agree to make records related to the Clinical Study available for inspection and copying.

16. I agree to maintain confidentiality regarding all information generated in the course of this Clinical Study. I further agree to ensure that the confidentiality of all information about subjects and the information supplied by Sponsor is respected by all persons, with the limitations discussed above.

17. I agree to submit and sign a Final Report of the Clinical Study within three months after termination or completion of the Clinical Study or of my part in the Clinical Study to the Ethics Committee.

I agree to abide by this Investigator Agreement.

Investigator Signature: _____

Date Signed: 21st Feb 2018

I agree to abide by this Investigator Agreement. (If applicable)

Sub-Investigator Signature: _____

Date Signed: 21/02/18

Exhibit B: Proposal (Budget)

Budget and Payment Terms

1. All payments would be made only upon fulfilment of responsibilities by the PI as described in Exhibit A and the services provided by the PI as is described in the clinical trial protocol including its amendments.

2. Biocad India Pvt. Ltd. offers to pay the PI **Rs. 1,72,500** which will be paid per subject as per Annexure I who completes full study (complete all study visits and procedures as required by the protocol)
   This payment is inclusive of all patient related cost as well as non-patient related cost such as all Overhead expenses, completion of case report forms, audits, administrative costs (e.g. Internet, telephone, Fax, Xerox, prints etc.), Hospitalization and infusion charges, pharmacy fees and lab costs for testing {for example CBC, Biochemistry, ECG, ECHO, as per protocol requirement}, patient travel costs, including unscheduled visits as per protocol, study/site staff fees. (Subject to deductions as per point No.4 below):

   *The payment will be made as per the visits completed by the patient

3. For Screening Failure, Rs. 5000 will be paid to PI which includes institutional overhead charges.

   Reimbursement will be not be made for any additional testing, treatment or procedures not required by the protocol, unless such additional testing, treatment or procedures are pre-approved by the sponsor.

   Below laboratory tests should be performed at the institution/local laboratory.
   Bone Scan, ECG, CBC, ESR & Biochemistry

   The costs for these are included in the budget. All other protocol specified laboratory examinations will be performed at sponsor identified central lab.

Terms of Payment:

- Payment will be made after verifying completed case report forms and completion of Resolution of Data Clarification Form/ Data queries raised by Data Management for that respective visit.

- In case the patient does not complete the milestone visits then the payment would be made as per the earliest milestone visit.

- Payment to the PI on the above milestones will be made on monthly basis only by a crossed A/C Payee Cheque in the favor of "**Father Muller Research Centre**". No payment shall be made in cash.

- The final payment will be subject to a final reconciliation, meaning after (i) all subjects have completed the study, and the database has locked, (ii) all study specific queries and issues (including data queries) has been satisfactorily resolved. (iii) The site close out visit has been completed (including the return of all study drugs) and (iv) Study records have been received by sponsor.

4. The following deductions will be made, if applicable:
    - Tax deduction at source for all payments of fee unless a valid tax exemption certificate is provided by the investigator/ institution.

    - Any capital expenses for the site incurred by Biocad on behalf of PI will be deducted from the fee payable to PI.

FOR BIOCAD INDIA PVT. LTD.

Mr Krishnamurthy Rao **Managing Director** **Biocad India Private Limited**	**Principal Investigator** **Dr. Ramesh Bhat M**	**Institute Head** **Rev .Fr. Richard Aloysius Coelho**
Seal: BIOCAD INDIA PVT. LTD. # 163/C, 3rd Cross, 3rd Phase, J.P. Nagar BANGALORE - 78	**Seal** DEPT. OF DERMATOLOGY, VENEREOLOGY AND LEPROSY Fr. Muller's Medical College Kankanady, Mangalore-575 002.	**Seal:** REV. FR RICHARD ALOYSIUS COELHO Director Father Muller Charitable Institutions Fr Muller Road, Kankanady MANGALORE-575002
Witness	**Witness**	**Witness**

NATIONAL CENTRE FOR DISEASE INFORMATICS AND RESEARCH

INDIAN COUNCIL OF MEDICAL RESEARCH

Department of Health Research, Ministry of Health and Family Welfare, Government of India
NirmalBhawan-ICMR Complex (II Floor), Poojanahalli, N.H–7, B. B. Road,
Kannamangala Post, Bengaluru–562 110 (India)

No. NCDIR/HBCR-DM/27/2017/1275

14 June 2018

Dr. Fr. Richard Aloysius Coelho
Father Muller Medical College Hospital,
Father Muller Road, Kankanady,
Mangaluru,
Karnataka 575002

Sir,

Sub: Extension of "Hospital Based Cancer Registries (HBCR)-Data Management Software for the period from 01.04.2018 to 31.03.2019.

I am directed to inform you that, Director General, ICMR, New Delhi and Director, NCDIR, Bengaluru has accorded approval for extension of above project for further period of one year w.e.f. 01.04.2018 to 31.03.2019.

The annual budget sanctioned for the financial year 2018-19 is enclosed.

Yours faithfully,

(Ramesha N.M.)
Administrative Officer
For Director

To CMS.

21-6-18

Tel +91 080 22176400, +91 080 22176300 Fax: 080 30723643, Email: ncdir@ncdirindia.org

Annual Budget for the project on "Hospital Based Cancer Registry – Data Management Software", at Father Muller Medical College Hospital, Mangalore for the financial year 2017-18 W.e.f 01-04-2018 to 31-03-2019.

Sl. No.	Designation	No. of Posts	Total per month	Total Budget per Annum
i	Social Worker @ Rs 32000/- Per Month x12 Months	1	32000/-	3,84,000
	Data Entry Operator (A) @ Rs 17000/- Per Month x12 Months	1	17000/-	2,04,000
ii	Contingency –Recurring			1,00,000
Grand Total				**6,88,000**

Clinical Trial Details (PDF Generation Date :- Thu, 18 Feb 2016 06:20:20 GMT)

CTRI Number	CTRI/2016/01/006515 [Registered on: 12/01/2016] - **Trial Registered Prospectively**
Last Modified On	15/02/2016
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	A Comparative Clinical trial to evaluate the Safety and Clinical Equivalence of Clotrimazole Troche/Lozenges USP, 10mg (Unique Pharmaceutical Laboratories, India) with Clotrimazole Troche 10mg (Roxane Laboratories Inc., USA) in subjects with Oropharyngeal Candidiasis.
Scientific Title of Study	"A Multi-Centre, Randomized, Double Blind, Parallel-Group, Comparative Clinical Trial to evaluate the Safety and Clinical Equivalence of Generic Clotrimazole Troche/Lozenges USP, 10mg (Unique Pharmaceutical Laboratories, India) to Clotrimazole Troche/Lozenges ® 10mg (Roxane Laboratories Inc., USA) in subjects with Oropharyngeal Candidiasis ".

Secondary IDs if Any

Secondary ID	Identifier
TPC-CLT-002	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Pradeep Walwaikar
Designation	Vice President, Medical
Affiliation	Unique Pharmaceutical Laboratories
Address	Neelam Centre, B wing, 4th Floor, Hind Cycle road, Worli, Mumbai 400030, India Mumbai MAHARASHTRA 400030 India
Phone	02224822360
Fax	
Email	walwaikar@jbcpl.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr Neeta Nargundkar
Designation	Head, Clinical Research Operations
Affiliation	THINQ Pharma-CRO Ltd
Address	A30, Road No. 10, MIDC, Wagle Estate, Thane, Maharashtra 400604, India. Thane MAHARASHTRA 400604 India
Phone	02225816800
Fax	
Email	neeta@thinqcro.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr Neeta Nargundkar
Designation	Head, Clinical Research Operations
Affiliation	THINQ Pharma-CRO Ltd
Address	A30, Road No. 10, MIDC, Wagle Estate, Thane, Maharashtra 400604, India. MAHARASHTRA

	400604 India
Phone	02225816800
Fax	
Email	neeta@thinqcro.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> THINQ Pharma-CRO Ltd., A30, Road No. 10, MIDC, Wagle Estate, Thane, Maharashtra 400604, India.

Primary Sponsor

Primary Sponsor Details	
Name	Unique Pharmaceutical Laboratories India
Address	Neelam Centre, B wing, 4th Floor, Hind Cycle road, Worli, Mumbai 400030, India
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Savita Lasrado	Father Muller Medical College Hospital	Department Of ENT OPD No. 41 Father Muller Road, Kankanady, Mangalore-575002, Karnataka, India Dakshina Kannada KARNATAKA	91-9945361819 savita_menezes@yahoo.com
Dr Kalpana Dasgupta	Government Medical Colllege Nagpur	HOD Department of ENT 1st floor, Government Medical College Near Hanuman Nagar Nagpur- 440009. Nagpur MAHARASHTRA	91-9822229496 drkalpanadasgupta@gmail.com
Dr Geeta Joshi	Gujrat Cancer Research Institute	Pain and pediatric 1st floor Room 102/103 Gujrat Cancer Research Institute Civil Hospital Campus, Asarwa,Ahmedabad-380 016.Gujarat, INDIA Ahmadabad GUJARAT	91-9824075707 dr.geetajoshi@gmail.com
Dr Shehnaz Kanthariya	Kailash cancer hospital and research center	Department of ENT Ground floor Muni Seva Ashram Campus, Waghodia Road, Vadodara - 390025 Vadodara GUJARAT	91-9537511001 shehnazkantharia@gmail.com
Dr Hanumanth Prasad	Mandya institute of medical science	Department of ENT Ground floor Room No. 18 Mandya institute of medical science	91-9916856058 drmhp@yahoo.com

		Bangalore - Mysore Road, Mandya, Karnataka 571401 Bangalore KARNATAKA	
Dr Anoop Raj	Maulana Azad Medical College	ENT Department 6th floor 122, Maulana Azad Medical College B.L. Taneja Block, Delhi Gate, Bahadur Shah Zafar Marg, New Delhi-110002 New Delhi DELHI	91-9968604231 dr.anoopraj@gmail.com
Dr Vimal Batra	Medical College Baroda & S.S.G Hospital	Department of Radiotherapy Ground floor Medical College Baroda & S.S.G Hospital Jail Road, Raopura, Vadodara - 390001, Vadodara GUJARAT	91-9825350509 vimalbatra@rediffmail.com
Dr B L N Prasad	Rajiv Gandhi Institute of Medical Science and RIMS Government General Hospital	Department of medicine 1st floor Room No. 13 Rajiv Gandhi Institute of Medical Science and RIMS Government General Hospital Hudco Colony, Balaga, Srikakulam, Andhra Pradesh 532001 Srikakulam ANDHRA PRADESH Srikakulam ANDHRA PRADESH	91-9848211931 amcmedicine@hotmail.com
Dr Dhrubajyoti Mukhopadhyay	Saroj Gupta Cancer Centre & Research Institute	Department Of ENT Ground floor Room No. 103 Saroj Gupta Cancer Centre & Research Institute Mahatma Gandhi road, Thakur pukur kolkata 700063 Kolkata WEST BENGAL	91-9831142992 researchccwhri@gmail.com
Dr Ashish Chikhale	Shree hospital and critical care centre	Department of ENT Ground floor Room No. 12 Shree hospital and critical care centre 799, Om Nagar, Opp Tajshree Building, Mirchi Bazar, Sakkardara Sq, Nagpur - 44009 Nagpur MAHARASHTRA	91-9850853253 shreehospitalcriticalcare@gmail.com
Dr Mohan Jagade	Sir JJ group of Hospital and Grant Government Medical College	Department of ENT,Main Building,3rd Floor Sir JJ group of	91-9323593627 mohanjagade@gmail.c

		Hospital and Grant Government Medical College Byculla Mumbai 400008 Mumbai MAHARASHTRA	om
Dr Dwarakadas Adwani	Sujan Surgical Cancer Hospital & Amravati cancer foundation, Amravati	Dental Department Ground floor 52 B Sujan Surgical Cancer Hospital, Eknath Puram Road, Shankar Nagar, AMRAVATI-444605 Amravati MAHARASHTRA	91-9823288672 dr.dgadwani1@gmail.com
Dr Devendra Chaukar	Tata Memorial Hospital	Department of Head & Neck Services 12th Floor, HBB Building,Tata Memorial Hospital Dr.E Borges Road Parel Mumbai 400012 India Mumbai MAHARASHTRA	91-9820506232 dchaukar@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Amravati Ethics Committee	Approved	28/12/2015	No
Ethics Committee, Rajiv Gandhi Institute of Medical Sciences & RIMS Government General Hospital	Approved	05/01/2016	No
Ethics Committee,MIMS , Mandya	Approved	25/01/2016	No
Fr muller Medical College, hospital.,Human Ethics Committee	Submittted/Under Review	No Date Specified	No
GCRI/GCS Ethics committee	Approved	02/12/2015	No
Grant Government Medical College & Sir J J Group of Hospital,	Submittted/Under Review	No Date Specified	No
IEC I and IEC II	Submittted/Under Review	No Date Specified	No
Institutional Ethic Committee for Human Research,medical college Baroda	Submittted/Under Review	No Date Specified	No
Institutional Ethics Committee Government Medical College,	Submittted/Under Review	No Date Specified	No
Institutional Ethics Committee MAMC	Submittted/Under Review	No Date Specified	No
Institutional Ethics Committee, Sir Ganga	Submittted/Under Review	No Date Specified	No

Ram Hospital			
Institutional Ethics Committee,Saroj Gupta Cancer Centre & Research Institute	Submittted/Under Review	No Date Specified	No
Kailash Cancer & Medical Centre Institutional Ethics Committee	Submittted/Under Review	No Date Specified	No
Shree Hospital Ethics Committee.	Approved	30/01/2016	No

Regulatory Clearance Status from DCGI

Status	Date
Awaited	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Oropharyngeal Candidiasis

Intervention / Comparator Agent

Type	Name	Details
Intervention	Clotrimazole troche/ lozenges USP, 10 mg (Unique Pharmaceutical Laboratories , India)	10mg troche 5 times a day for 14 consecutive days
Comparator Agent	Clotrimazole Troche/Lozenges ® 10mg (Roxane Laboratories Inc., USA)	10mg troche 5 times a day for 14 consecutive days

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	1. Presence of specific signs and symptoms of Oropharyngeal Candidiasis, including erythematous areas, white patches(thrush), mouth pain, irritation, burning, glossitis, altered taste, pruritis, dysphagia and odynophagia. 2. Clinical examination of oropharynx consistent with a diagnosis of oral candidiasis (such as creamy, white, curd-like patches of "thrush" or erythematous lesions on mucosal surfaces). 3. Confirmation of Candidiasis by findings on direct microscopic examination (potassium hydroxide smear) consistent with Candida species or positive fungal culture for Candida species, with culture obtained in the 2 days preceding initiation of therapy with the study drug. 4. Subjects who are able and willing to give Informed Consent.

Exclusion Criteria

Exclusion Criteria	
Details	1. Female subjects who are pregnant, lactating or planning to become pregnant during the study period. 2. Subjects diagnosed with disseminated candidiasis or requiring systemic antifungal therapy. 3. Subjects diagnosed with hairy leukoplakia. 4. Presence of only perioral lesions, e.g., angular chelitis. 5. History of intolerance or sensitivity to clotrimazole (or other imidazole or azole compounds) or any constituent of Roxane ® or the generic Clotrimazole Troche/ Lozenges or unable to tolerate oral medication. 6. Subjects having history of resistance to treatment with clotrimazole. 7. Subjects who have received any oral or systemic antifungal therapy within fourteen (14) days prior to randomization.

	8. Subjects who have received any investigational therapy within 30 days prior to randomization. 9. Subjects who have been diagnosed with any concomitant condition that, in the opinion of the investigator, could interfere with the evaluation of efficacy or safety, or would make it unlikely that the subject would complete the study. 10. Subjects who have been treated with protease inhibitors for the first time within 30 days. 11. Subjects who have been taking medications known to have significant interaction with azoles (e.g., antacids, H2-receptor blockers, rifampin, phenytoin, carbamazepine, astemizole). 12. Subjects who have a history of candidal prophylaxis with any azole antifungal medication. 13. Any subject with recurrent Oropharyngeal Candidiasis. 14. Any subject who is chronically infected with Candida. 15. Any subject with baseline liver function tests greater than 3 times the upper limit of normal (ULN). 16. CD4 cell count less than 200 cells/mm3. 17. Absolute neutrophil count less than 500/mm3. 18. Subject with history of Type II Diabetes Mellitus with Uncontrolled Blood Sugar levels. (I.e. Random Blood Sugar level > 350). 19. Suspected inability (or) unwillingness to comply with the study procedures.
Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Pre-numbered or coded identical Containers
Blinding/Masking	Participant and Investigator Blinded

Primary Outcome

Outcome	Timepoints
Clinical cure i.e., complete resolution of all signs and symptoms of Oropharyngeal Candidiasis	Day 17-25

Secondary Outcome

Outcome	Timepoints
Mycological cure (negative culture and negative KOH for Candida species)	Day 15-17

Target Sample Size	**Total Sample Size=**360 **Sample Size from India=**360
Phase of Trial	Phase 3
Date of First Enrollment (India)	01/02/2016
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**4 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	NIL
Brief Summary	**Study Title:- A Multi-Centre, Randomized, Double Blind, Parallel-Group, Comparative Clinical Trial to evaluate the Safety and Clinical Equivalence of Generic Clotrimazole Troche/Lozenges USP, 10mg (Unique Pharmaceutical Laboratories, India) to Clotrimazole Troche/Lozenges ® 10mg (Roxane Laboratories Inc., USA) in subjects with Oropharyngeal Candidiasis** **Study Rationale: - Oropharyngeal Candidiasis is a mycosis (yeast/fungal infection) of Candida species on the mucous membranes of the mouth. Clotrimazole is a broad-spectrum antifungal agent which is**

fungistatic and fungicidal and has not shown any serious adverse events. Topical drugs show increased bioavailability. By administration of a topical alternative, the affected area can be treated directly in a manner which greatly minimizes the adverse effects associated with oral medications. Hence, topical alternative minimizes the adverse events. Clotrimazole troche persists in the saliva at sufficient concentration for around 3 hours. This long term persistence of drug in saliva appears to be related to the slow release of clotrimazole from the oral mucosa to which the drug is apparently bound. Also, given as a troche, it may be the best choice nowadays owing to its high clinical success rate, safety, cost effectiveness, and high subject acceptability.

Primary Objective is to evaluate the clinical cure i.e. complete resolution of all signs and symptoms of Oropharyngeal Candidiasis, 7 days after the end of the therapy, (Day 21(+4)), which will be assessed using the Murray scale. According to the Murray Scale, lesion score 0 (0=none, 1=single, localized, 2=multiple, localized, 3=extensive, confluent) and symptom score 0 (0=absent, 1=mild, 2=moderate, 3=severe) will be considered as clinical cure

Secondary Objective is to assess the mycological cure (negative culture and negative KOH for Candida species) and complete resolution of all signs and symptoms of Oropharyngeal Candidiasis at Day 15(+2).

Sample Size: - 360 randomized, completed subjects in order to achieve at least 250 per-protocol (PP) subjects.

Study Design: - A Multi-Centre, Randomized, Double Blind, Parallel-Group, Comparative Clinical Trial. The subjects would be assigned to test product and reference product in the ratio of 1:1.

Arm A: Test Product: Clotrimazole troche/ lozenges USP, 10 mg (Unique Pharmaceutical Laboratories, India)

Arm B: Reference Product: Clotrimazole Troche/ Lozenges USP, 10 mg (Roxane Laboratories Inc., USA)

Duration of the Clinical Trial:- Total duration of the study will be approximately 5 months. After Randomization, the treatment will be for 14 consecutive days, and follow-up will be conducted on Day 8(+2), Day 15(+2) and Day 21($\pm$4).

Statistical analysis: - Continuous data will be described using Mean, Standard Deviation, Median, Minimum and Maximum values. Categorical data will be described using counts and percentages. P value less than 0.05 will be considered as statistically significant.

The Per-Protocol population (PP) will include all randomized subjects who met all inclusion/exclusion criteria, had a positive baseline Candida culture, complied with minimum treatment course, returned to study site for primary end point assessment visit (Day 21 ($\pm$ 4)) or discontinued from the study as treatment failure and did not have any protocol violations. This PP population will be used for efficacy analysis.

Efficacy: The efficacy evaluation will be calculated based on the primary and secondary endpoints of the study.

Safety: Safety will be evaluated by assessing laboratory parameters on visit 1 and visit 5 which includes (CBC, BSL (R), Blood urea and Serum creatinine) & LFT [T.Bil, ALKP, SGPT & SGOT]. Vital signs will be measured at all visits and will be used for safety assessment. Safety parameters will also be assessed by adverse event monitoring throughout the study.

Clinical Trial Details (PDF Generation Date :- Thu, 18 Feb 2016 06:20:20 GMT)

CTRI Number	CTRI/2016/01/006515 [Registered on: 12/01/2016] - **Trial Registered Prospectively**
Last Modified On	15/02/2016
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	A Comparative Clinical trial to evaluate the Safety and Clinical Equivalence of Clotrimazole Troche/Lozenges USP, 10mg (Unique Pharmaceutical Laboratories, India) with Clotrimazole Troche 10mg (Roxane Laboratories Inc., USA) in subjects with Oropharyngeal Candidiasis.
Scientific Title of Study	"A Multi-Centre, Randomized, Double Blind, Parallel-Group, Comparative Clinical Trial to evaluate the Safety and Clinical Equivalence of Generic Clotrimazole Troche/Lozenges USP, 10mg (Unique Pharmaceutical Laboratories, India) to Clotrimazole Troche/Lozenges ® 10mg (Roxane Laboratories Inc., USA) in subjects with Oropharyngeal Candidiasis ".

Secondary IDs if Any

Secondary ID	Identifier
TPC-CLT-002	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Pradeep Walwaikar
Designation	Vice President, Medical
Affiliation	Unique Pharmaceutical Laboratories
Address	Neelam Centre, B wing, 4th Floor, Hind Cycle road, Worli, Mumbai 400030, India Mumbai MAHARASHTRA 400030 India
Phone	02224822360
Fax	
Email	walwaikar@jbcpl.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr Neeta Nargundkar
Designation	Head, Clinical Research Operations
Affiliation	THINQ Pharma-CRO Ltd
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Phone	02225816800
Fax	
Email	neeta@thinqcro.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr Neeta Nargundkar
Designation	Head, Clinical Research Operations
Affiliation	THINQ Pharma-CRO Ltd
Address	A30, Road No. 10, MIDC, Wagle Estate, Thane, Maharashtra 400604, India. MAHARASHTRA

	400604 India
Phone	02225816800
Fax	
Email	neeta@thinqcro.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> THINQ Pharma-CRO Ltd., A30, Road No. 10, MIDC, Wagle Estate, Thane, Maharashtra 400604, India.

Primary Sponsor

Primary Sponsor Details	
Name	Unique Pharmaceutical Laboratories India
Address	Neelam Centre, B wing, 4th Floor, Hind Cycle road, Worli, Mumbai 400030, India
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Savita Lasrado	Father Muller Medical College Hospital	Department Of ENT OPD No. 41 Father Muller Road, Kankanady, Mangalore-575002, Karnataka, India Dakshina Kannada KARNATAKA	91-9945361819 savita_menezes@yahoo.com
Dr Kalpana Dasgupta	Government Medical Colllege Nagpur	HOD Department of ENT 1st floor, Government Medical College Near Hanuman Nagar Nagpur- 440009. Nagpur MAHARASHTRA	91-9822229496 drkalpanadasgupta@gmail.com
Dr Geeta Joshi	Gujrat Cancer Research Institute	Pain and pediatric 1st floor Room 102/103 Gujrat Cancer Research Institute Civil Hospital Campus, Asarwa,Ahmedabad-380 016.Gujarat, INDIA Ahmadabad GUJARAT	91-9824075707 dr.geetajoshi@gmail.com
Dr Shehnaz Kanthariya	Kailash cancer hospital and research center	Department of ENT Ground floor Muni Seva Ashram Campus, Waghodia Road, Vadodara - 390025 Vadodara GUJARAT	91-9537511001 shehnazkantharia@gmail.com
Dr Hanumanth Prasad	Mandya institute of medical science	Department of ENT Ground floor Room No. 18 Mandya institute of medical science	91-9916856058 drmhp@yahoo.com

		Bangalore - Mysore Road, Mandya, Karnataka 571401 Bangalore KARNATAKA	
Dr Anoop Raj	Maulana Azad Medical College	ENT Department 6th floor 122, Maulana Azad Medical College B.L. Taneja Block, Delhi Gate, Bahadur Shah Zafar Marg, New Delhi-110002 New Delhi DELHI	91-9968604231 dr.anoopraj@gmail.com
Dr Vimal Batra	Medical College Baroda & S.S.G Hospital	Department of Radiotherapy Ground floor Medical College Baroda & S.S.G Hospital Jail Road, Raopura, Vadodara - 390001, Vadodara GUJARAT	91-9825350509 vimalbatra@rediffmail.com
Dr B L N Prasad	Rajiv Gandhi Institute of Medical Science and RIMS Government General Hospital	Department of medicine 1st floor Room No. 13 Rajiv Gandhi Institute of Medical Science and RIMS Government General Hospital Hudco Colony, Balaga, Srikakulam, Andhra Pradesh 532001 Srikakulam ANDHRA PRADESH Srikakulam ANDHRA PRADESH	91-9848211931 amcmedicine@hotmail.com
Dr Dhrubajyoti Mukhopadhyay	Saroj Gupta Cancer Centre & Research Institute	Department Of ENT Ground floor Room No. 103 Saroj Gupta Cancer Centre & Research Institute Mahatma Gandhi road, Thakur pukur kolkata 700063 Kolkata WEST BENGAL	91-9831142992 researchccwhri@gmail.com
Dr Ashish Chikhale	Shree hospital and critical care centre	Department of ENT Ground floor Room No. 12 Shree hospital and critical care centre 799, Om Nagar, Opp Tajshree Building, Mirchi Bazar, Sakkardara Sq, Nagpur - 44009 Nagpur MAHARASHTRA	91-9850853253 shreehospitalcriticalcare@gmail.com
Dr Mohan Jagade	Sir JJ group of Hospital and Grant Government Medical College	Department of ENT,Main Building,3rd Floor Sir JJ group of	91-9323593627 mohanjagade@gmail.c

		Hospital and Grant Government Medical College Byculla Mumbai 400008 Mumbai MAHARASHTRA	om
Dr Dwarakadas Adwani	Sujan Surgical Cancer Hospital & Amravati cancer foundation, Amravati	Dental Department Ground floor 52 B Sujan Surgical Cancer Hospital, Eknath Puram Road, Shankar Nagar, AMRAVATI-444605 Amravati MAHARASHTRA	91-9823288672 dr.dgadwani1@gmail.com
Dr Devendra Chaukar	Tata Memorial Hospital	Department of Head & Neck Services 12th Floor, HBB Building,Tata Memorial Hospital Dr.E Borges Road Parel Mumbai 400012 India Mumbai MAHARASHTRA	91-9820506232 dchaukar@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Amravati Ethics Committee	Approved	28/12/2015	No
Ethics Committee, Rajiv Gandhi Institute of Medical Sciences & RIMS Government General Hospital	Approved	05/01/2016	No
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Ram Hospital			
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Kailash Cancer & Medical Centre Institutional Ethics Committee	Submittted/Under Review	No Date Specified	No
Shree Hospital Ethics Committee.	Approved	30/01/2016	No

Regulatory Clearance Status from DCGI

Status	Date
Awaited	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Oropharyngeal Candidiasis

Intervention / Comparator Agent

Type	Name	Details
Intervention	Clotrimazole troche/ lozenges USP, 10 mg (Unique Pharmaceutical Laboratories , India)	10mg troche 5 times a day for 14 consecutive days
Comparator Agent	Clotrimazole Troche/Lozenges ® 10mg (Roxane Laboratories Inc., USA)	10mg troche 5 times a day for 14 consecutive days

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	1. Presence of specific signs and symptoms of Oropharyngeal Candidiasis, including erythematous areas, white patches(thrush), mouth pain, irritation, burning, glossitis, altered taste, pruritis, dysphagia and odynophagia. 2. Clinical examination of oropharynx consistent with a diagnosis of oral candidiasis (such as creamy, white, curd-like patches of "thrush" or erythematous lesions on mucosal surfaces). 3. Confirmation of Candidiasis by findings on direct microscopic examination (potassium hydroxide smear) consistent with Candida species or positive fungal culture for Candida species, with culture obtained in the 2 days preceding initiation of therapy with the study drug. 4. Subjects who are able and willing to give Informed Consent.

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Details	1. Female subjects who are pregnant, lactating or planning to become pregnant during the study period. 2. Subjects diagnosed with disseminated candidiasis or requiring systemic antifungal therapy. 3. Subjects diagnosed with hairy leukoplakia. 4. Presence of only perioral lesions, e.g., angular chelitis. 5. History of intolerance or sensitivity to clotrimazole (or other imidazole or azole compounds) or any constituent of Roxane ® or the generic Clotrimazole Troche/ Lozenges or unable to tolerate oral medication. 6. Subjects having history of resistance to treatment with clotrimazole. 7. Subjects who have received any oral or systemic antifungal therapy within fourteen (14) days prior to randomization.

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Method of Generating Random Sequence	Computer generated randomization
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Primary Outcome

Outcome	Timepoints
Clinical cure i.e., complete resolution of all signs and symptoms of Oropharyngeal Candidiasis	Day 17-25

Secondary Outcome

Outcome	Timepoints
Mycological cure (negative culture and negative KOH for Candida species)	Day 15-17

Target Sample Size	**Total Sample Size=**360 **Sample Size from India=**360
Phase of Trial	Phase 3
Date of First Enrollment (India)	01/02/2016
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**4 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
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Publication Details	NIL
Brief Summary	**Study Title:- A Multi-Centre, Randomized, Double Blind, Parallel-Group, Comparative Clinical Trial to evaluate the Safety and Clinical Equivalence of Generic Clotrimazole Troche/Lozenges USP, 10mg (Unique Pharmaceutical Laboratories, India) to Clotrimazole Troche/Lozenges ® 10mg (Roxane Laboratories Inc., USA) in subjects with Oropharyngeal Candidiasis** **Study Rationale: - Oropharyngeal Candidiasis is a mycosis (yeast/fungal infection) of Candida species on the mucous membranes of the mouth. Clotrimazole is a broad-spectrum antifungal agent which is**

fungistatic and fungicidal and has not shown any serious adverse events. Topical drugs show increased bioavailability. By administration of a topical alternative, the affected area can be treated directly in a manner which greatly minimizes the adverse effects associated with oral medications. Hence, topical alternative minimizes the adverse events. Clotrimazole troche persists in the saliva at sufficient concentration for around 3 hours. This long term persistence of drug in saliva appears to be related to the slow release of clotrimazole from the oral mucosa to which the drug is apparently bound. Also, given as a troche, it may be the best choice nowadays owing to its high clinical success rate, safety, cost effectiveness, and high subject acceptability.

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Duration of the Clinical Trial:- Total duration of the study will be approximately 5 months. After Randomization, the treatment will be for 14 consecutive days, and follow-up will be conducted on Day 8(+2), Day 15(+2) and Day 21($\pm$4).

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The Per-Protocol population (PP) will include all randomized subjects who met all inclusion/exclusion criteria, had a positive baseline Candida culture, complied with minimum treatment course, returned to study site for primary end point assessment visit (Day 21 ($\pm$ 4)) or discontinued from the study as treatment failure and did not have any protocol violations. This PP population will be used for efficacy analysis.

Efficacy: The efficacy evaluation will be calculated based on the primary and secondary endpoints of the study.

Safety: Safety will be evaluated by assessing laboratory parameters on visit 1 and visit 5 which includes (CBC, BSL (R), Blood urea and Serum creatinine) & LFT [T.Bil, ALKP, SGPT & SGOT]. Vital signs will be measured at all visits and will be used for safety assessment. Safety parameters will also be assessed by adverse event monitoring throughout the study.

FATHER MULLER CHARITABLE INSTITUTIONS

Fr Muller Road, Kankanady, Mangalore – 575 002

Units : Father Muller Medical College & Allied Health Sciences, Father Muller Homoeopathic Medical College, Father Muller College of Nursing, Father Muller School of Nursing, Father Muller College of Speech & Hearing, Father Muller Medical College Hospital, Father Muller Homoeopathic Medical College Hospital, Father Muller Simulation & Skill Centre, Father Muller Hospital-Thumbay, St Joseph Leprosy Hospital, Homoeopathic Pharmaceutical Division, Rehabilitation Unit, De-addiction Centre, Father Muller Convention Centre and Father Muller Indoor Stadium.

Tel : 0824-2238000
Fax : 0824-2436661

Email : muller@fathermuller.in
Website : www. fathermuller.edu.in

ESTD 1880

GENERAL MEMORANDUM OF UNDERSTANDING (MoU) FOR ACADEMIC AND RESEARCH COOPERATION BETWEEN FATHER MULLER CHARITABLE INSTITUTIONS, MANGALORE AND ST JOSEPH ENGINEERING COLLEGE, VAMANJOOR, MANGALORE.

Father Muller Charitable Institutions (FMCI), Kankanady, Mangalore and St Joseph Engineering College, Mangalore, establish this General Agreement to foster mutual co-operation in education and research.

Both parties agree to encourage the following activities to promote academic co-operation and exchange of domain knowledge;

a) Exchange of materials in education and research, publications and academic information;
b) Facility to the research scholars to exchange data, ideas and knowledge;
c) Joint research and meeting for education and research;
d) Technical assistance;

Both parties shall discuss the issues concerned to the satisfaction of each party and enter into specific activity agreements based on mutually agreed objectives and outcomes of the relationship.

1. This General Agreement shall be applicable to educational and research organizations attached to each party.
2. This Agreement constitutes the entire agreement between the parties and all prior discussions, agreements and understandings, whether verbal or writing are assumed to be merged in this agreement.
3. This is not considered to be a contract creating legal and financial relationship between the parties. Rather, it is designed to facilitate and develop a genuine and mutually beneficial exchange process/ research relationship and so forth.
4. This General Agreement shall become effective as on the date of signature of both parties. The Agreement may be amended by the written consent of the parties.
5. This Agreement should be reviewed at the end of five years to evaluate the progress and the quality of the mutual cooperation. The Agreement may be extended upon the written consent of both parties. If the agreement is not renewed by mutual consent, the Agreement will conclude at the end of the specific time period, or after activities in progress have concluded.
6. This Agreement may be terminated by either party with a minimum of 30 days written notice. However, activities in progress at the time of termination of this agreement shall be permitted to conclude as planned unless otherwise agreed.
7. Both institutions subscribe to a policy of equal opportunity and do not discriminate on the basis of race, color, gender, age, caste, creed, ethnicity, region, religion or nationality and on similar issues.
8. All disputes or difference arising between the parties as to the affect, validity or interpretation of this MoU or as to their rights, duties or liabilities shall be resolved by mutual discussion between representatives of St Joseph Engineering College and Father Muller Charitable Institutions.
9. Neither St Joseph Engineering College, nor Father Muller Charitable Institutions will be held responsible for any liability to the other party, and neither party shall be required to purchase any insurance against loss or damage to any property due to activities to which agreement relates.
10. Each party shall designate a person or office to serve as liaison for implementing this agreement. For Father Muller Charitable Institution, Kankanady Mangalore, the contact person will be Dr D V Muralidhara, Chief Research Officer. For St Joseph Engineering College, contact person will be Dr Dayakshini, Head of the Department of Electronics and Communication Engineering.

11. All collaborations will have its own agreement/contract which addresses issues such as publications, IPR, funding pattern, disclosure of information etc., This has to be based on the mutual discussion and agreement finalized by the concerned people involved in it.

Signatories:

For

Father Muller Charitable Institutions

Kankanady, Mangalore

.....

Rev. Fr Richard Aloysius Coelho

Director

Date: 16-02-2019.

Witness

Dr Jayaprakash Alva

Dean:

Date: 20.2.19.

For

St Joseph Engineering College,

Vamanjoor, Mangalore

.....

Rev. Fr Wilfred Prakash D'Souza

Director

Date: 15/2/19

15/2/19

Dr Rio D'Souza

Principal:

Date: 15/2/19

FATHER MULLER MEDICAL COLLEGE
KANKANADY
MANGALORE
575 002

ST. JOSEPH ENGINEERING COLLEGE
MANGALORE
575 028

MEMORANDUM OF UNDERSTANDING
BETWEEN
Swami Vivekananda Yoga Anusandhana Samsthana (S-VYASA),
Bengaluru
AND
Father Muller Research Center,
Unit of Father Muller Charitable Institutions, Mangalore

(Constituent Colleges * Father Muller Medical College.
Father Muller Homeopathic Medical College.
Father Muller College of Nursing. Father Muller College of Allied Health Sciences.
Father Muller of College of Speech and Hearing)

FOR COOPERATION IN THE FIELD OF RESEARCH & EDUCATION

This Memorandum of Understanding is made on this **09th of January, 2019**

PREAMBLE

Swami Vivekananda Yoga Anusandhana Samsthana (S-VYASA), located at Bangalore, India is a Deemed to be University recognized by the Ministry of Human Resource Development, Govt. of India. It offers Bachelors, Masters, Post-graduate programs, and Doctoral Programs in the field of Yoga. The S-VYASA University is a pioneer in the field of Yoga Research and Education.

The Father Muller Research Center(FMRC), located in Mangalore ,DK District, Karnataka is an interdisciplinary research laboratory of all the constituent Medical Institutions run by the Father Muller Charitable Institution devoted to research and education.

SCOPE OF AGREEMENT

This MoU is signed between Swami Vivekananda Yoga Anusandhana Samsthana and Father Muller Research Center for the purpose of Research and Education in the field of Yoga.

Swami Vivekananda Yoga Anusandhana Samsthana
No.19, Eknath Bhavan, Gavipuram Circle, K.G. Nagar, Bangalore-19

REV. FR RICHARD ALOYSIUS COELHO
Director
Father Muller Charitable Institutions
Fr Muller Road, Kankanady
MANGALORE-575002

Objectives of MoU

- ✓ Both the parties mutually intend to conduct high quality research projects and publish in high impact journals
- ✓ To combine the best of the technology with the best of the traditional wisdom to innovate new tools for health and wellness
- ✓ To conduct and support joint workshops and seminars to disseminate usefulness of Technology in Traditional medicine

Areas of Cooperation

- ✓ Collaborative research projects on Yoga
- ✓ Developing health screening tools, particularly tools which may use alternative medicine diagnostic methods
- ✓ Participating in community health projects including health camps disease screening, field runs and health education
- ✓ Developing wearable sensors / measurement tools to assess Yoga and Meditation
- ✓ Conducting workshops and seminars related to the topic of technology and alternative medicine
- ✓ Faculty exchange programs, to the extent possible within existing programs at each institution

Terms of Agreement

This memorandum is effective immediately upon its signature by the parties. Progress in achieving the objectives referred to herein will be reviewed periodically as mutually agreed and the memorandum may be amended at any time by mutual consent. Both parties reserve the right to terminate this memorandum by either party with one month written notice given to the other party.

Confidentiality

Neither party shall, at any time disclose to any third party any confidential information of the other party which is acquired in the course of activities under this Memorandum, a collaborative project, without the prior written consent of the other party. The confidential obligations herein will not apply to information in the public domain; information in the possession of the receiving party prior to the disclosure of the information; information which is independently developed by the receiving party; information required to be released by law; or information which is rightfully received by the receiving party from third parties without any breach of confidentiality obligations.

Vivekananda Yoga Anusandhana Samsthana
No.19, Eknath Bhavan, Gavipuram Circle, K.G. Nagar, Bangalore

REV. FR RICHARD ALOYSIUS COELHO
Director
Father Muller Charitable Institutions
Fr Muller Road, Kankanady
MANGALORE-575002

Intellectual Property

Joint Inventions: Inventions made jointly by employees and/or students of S-VYASA with employees and/or students of FMRC, and make use of data produced from the collaborative work, shall be jointly owned by S-VYASA and FMRC. S-VYASA and FMRC also agree to notify each other after an invention disclosure is received by either organization's technology licensing office.

S-VYASA Inventions: Title to any invention conceived or first reduced to practice solely by employees of S-VYASA apart from the collaborative work, or prior to the start of the collaborative work, shall remain with S-VYASA.

FMRC Inventions: Title to any invention conceived or first reduced to practice solely by employees of FMRC apart from the collaborative work, or prior to the start of the collaborative work, shall remain with FMRC.

Ethics Approvals

It is the responsibility of the investigators from each site to obtain necessary approvals for conducting this study and to ensure compliance with national and global guidelines on biomedical ethics. Each investigator is responsible for any litigation that arises from data collection at their site.

Publications

Parties agree that any publication or conference presentation that makes use of the results and data produced from the collaborative work between FMRC and S-VYASA shall be mutually approved by both parties, and the principal investigators from both parties shall be invited to be co-authors of the publication or presentation. Each investigator has the right to decline the invitation to be a co-author. Both parties acknowledge that it may be necessary to delay publication in order to identify patentable subject matter and allow time for patents to be filed.

Validity and Termination

- ✓ Memorandum will enter in to force on the date of signing
- ✓ Memorandum is valid for the period of five years
- ✓ Parties may terminate this MoU at any time by written notice to the other party not later than one month.

REV. FR RICHARD ALOYSIUS COELHO
Director
Father Muller Charitable Institutions
Fr Muller Road, Kankanady
MANGALORE-575002

For S-VYASA

Signature:

Dr. Srinidhi K Parthasarathi,
Registrar,
Swami Vivekananda Yoga
Anusandhana Samsthana,
(S-VYASA), Bengaluru, India

Witnesses:

Dr. Manjunath N K,
Director-R & D and
International Affairs,
Swami Vivekananda Yoga
Anusandhana Samsthana,
(S-VYASA), Bengaluru, India

Swami Vivekananda Yoga Anusandhana Samsthana
No.19, Eknath Bhavan, Gavipuram Circle, K.G. Nagar, Bangalore-19

For FMRC/FMCI

Signature:

Rev Fr. Richard Aloysius Coelho,
Director,
Father Muller Charitable Institutions,
Father Muller Road, Kankanady,
(FMRC), Mangaluru, India

REV. FR RICHARD ALOYSIUS COELHO
Director
Father Muller Charitable Institutions
Fr Muller Road, Kankanady
MANGALORE-575002

Dr B. Sanjeev Rai,
Chief of Research,
Father Muller Charitable Institutions,
Father Muller Road, Kankanady,
(FMRC), Mangaluru, India

CLINICAL STUDY AGREEMENT

This Clinical Agreement ("**Agreement**") is entered into as of 15th Feb 2019 ("**Effective Date**") between **Novartis Healthcare Private Limited, a company registered under the Companies Act, 1956** and having its registered office at 6 & 7 floor , Inspire BKC, G Block, BKC Main Road, Bandra Kurla Complex, Bandra (East), Mumbai – 400051 ("**Novartis**") which expression shall mean and include its successors and assigns of the ONE PART;

AND

Father Muller Medical College Hospital, located at **Mangalore** ("**Institution**") registered under Father Muller Medical College Hospital (A unit of charitable Institutions) Certificate No: H-2015-0313 and having its address at **Father Muller Medical College Hospital, Father Muller Charitable Institutions, Father Muller Road, Kankanady, Mangalore 575002, Karnataka** India which expression shall mean and include its successors and assigns of the SECOND PART;

AND

Dr Ramesh Bhat M. as clinical practitioner in the field of **Professor, Department of Dermatology** acting in the role of principal investigator ("**Principal Investigator**") which expression shall mean and include his/her heirs, executors, administrators and assigns of the THIRD PART;

Novartis and Institution and Principal Investigator are hereinafter individually referred to as the "**Party**" and jointly as the "**Parties**".

RECITALS:

WHEREAS, Novartis is to perform a clinical trial (hereinafter the "Study") to evaluate the following drug: Secukinumab, AIN457M (hereafter the "Study Drug") in accordance with a protocol entitled _**A randomized, double-blind, multicenter study assessing short (16 weeks) and long-term efficacy (up to 1 year), safety, and tolerability of 2 subcutaneous secukinumab dose regimens in adult patients with moderate to severe hidradenitis suppurativa (SUNSHINE), AIN457M2301** and its amendments (hereinafter collectively the "Protocol") attached hereto in Annex 3, and,

WHEREAS, the Institution and the Principal Investigator having each reviewed the Protocol for the Study and sufficient information regarding the Study Drug to evaluate their interest in participating in the Study, wish to conduct in the Study and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Study,

WHEREAS, the Parties wish to set forth certain the terms and conditions under which the Study shall be conducted;

NOW THEREFORE, the Parties, in consideration of the above and the mutual promises set forth below, agree as follows:

1. CONFORMANCE WITH LAW AND ACCEPTED PRACTICE

The Institution and Principal Investigator shall carry out the Study in accordance with:

(a) the Protocol as amended from time to time,

(b) Good Clinical Practice;

(c) the Declaration of Helsinki;

(d) any applicable direction received from a regulatory authority (DCGI) or ethics committee with jurisdiction over the Study;

(e) any "**Applicable Law(s)**" being hereinafter defined as : all regional, federal, state, and local directives, laws, including but not limited to Schedule Y of Drugs and Cosmetics Act 1940, those related to anti-bribery and promotion, rules, regulations, orders, published guidelines, operating procedures applicable to the Study and/or the Parties including but not limited to, legislation applicable to clinical Studies, the Parties, medical treatment and the processing of personal and medical data.

(f) comply with all guidelines provided to it by Novartis from time to time individually but not limited to Novartis global Antibribery Policy and Professional Practices Policy

The Institution warrants that the Principal Investigator and the Institution's employees and collaborators involved in the Study will comply with all Applicable Laws.

2. PROTOCOL

2.1 The Parties agree that the Protocol, including any subsequent amendments and the Annexes form an integral part of this Agreement.

2.2 Institution and Principal Investigator agree to use their best efforts and professional expertise to perform the Study in accordance with the Protocol, all Applicable Laws, the identified timelines and the terms and conditions of this Agreement. Institution and Principal Investigator may not start the clinical trial without prior approval of the appropriate Ethics Committee and Regulatory Authority.

3. APPROVALS

The Study shall not commence until:

(a) all the necessary approvals of the relevant regulatory authority hence been obtained by Novartis and the competent Ethics Committee have been obtained in writing by the Principal Investigator. Such approvals shall be forwarded to Novartis no sooner they are obtained;

(b) the written approval of relevant authority or organisation that owns or is responsible for the administration of the facility in which the Study is to be performed has been obtained, if such authority or organisation is not the Institution.

(c) the Informed Consent Form as defined in Section 6.4 provided by Novartis, has been approved by the Principal Investigator and/or the ethic committee.

4. DURATION OF THE STUDY

The Study shall commence on ***1 Mar 2019*** subject to the requirements of Section 3 have been met prior to this date. The Institution shall use its best efforts to complete the Study and to perform its obligations under this Agreement by ***31 Mar 2023*** or as may be extended by a formal writing between the parties in that behalf

5. TERM OF THIS AGREEMENT

5.1 This Agreement shall be effective upon 01-Mar-2019 ('Effective Date') and shall expire upon 28-Feb-2022 (both days inclusive) unless extended or terminated in terms of this Agreement.

5.2 The following provisions shall survive the termination or expiry of this Agreement: Section 12 (Intellectual Property), Section 14 (Publication) and Section 15 (Confidentiality), as well as any other provisions which by their terms are understood to survive the termination or expiry of this Agreement, including compliance with Applicable Laws.

5.3 In the event that the Principal Investigator decides to no longer conduct the Study both Principal Investigator and the Institution shall provide written notice to Novartis as soon as possible, and at the latest, within 30 days prior to such departure. It is clarified that Principal Investigator shall not be discharged of his/her obligations under this Agreement unless the Novartis and the Institution have been provided sufficient notice in terms of this clause. Upon expiry of the notice period this Agreement shall expire. Novartis shall have the right to approve any new Principal Investigator designated by Institution and parties shall execute a fresh agreement in that behalf

6. PERFORMANCE OF THE STUDY

Principal Investigator and the Institution shall jointly and severally be responsible for the performance of the Study, in particular for the following:

6.1 Principal Investigator may appoint individuals and investigational staff as they may deem appropriate as sub-investigator (the "**Sub-Investigators**") to assist in the conduct of the Study. All Sub-Investigators and investigational staff will be adequately qualified, timely appointed and an updated list will be maintained. Principal Investigator shall alone be responsible for hiring, leading, supervising and reimbursing such team of Sub-Investigators and investigational staff, who, in all respects, shall be bound by the same terms and conditions as the Principal Investigator under this Agreement. The Principal Investigator shall be responsible for the conduct of the clinical investigation in its entirety and the well-being of the study subjects ("**Study Subjects**") and undertake in particular to have it executed by competent resources.

6.2 **Study Site**

The Study shall be conducted at the premises of Institution at the **Dermatology Department, Father Muller Medical College Hospital, Father Muller Road, Kankanady, Mangalore - 575002, Karnataka:** (hereinafter the "**Study Site**").

6.3 **Use of Study Drug:**

Novartis shall provide **Secukinumab** (hereinafter called "**Study Drug**") in sufficient quantity to conduct the Study. For purposes of this Agreement only, the Study Drug shall be supplied to Institution free of charge. In all events, the Study Drug shall remain the sole property of Novartis.

The Principal Investigator shall

(a) at his/her risks, costs and expenses ensure the safe receipt, handling, storage, use and administration of the Study Drug and take all reasonable measures to ensure that it is kept secure;

(b) not permit Study Drug to be used for any purpose other than the conduct of the Study in compliance with the Protocol;

(c) shall not make the Study drug available to any third party other than as specified in the Protocol without Novartis' prior written consent;

(d) shall fully comply with all the responsibilities set out under the law;

(e) keep full and accurate records of who dispenses the Study Drug, the quantity dispensed, and the quantity returned which shall be available for review and /or collection by Novartis and/or designated monitor ("Novartis Monitor") at any scheduled monitoring visit; and

(f) upon any earlier expiration or termination of this Agreement, at Novartis's expense, return any remaining quantities of the Study Drugs to Novartis.

6.4 **Study Subject consent and entry into Study:** Before entering a Study Subject into the Study, the Principal Investigator shall:

(a) Exercise independent medical judgement as to the compatibility of each prospective Study Subject with the requirements of the Protocol;

(b) advise Novartis of all instances in which, in the Principal Investigator's judgement, there is any question as to any prospective Study Subject's suitability for participation in the Study, and abide by Novartis's decision as to whether or not to enroll that Study Subject;

(c) ensure that, before their participation in the Study, the Study Subject, and/or as the case may be, her/his legal representative, are duly informed in language understandable to them, about all aspects of the Study that are relevant to them, including: (i) the purpose, duration, nature, significance, implications, potential benefits and/or risks of the Study; and (ii) the processing, auditing, and monitoring of data (including personal data) under this Agreement;

(d) ensure that, before his /her participation in the Study, each Study Subject and/or as the case may be her/his legal representative has given his or her Informed Consent on the basis of the information described in Clause 6.4. (c) by signing a consent form ("Informed Consent Form" or "ICF") in accordance with the Protocol and without the undue influence or coercion of any person directly involved in the Study, and in accordance with Applicable Laws. An example ICF is attached hereto as Annex 3;

(e) ensure that a copy of the signed Informed Consent Form be provided to the Study Subject, and/or as the case may be, his/her legal representative;

(f) acknowledge that the use of the Informed Consent Form does not release the Principal Investigator from his or her legal, regulatory and contractual obligations relating to Informed Consent, and that it remains the Principal Investigator's responsibility to ensure that those obligations are complied with;

(g) comply with the procedures described in the Protocol in relation to that Study Subject; and,

(h) provide details of the proposed Study Subject to Novartis.

6.5 **Study Subject Recruitment**

Principal Investigator has estimated that he/she can recruit the number of Study Subjects as specified in Annex 1. This target of recruitment can be increased only upon written agreement of Novartis. The Principal Investigator undertakes to comply with these limitations and conditions for further recruitment at the Study Site as required by Novartis.

Novartis will review the Study Subjects recruitment on an on-going basis to ensure that the enrollment continues at an acceptable rate. Novartis is empowered to discontinue the Study at Institution medical facilities in case of no or poor enrollment.

In a multicentre study, Novartis reserves the right, at its sole discretion, to require Institution and Principal Investigator to cease enrollment of Study Subjects prior to enrollment of the targeted number of Study Subjects. Institution and Principal Investigator undertake to cease such enrollment upon request of Novartis and further undertake not to seek any compensation therefor.

6.6 **Recordkeeping, Reporting, Access and Inspections**

(a) **Recordkeeping, Reporting**

The Institution and the Principal Investigator shall perform the following recordkeeping and reporting obligations in a timely fashion:

(i) Preparation and maintenance of complete, accurately written and electronic records, including accounts, notes, reports, Case Reports Forms, records of Study Subject identifications, medical notes, clinical observations, laboratory tests, and the receipt and disposition of the Study Drug and all supportive documentation and data for each Study Subject of this Study (hereinafter "Records").

(ii) Maintain a copy of all documents related to this Study for the longer of a) fifteen (15) years after the Study is completed or discontinued by Novartis) as required by applicable laws and regulations.

(iii) Meet with a representative of Novartis to discuss the progress of the Study; and Notify Novartis immediately upon discovering any significant violations of the Protocol.

(iv) In accordance with the procedure set out in the Protocol : Complete a Case Report Form for each Study Subject; review and sign each of the Case Report Forms to ensure and confirm their accuracy and completeness; promptly submit the Case Report Forms to Novartis following their completion,

(v) Cooperate with Novartis in all their efforts to monitor the Study and to support Novartis in all matters of data collection, verification and discrepancy resolution

(vi) Maintain all documents and other Records generated in the Study in safe keeping for such period as is required by any applicable regulations, and in any event for 15 years following termination of the Study; and obtain Novartis approval prior to disposing of any Record, provided that 'safe disposal' of any Record shall at all times be in compliance with 'Data Privacy and Protection' provisions set out in this Agreement. In the event of the insolvency or bankruptcy of Institution, Institution agrees to promptly transmit all copies of such records to Novartis in accordance with Novartis' written instructions and in line with the transfer and disclosure terms set out in the ICF signed by concerned trial participants, at Novartis' expense.

(vii) Ensure the hospital records of Study Subjects are kept safely in a known and accessible location during the period defined here-above.

(viii) Make all Records available to Novartis or its nominee promptly upon request for monitoring and/or auditing purposes;

(ix) Be responsible for making any necessary applications for registration under the data protection legislation in connection with data obtained under this Agreement, as provided in Article 27.

(b) **Access and Inspection**

It is agreed that the authorized representatives of Novartis, and regulatory authorities to the extent required by law, shall be entitled to:

(i) Examine and inspect the Institution's facilities required for performance of the Study; and

(ii) Inspect and copy all data and work products relating to the Study (including, without limitation, access to records as necessary for study monitoring or to audit the conduct of the Study in accordance with Novartis standards). Sponsor will maintain the confidentiality of any subject-identifiable medical records.

(iii) If any governmental or regulatory authorities notifies Institution or the Principal Investigator that it will inspect Institution's records, facilities, equipment, or procedures, or otherwise take action related to the Study, Institution shall promptly notify Novartis or any designated person within 24 hours, allow Novartis to be present at the inspection/action or participate in any response to the inspection/action, and provide Novartis with copies of any reports or information issued by the authority and Institution's proposed and final response.

(iv) Grant access to Novartis or its representative to visit periodically, as frequently as required for the proper performance and oversight of the Study, the Study Site in order to proceed with any and all monitoring activities required for the Study.

(v) The Institution and the Principal Investigator will use their best efforts to facilitate the performance of any audit and inspection and shall give Novartis and any person designated by them access to all necessary facilities, data and documents.

(vi) The Institution and the Principal Investigator shall take appropriate measures required by Novartis to correct without delay all observations found during the audits or inspections.

(vii) It is expressly agreed between the Parties that Novartis will not compensate the Institution or the Principal Investigator for the audits and inspection.

The rights and obligations under this Article shall remain in effect for fifteen (15) years after the end of the Study.

6.7 **Reporting**: The Principal Investigator shall, either by himself/herself or his/her duly authorized representative, on reasonable notice

(a) Meet with a representative of Novartis to discuss the progress of the Study; and

(b) Make the hospital notes and Case Report Forms for each Study Subject available for source data verification or auditing purposes by representatives of Novartis representatives and the officers of any competent authority.

(c) On discovering any significant violations of the Protocol, the Principal Investigator shall notify Novartis immediately.

6.8 **Reporting of Safety Information:**

The Principal Investigator shall notify Novartis of each Serious Adverse Event encountered in the Clinical Trial within twenty-four (24) hours of becoming aware of it in accordance with the instructions set forth in the Protocol as well as local regulatory requirements. Each such notice shall be given by telefax or e-mail on a Novartis Serious Adverse Event Report form, whether or not notification was initially given by telephone. Section 6.6 shall apply to both the original copy of each Serious Adverse Event Report form and the telefax confirmation sheet or e-mail reflecting its transmission to Novartis.

The Principal Investigator shall also ensure that any person involved in the conduct of the study shall:

(a) Immediately report to Novartis according to the procedure set out in the Protocol, any new safety findings on the Study Drug, including Serious Adverse Event or Serious Adverse Reaction affecting or which could have an impact on the safety of the Study Subject or which could result in a re-assessment of the risk-benefit ratio of the Study Drug. The Principal Investigator shall follow up such immediate reports and provide the additional information in a detailed, written manner to Novartis in accordance with the Protocol and local regulatory requirements;

(b) Report to Novartis all Adverse Events (refer definition of adverse event as per ICH E6 guidelines for Good Clinical Practice and/or as mentioned in the protocol) in accordance with the study Protocol, applicable study procedures for safety data reporting;

(c) Cooperate with and supply any further information required by Novartis and/or any relevant ethics committee or Regulatory Authority with jurisdiction over the Study.-

These reporting obligations shall survive expiration or earlier termination of the Agreement.

Novartis shall further report the adverse events to the competent Regulatory Authorities, in accordance with the current Applicable Laws. Novartis will furthermore provide the Principal Investigator with safety-related information from other investigational sites in order to inform the ethics committees IRB/IEC, as required.

After completion of the Study and evaluation of the results, Novartis will inform the Principal Investigator about relevant safety-related findings in accordance with the guidelines and Study procedures.

6.9 **Items supplied by Novartis**

Novartis shall provide directly or indirectly the Principal Investigator and/or the Institution with all necessary information, documents and materials, including but not limited to:

(a) the Investigator Brochure (IB)

(b) the Protocol,

(c) the CRF/e-CRF

(d) he Study Drug

(e) the study related equipments on returnable basis listed in Annexure 1

6.10 The Principal Investigator, or coordinating investigator for multicentre studies, shall sign the clinical Study reports, which form part of the marketing authorization submission.

7. LIABILITY-INDEMNIFICATION

7.1 In the case of any injury occurring to a clinical trial subject or in the event of clinical trial related death of the subject, Novartis assumes responsibility to the extent and in the manner under the applicable laws

7.2 The Institution and Principal Investigator ("**Indemnifying Party**") will indemnify and hold harmless Novartis from and against any and all liabilities, claims, damages, losses, settlements, penalties, fines, costs and expenses, including attorneys' fees, (collectively, "**Damages**") of whatever kind or nature (but not including taxes) arising from any third party demand, investigation, claim, action or suit in the based on (i) the gross negligence, bad faith or willful or intentional misconduct of the Indemnifying Party (ii) a material breach by the Indemnifying Party of any term of this Agreement, or (iii) a violation of any relevant law, rule or regulation by the Indemnifying Party in the performance of its duties under this Agreement.

8. INSURANCE

The Institution warrants that it has appropriate and adequate professional indemnity insurance to cover claims or damages including those arising out of negligence of the Principal Investigator for which it shall be liable under this Agreement. The Institution shall provide evidence of its insurance upon request by Novartis.

Novartis warrants that it has insurance for the Study Subjects included in the Study in place at Study start.

9. COMPENSATION

9.1 In consideration for the satisfactory performance of the Study according to this Agreement and the Protocol, The Principal Investigator agrees to Payment Schedule attached hereto as Annex 1.

9.2 Novartis reserves the right to terminate the Agreement immediately if no subjects have been recruited at the Study Site by 29 Jan 2021.

9.3 Subjects not completing the Study will be paid for on a prorated basis according to the number of completed visits. All payment will be made for subject visits according to the above Payment Schedule attached as Annex 1. No payment will be made for any Study Subject excluded from analysis because of Protocol violations that were within the Institution or Principal Investigator's control. Reimbursement for expenses related to screening failures, patient travel, and local lab test will be made according to the Payment Schedule in Annex 1.

9.4 The Principal Investigator shall send the invoices to:

Novartis Healthcare Private Limited
GDO Trial Monitoring, India
Nisha Mahajan/ Isha Khopkar
6 & 7 floor , Inspire BKC
G Block, BKC Main Road
Bandra Kurla Complex
Bandra (East), Mumbai – 400051
Maharashtra, India

9.5 Each invoice shall specify the Study Code. Novartis shall make payments into the account indicated by the Institution and Principal Investigator within 60 (sixty) days of receipt of an invoice from the Institution.

10. EQUIPMENT

10.1 If necessary and based upon Novartis' assessment of Institution existing equipment, Novartis may provide equipment (the "**Equipment**") to the Institution and/or Investigator strictly on a returnable basis as detailed in Annex 1 The Equipment shall remain the sole and exclusive property of Novartis. It shall be used exclusively by the Institution and/or the Investigator: The Equipment shall only be used for the conduct of the Study in accordance with the Protocol, Novartis instructions and until the Study is completed or discontinued.

10.2 If Novartis, or its designee, provides the Institution and/or Investigator with Equipment for the purpose of this Study, the Institution and Investigator agree that the Equipment shall remain in the same condition during the Study, with the exception of ordinary depreciation.

10.3 During the term of the Study, Institution and/or Investigator shall be responsible for immediately notifying Novartis of any malfunctioning Equipment.

10.4 Following completion of the Study or upon discontinuation of the Study for any reason, the Institution and/or Investigator, as the case may be, shall return the Equipment to Novartis or alternatively, in the event the Equipment remains with the Institution and/or Investigator, the cost of such Equipment will be deducted from the last payment(s) to be made to either the Institution or Investigator, as the case may be.

11. TERMINATION

11.1 Either party may terminate this Agreement for any safety and/or efficacy concerns or other ethical grounds by giving written notice to the other party with immediate effect. In case of early termination the ***Father Muller Medical College Hospital/Dr Ramesh Bhat*** shall notify the relevant Ethics Committee of the early termination, and Novartis shall notify the regulatory authorities and any other competent authorities as relevant and appropriate within specified timelines

11.2 Novartis may terminate this Agreement for convenience by giving written notice to the Institution with immediate effect.

11.3 If Novartis terminates this Agreement, Novartis shall have no obligations under this Agreement except to reimburse the Institution for such reasonable costs and non-cancellable obligations

which has been approved by Novartis incurred in the performance of the Study prior to receiving notice of termination.

11.4 The termination or expiry of this Agreement shall not affect the rights and obligations of the parties which accrue prior to the date of termination. In particular, the Institution/Principal Investigator shall provide all outstanding Case Report Forms to Novartis and return to Novartis all documents and Equipment provided by Novartis under this Agreement.

12. INTELLECTUAL PROPERTY

12.1 All data, information and documents provided to the Institution by or on behalf of Novartis, whether in paper, oral, electronic or other form, shall remain the sole property of Novartis.

12.2 All data, information, documents, inventions and discoveries, resulting from or developed in the performance of the Study or this Agreement shall be the sole property of Novartis and may be used and/or transferred by Novartis in its sole discretion with no further payment or other obligation to the Institution. The Institution shall have no rights whatsoever therein.

12.3 The Institution agrees to, and to cause its employees and collaborators and the Principal Investigator to, execute promptly all documents and take all such other action as may reasonably be requested by Novartis to enable Novartis to obtain the benefit of its rights under this Agreement. This includes without limitation taking all necessary steps for the transfer of ownership of all data, information, documents, inventions and discoveries to Novartis in accordance with this Agreement, and assisting Novartis in the preparation and prosecution of patent applications. Furthermore, Institution and Investigator shall execute, or procure the execution of, and enforce all documents and deeds and do, or procure the doing of, all things as Novartis including but not limited to assignment of any and all rights, title and interest in resulting intellectual property in Novartis.

12.4 The Institution shall ensure that the Principal Investigator and the Institution's employees and collaborators involved in the Study will comply with its obligations under this Agreement.

13. TAXES AND SOCIAL SECURITY CONTRIBUTIONS

It shall be the Institution's responsibility to comply with all obligations in respect of taxes and social security contributions, if applicable, which relate to the subject matter of this Agreement, including without limitation those which relate to the Principal Investigator, the Institution and its employees and/or collaborators.

14. PUBLICATION

14.1 Novartis recognizes the Institution's interest in making publications and presentations relating to the Study in journals, at meetings or otherwise, and may therefore permit such publications and presentations, provided however that the Institution shall provide to Novartis any proposed presentation at least 15 (fifteen) working days prior to being disclosed and any other proposed publication at least 45 (forty-five) working days prior to being disclosed, and provided that Novartis shall have the right to require amendments to any such proposed presentation or publication on reasonable grounds including without limitation:

(a) to ensure the accuracy of the presentation or publication;

(b) to ensure that proprietary information is not inadvertently divulged;

(c) to enable intellectual property rights to be secured;

(d) to enable relevant supplementary information to be provided.

14.2 Authorship of any publications relating to the Study shall be determined by mutual agreement.

14.3 Novartis may require any proposed publication or presentation to be delayed for up to 4 (four) months to enable a patent application to be prepared and filed. The 4 (four) month period shall commence on the date of receipt of the proposed publication or presentation, or from the date when all relevant data from the Study are made available to Novartis, whichever is later.

14.4 If the Study is a multi-centre study, the first publication of data shall be based on consolidated data from all centres analysed according to the Protocol, unless otherwise agreed in writing by all the Principal Investigators involved in the Study and Novartis.

14.5 Except as otherwise required by law or regulation, neither Party shall release or distribute any materials or information containing the name of the other Party or any of its officers, agents or

employees without the prior written consent by an authorised representative of the non-releasing Party.

15. CONFIDENTIALITY

15.1 All information and data, trade secrets, privileged records and other confidential or proprietary information (including but not limited to the Protocol, CRFs and information on password-protected Novartis websites) disclosed to or collected or developed by the Institution, the Principal Investigator and/or the Institution's employees and/or collaborators in connection with this Agreement or the Study (collectively "**Information**") shall be treated as confidential. The Institution and/or the Principal Investigator agree not to disclose to any third parties or to use any Information for any purpose other than the performance of the Study. The Institution and/or the Principal Investigator shall ensure that the Institution's employees and collaborators are bound by confidentiality obligations not less strict than those set out herein prior to receiving any Information.

15.2 Upon termination or expiry of this Agreement, the Institution and / or Principal Investigator shall safely destroy (as set in the Data Privacy and Protection annexure to this Agreement) or return to Novartis, as per Novartis' request, all documents, samples and material containing or relating to Information, except for one copy of Information which is to be retained in the confidential files of the Institution for record purposes only. If requested by Novartis, such safe destruction shall be promptly confirmed in writing by the Institution to Novartis.

15.3 The confidentiality obligations set out above shall not apply to:

(a) Information which is, at the time of disclosure, in the public domain or thereafter becomes part of the public domain otherwise than by the act or omission of the Institution, the Principal Investigator, or the Institution's employees and/or collaborators;

(b) Information that the Institution can demonstrate by written evidence was in its possession prior to its disclosure by Novartis or that said information, its collection or creation did not occur during or in connection with the Study;

(c) Information which the Institution received from any third party not engaged in the activities which are the subject of this Agreement, where such information is not subject to an obligation of confidentiality in favour of Novartis or any of its affiliates.

16. NOTICES

Any notice given in connection with this Agreement shall, unless otherwise provided herein, be in writing and shall be delivered personally, or sent by registered mail or facsimile to the address given in this Agreement

Mr Murugananthan, K
GDO Trial Monitoring, India
Novartis Healthcare Private Limited
6 & 7 floor , Inspire BKC
G Block, BKC Main Road
Bandra Kurla Complex
Bandra (East), Mumbai - 400051
Maharashtra, India
Telephone: 02250243544
Fax: 022- 50243005

or to such other address as may have notified to the other party in writing.

17. ASSIGNMENT

Neither Party may assign its rights and obligations under this Agreement without the other Party's prior written consent, except that Novartis may (a) assign its rights and obligations under this Agreement or any part hereof to one or more of its Affiliates; or (b) assign this Agreement in its entirety to a successor to all or substantially all of its business or assets to which this Agreement relates. Any permitted assignee will assume all obligations of its assignor under this Agreement (or related to the assigned portion in case of a partial assignment). Any attempted assignment in contravention of the foregoing will be void. Subject to the terms of this Agreement, this Agreement will be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

18. SUBCONTRACTING

The Institution and /or Principal Investigator shall not retain any subcontractor to perform any of its obligations under this Agreement without the prior written consent of Novartis. Any such consent shall not relieve the Institution and/or Principal Investigator of its obligations hereunder.

19. SEVERABILITY

The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision hereof.

20. WAIVER

No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or of any other term, provision or condition of this Agreement.

21. ENTIRE AGREEMENT

This Agreement (including the Protocol) represents the entire understanding between the parties with respect to the subject matter hereof. No amendment to this Agreement will be effective or binding unless it is in writing signed by both parties and refers to this Agreement.

22. DEBARMENT

Neither the Principal Investigator nor the Institution, nor any person employed thereby nor any collaborator who is involved in the performance of the Study has been debarred under the law including but not limited to provisions of the Indian Medical Council Act, 1956 as amended, Drug and Cosmetics Act, 1940 and no debarred person will in the future be employed or engaged by the Institution in connection with any work to be performed for or on behalf of Novartis. If at any time after the execution of this Agreement, the Institution becomes aware that the Principal Investigator or the Institution or any person employed or engaged thereby is debarred, or is in the process of being debarred, the Institution hereby certifies that the Institution will so notify Novartis at once.

23. CONFLICT OF INTEREST, FINANCIAL DISCLOSURE

The Institution and the Principal Investigator confirm that there is no conflict of interests between the Parties that would inhibit or affect their performance of the work specified in this Agreement. The Institution and the Principal Investigator further certify that they will promptly inform Novartis in the event any conflict of interests arises during the performance of this Agreement and certify that their performance hereunder does not violate any other agreement they may have with any other third party.

24. TRANSPARENCY/DISCLOSURE

24.1 In all materials relating to Services intended for an external audience, Principal Investigator shall disclose:

(a) that Novartis has retained Principal Investigator for professional services in relation to the conduct of the Study; and

(b) any other relationships that Novartis has with Principal Investigator which a reasonable and ethical person would expect to be disclosed.

24.2 Both parties agree to make all other disclosures and/or notifications as may be required in connection with entering into, performing, or receiving compensation under this Agreement, and Principal Investigator shall follow all Applicable Laws in this respect, including those relating to Principal Investigator's professional relationships with decision-making authorities or bodies (if any), such as, for instance, recusal from any votes, discussions or recommendations regarding investigational or marketed products of Novartis, regardless of whether such are subject to the Services.

24.3 The Institution and Principal Investigator understand and agree that Novartis may be required to disclose certain information to governmental agencies in different jurisdictions in order to comply with local laws regulating clinical trials. The Institution and Principal Investigator consent to the disclosure of certain information that otherwise may constitute personal data in order to comply with laws regulating clinical trials, including but not limited to the Institution's and/or Principal Investigator's name, clinical trial Study Site contact information, name of the clinical trial, sponsor,

copy of the Agreement, and costs and fees relating to Study Site's activities performed under the Agreement. Novartis will provide upon written request a list of any such disclosure made regarding the Institution and/or the Principal Investigator.

25. JURISDICTION AND APPLICABLE LAW

This Agreement shall be governed by and construed in accordance with the laws of India. The parties hereby submit to the exclusive jurisdiction of the competent courts of Mumbai, India without restricting any right of appeal.

26. DATA PROTECTION

A form regarding the disclosure of the Principal Investigator's personal data **together with the general provisions** regarding any personal information processed by the Institution under this Agreement is attached as Annex 2.

27. COUNTERPARTS

This Agreement may be executed in two or more counterparts each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

28. PRECEDENCE

To the extent that there may be any inconsistency between this Agreement and the Protocol, the Protocol shall take precedence in ONLY in relation with trial procedures while in all other instances the agreement shall prevail.

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorised representatives.

NOVARTIS HEALTHCARE PRIVATE LIMITED

By: _____

Name: Sachin Patil

Title: Clinical Study Manager

Date: 15th/Feb/2019

[Father Muller Medical College Hospital]

By: _____

Name: Rev. Fr Richard Aloysius Coelho

Title: Director, Father Muller Charitable Institutions

Date: 04 Feb 2019

Mar

[Principal Investigator]

By: _____

Name: Dr Ramesh Bhat M

Title: Principle Investigator

Date: 04/Feb/2019

Mar

FATHER MULLER CHARITABLE INSTITUTIONS
KANKANADY
MANGALORE
575 002

ANNEX 1: PAYMENT SCHEDULE

STUDY NUMBER: AIN457M2301

STUDY NAME: **A randomized, double-blind, multicenter study assessing short (16 weeks) and long-term efficacy (up to 1 year), safety, and tolerability of 2 subcutaneous secukinumab dose regimens in adult patients with moderate to severe hidradenitis suppurativa (SUNSHINE)**

Investigator's Name: Dr Ramesh Bhat M

Institute Name: Father Muller Medical College Hospital

Payee Name: Father Muller Research Centre

Pan Card Number: AAATF0345D

GSTIN: 29AAATF0345D1Z4

Committed Number of Study Subjects: 3

List of Equipments provided to Institution / Principal Investigator:

- ePRO Tablets
- Refrigerator for storage of study medications
- Thermohygrometer

Payment Schedule:

	Screening		***Treatment Period 1***							
Visit number	***Scr 1***	***Scr 2***	***baseline***	***wk 1***	***wk 2***	***wk 3***	***wk 4***	***wk 8***	***wk 12***	***wk 16/EOT1***
Day	(-28 to -14)	(-13 to -1)	1	8	15	22	29	57	85	113
Hospital Expenditures	*1500*	*1500*	*1500*	*1500*	*1500*	*1500*	*1500*	*1500*	*1500*	*1500*
Protocol Assessment Fess for PI	*10000*	*7500*	*10500*	*5500*	*6500*	*5500*	*6500*	*5500*	*5500*	*8500*
Co-I Fees	*1000*	*1000*	*1000*	*1000*	*1000*	*1000*	*1000*	*1000*	*1000*	*1000*
Institutional Overhead (20%)	*2500*	*2000*	*2600*	*1600*	*1800*	*1600*	*1800*	*1600*	*1600*	*2200*
TOTAL	***15000***	***12000***	***15600***	***9600***	***10800***	***9600***	***10800***	***9600***	***9600***	***13200***

Visit number	wk 17	wk 18	wk 19	wk 20	wk 24	wk 28	wk 32	wk 36	wk 40	wk 44	wk 48	wk 52/EOT2	wk 60/F8	Total
Day	120	127	134	141	169	197	225	253	281	309	337	365	421	
Hospital Expenditures	*1500*	*1500*	*1500*	*1500*	*1500*	*1500*	*1500*	*1500*	*1500*	*1500*	*1500*	*1500*	*1500*	34500
Protocol Assessment Fess for PI	*5500*	*5500*	*5500*	*5500*	*5500*	6500	6500	5500	5000	5500	5000	7500	7500	148000
Co-I Fees	*1000*	*1000*	*1000*	*1000*	*1000*	*1000*	*1000*	*1000*	*1000*	*1000*	*1000*	*1000*	*1000*	*23000*
Institutional overhead (20%)	*1600*	*1600*	*1600*	*1600*	*1600*	*1800*	*1800*	*1600*	*1500*	*1600*	*1500*	*2000*	*1500*	*40600*
TOTAL	**9600**	**9600**	**9600**	**9600**	**9600**	**10800**	**10800**	**9600**	**9000**	**9600**	**9000**	**12000**	**11500**	**246100**

Payment Terms:

- The amount of payment due to the Institution/Investigator will be calculated in respect of each patient visit according to the attached budget schedule.
- The budget includes Investigator, Sub investigator fee and protocol procedure charges which include all assessments to be performed at individual patient visit including study drug administration, vitals & all other assessments as per protocol visit assessment schedule
- Screen failure cost is inclusive of the above budget, and no separate screen failure cost will be provided by sponsor.
- Any other third parties designated by the Institution/Investigator that would receive remuneration, will be managed by & paid by the Institution/Investigator.
- Sponsor shall reimburse patient's travel cost per protocol visit as per actuals for which institution/PI shall provide original invoice along with the supporting bills.
- Ethics Committee fees will be paid as per actuals and subject to TDS deduction
- All payments are based on actual patient visits.
- All values are in INR. All budget schedule payments are subject to TDS (subject to Government of India, Tax regulations) and GST as applicable. GST will be paid on providing valid tax invoice with relevant details mentioning GST registration number on it.
- Rescue medication & antiseptic cost shall be reimbursed separately.

ANNEX 2: PRINCIPAL INVESTIGATOR – PERSONAL DATA DISCLOSURE FORM

Novartis wants to ask your permission to include certain elements of your personal data in a database maintained by a third party. The Grant Plan database, which is maintained and provided to pharmaceutical research sponsors by a company called TTC in the United States, is intended to assist research sponsors with transparency relating to clinical trial expenses. The database is used to support country specific forecasts for clinical trial costs and to provide benchmarking information in order to achieve transparency and fairness in setting costs for performing clinical trials.

The information is entered into the database in such a way that it is not possible for anybody except the personnel of TTC to view your name or link your site to a particular clinical trial or sponsor company.

In that regard, Novartis is asking for your permission to submit your name, clinical trial site contact information, name of the clinical trial, sponsor, copy of the clinical trial agreement, and costs and fees relating to your site's retention, to a third party administrator of this database. This information will be maintained in that database for five years. If you are conducting research for Novartis in countries other than the United States, such as those in Europe, you should note that the United States does not offer the same standards of privacy protection as those offered in Europe. You are not required to give consent to this disclosure in order to proceed with this clinical study. However, by doing so, you are helping to collect information on fair costs in clinical trials.

- ☐ Yes, I hereby agree that Novartis may disclose my personal data in connection with the Grant Plan database.
- ☐ No, I do not give my permission to disclose my personal data in connection with the Grant Plan database.

Place and Date: 04/Mar/2019
Mangalore.

Name: Dr Ramesh Bhat

Principal Investigator

Data Privacy and Protection

Provisions regarding any Personal Information Processed by Institution under this Agreement:

Defined Terms. For the purposes of this Section, the following terms shall have the meanings given below:

"**Personal Information or Data**" means any information that relates to an identified or identifiable person including without limitation electronic data and paper based files that include such information such as: (a) name or initials; (b) home or other physical address; (c) work, cell or home telephone number; (d) work or home email address or online identifier associated with the individual; (e) identification code; (f) credit card number; and (e) employment information, that is Processed directly or indirectly, by Institution on behalf of Novartis in connection with this Agreement.

"**Sensitive Personal Information or Data**" – constitutes a subset of Personal Information and relates to of an individual's (a) physical, physiological or mental characteristics, (b) economic status, (c) racial or ethnic origin, (d) political, ideological, religious opinions or philosophical beliefs, (e) trade union membership, (f) health or medical information including information related to payment for health services, (g) sex life or sexual preference, (h) genetic material or information, (i) human biological samples or cells, (j) unique biometric data, (k) Personality Profiles or (ii) an individual's name in combination with the individual's (a) Social Security number, (b) alien registration number, (c) driver's license number, (d) passport number, visa number or other government identifier, (e) credit card, debit card, or other financial account numbers, with or without any associated code or password that would permit access to such account, or (f) mother's maiden name; and as applicable under local laws.

"**Data Subject**" – and identified or identifiable person who's Agreement Personal Data are processed, accessed, received, transmitted, or maintained by the Supplier. An identifiable perosn is one sho can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological ,mental, economic, cultural or social identity.

"**Processing**" means any operation or set of operations which is performed upon personal information, whether or not by automatic means, such as collection, recording, organisation, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction or any other operation or set of operations otherwise defined in applicable Data Privacy Laws. This also includes the processing of personal information in structured manual files.

"**Institution Third Parties**" – any third party that assists Institution in performing its obligations under the Agreement, including an affiliate or direct or indirect subcontractor of Supplier.

General Obligations of Institution:

a. Compliance with Applicable Laws and Permitting Processing. Institution will, and will cause all Institution Third Parties to, hold Personal Information in confidence, use Process such data only for the benefit of Novartis and its Affiliates and Process such information in compliance with (i) all Applicable Data Protection Laws, (ii) the Agreement, (iii) any consent, authorization of a Data Subject or other authorized participant, such as subject's legal representative, (iv) industry standards, and (v) this Data Privacy and Protection Exhibit; provided, however, that Institution (or Institution's Third Party) may Process Personal Information only under the written instructions of an authorized signatory of Novartis.

To the extent that the Agreement involves the processing of personal information owned by or licensed to Institution prior to or separately from the Services, Institution represents and warrants that such data has been obtained in compliance with applicable laws and regulations, including Applicable Data Protection Laws and all necessary consents and authorizations, including those of any patient, if applicable. Institution further represents and warrants that Institution and/or Novartis is authorized to use such data as contemplated by this Agreement.

b. Obligations with respect to the Data Subjects participating in trials:
Institution shall take reasonable steps to ensure that each individual whose Personal Information were, or are, in its possession is able to assert his or her rights under local law, including but not limited to right of access to view and correct his or her Personal Data, right to withdraw consent and file complaint or grievance if any, with the Institution.

c. Obligations with Respect to Institution's Third Parties.

Within seven (7) business days of Novartis' written request, Institution will produce clear and accurate information stating who is holding and processing Agreement Personal Data, and in what country they

are located. In all such arrangements, Supplier will enter into agreements with Supplier Third Party(ies) that are substantially similar to this Data Privacy Exhibit. Supplier shall provide copies of such agreements to Novartis within seven (7) business days following a written request from Novartis therefor.

Data Safeguards. The parties agree to comply with the following:

(a) Without limitation of any provision of this Agreement, the parties agree to comply with all applicable Laws governing the privacy and security of Personal Information that Institution shall create, acquire, access or receive as a result of this Agreement, to the extent that such Laws apply to either party.

(b) Institution agrees to implement administrative, technical and physical security measures to protect Personal Information, from (i) unauthorised or accidental destruction, (ii) theft, forgery or loss, (iii) technical faults, (iv) forgery, theft or unlawful use (v) unauthorised alteration, copying access; or (vi) any other unauthorised processing.

(c) Security measures implemented by Institution must take into account (i) the purpose of the data processing, (ii) nature and extent of the processing, (iii) assessment of possible risks to the data subject; and (iv)current industry best practices and state of the art technologies, including but not limited to encryption of information at rest and in transit. Security measures shall be reviewed on a periodic basis and updated as required.

(d) All email communication with Novartis, especially those involving trial related information should happen via secure 'Institutional email Ids'. Exceptions (i.e. use of non-institutional email Ids), if any must be discussed with Novartis and a secure communication solution, as mutually agreed and in line with Novartis' security standards, is implemented.

(e) Institution shall not sub-contract any of its rights or obligations without the prior written notification to Novartis. In the event that any Institution Subcontractor shall have access to Personal Information, such access shall be permitted under a need-to-know basis and only to the extent required for the due performance of Institution's obligations. Institution shall enter into Agreements with its' subcontractors that contain privacy and security provisions that are equivalent to the provisions under this Agreement.

(f) Institution shall ensure that personnel who will be undertaking the Processing of Novartis Personal Information, including that by Institution's Third Party (if any) have appropriate skills and privacy and security training to handle Sensitive Personal Information.

(g) If Institution disposes of any paper, electronic or other record containing Agreement Personal Data, Supplier shall do so by taking all reasonable steps to destroy the information by (a) shredding; (b) permanently erasing and deleting; (c) degaussing; or (d) otherwise modifying the Agreement Personal Data in such records to make it unreadable, un-reconstructable and indecipherable.

(h) Institution shall maintain procedures to detect and respond to a Data Security Breach. Institution shall notify Novartis of any Data Security Breach within 24 hours of discovery of a data security breach. Institution shall promptly make available to Novartis details of the Data Security Breach and shall use commercially reasonable efforts to investigate and prevent the recurrence of such Data Security Breach. The parties shall reasonably cooperate to remediate a Data Security Breach and prevent any recurrence. Novartis, at its sole discretion, after consultation with Institution, shall determine whether and when to notify any individuals or persons (including Governmental Authorities) regarding any Data Security Breach affecting Novartis Personal Information. Institution, as determined in its sole discretion, shall comply with all applicable Laws to which it is subject with regard to the Data Security Breach.

ANNEX 3: NOVARTIS POLICIES & STUDY DOCUMENTS

I / We, the undersigned Institution and Principal Investigator for study number AIN457M2301 declare that I have received a copy of;

(a) Novartis global Antibribery Policy

(b) Professional Practices Policy

I / We, have read the policy (ies) understood its meaning and shall comply with the same.

[NAME OF INSTITUTION] _____	[PRINCIPAL INVESTIGATOR] _____
By: _____	By: _____
Name: REV. FR RICHARD ALOYSIUS COELHO	Name: DR. RAMESH BHAT M.
Title: DIRECTOR	Title: PI
Date: 04/Mar/2019	Date: 04/Mar/2019.

FATHER MULLER CHARITABLE INSTITUTIONS
KANKANADY
MANGALORE
575 002

NOVARTIS

Anti-Bribery Third Party Guideline

Novartis Global Guideline for engaging Third Parties

Effective: May 1, 2017

Version GIC 100.18.V3.EN

Group I&C

Contents

Glossary

Associate – Directors, officers, managers, and employees of Novartis AG and its affiliates.

Business Owner - The person from the business unit who requests or sponsors the engagement of a Third Party and who is responsible for the business impact of such engagement.

Compliance Confirmation – A Compliance Confirmation is an attestation requested from the Third Party to confirm their compliance with the law and to confirm the validity of the information collected as part of the due diligence. A template for the Compliance Confirmation is attached to Annex 5 of this Guideline.

Due Diligence Checklist – The Due Diligence Checklist is a document that is designed to help the Due Diligence Coordinator to conduct and document the efforts related to the due diligence. This checklist (issued by Group I&C) is not an exhaustive list but ensures that the main sources of information will be collected.

Due Diligence Coordinator – The person who receives the request to perform the risk-based Due Diligence on the prospective Third Party.

Executive Summary – The Executive Summary is a document that captures and summarizes the information collected during the due diligence process, the identified Red Flags, the proposed measures to address the risks identified with the proposed Third Party engagement, and the decision whether or not to engage the prospective Third Party.

Guideline – The term Guideline refers to this Anti-Bribery Third Party Guideline.

Material Change to the Structure of the Third Party – A material change to the structure of a Third Party covers the following two situations:

(a) **Change in ownership/control:** the Third Party or any person who Controls the Third Party has a change of Control. "Control" in this context means the direct or indirect ownership of more than 50% of the equity interest or voting rights in a corporation or business entity, or the ability in fact to control the management decisions of such corporation or business entity (e.g., by the appointment of a majority of the directors or management or otherwise); or

(b) **Change to membership of the executive body of the Third Party:** there is a change to the membership of the executive body of the Third Party. For example, a change to the **executive** management of the Third Party (e.g., CEO, N-1 to CEO).

Questionnaire for Third Parties – The Questionnaire is designed to assist the Due Diligence Coordinator to gather information from the Third Party amongst others about their business, their ownership and structure, government relations, compliance with laws and commercial references.

Red Flag – A Red Flag is information that indicates an increased risk of corruption or another potential issue with a Third Party, such as any undesirable characteristic that pertain to a company's ownership, business structure or relationships and/or compliance with laws.

Third Party – The term Third Party is defined in Section 2.8 of the Anti-Bribery Policy as any natural person or legal entity with whom Novartis interacts and who poses, due to the nature of their business, a particular level of bribery risk. Section 1.4 of this Guideline sets out the specific types of services that pose a bribery risk.

List of Acronyms

DDC – Due Diligence Coordinator

Group I&C – Group Integrity & Compliance

LCO – Local Compliance Officer

PEP – Politically Exposed Person

RCO – Regional Compliance Officer

1 Introduction

1.1 Purpose

Our continued commitment to ethical business conduct is central to earning and maintaining the trust and support of our key stakeholder groups and realizing our aspiration to be a trusted leader in changing the practice of medicine.

To achieve this aspiration, it is essential that Novartis only engages Third Parties that are suitable from an anti-bribery perspective. We expect Third Parties with whom we work to comply with bribery and corruption laws and to observe our requirements concerning anti-bribery.

This Guideline elaborates on section 2.8 of the Novartis Anti-Bribery Policy, and gives Associates instructions as to the requirements for the management of Third Parties from an Anti-Bribery perspective.

1.2 Scope and Applicability

This Guideline applies to all Associates.

It enters into force as of May 1, 2017 and replaces the previous version of the Novartis Third Party Guideline dated March 1, 2012.

This Guideline is not intended to override or supersede more restrictive laws relating to bribery. In addition to this Guideline, other Novartis principles and practices or equivalent documents may apply to the engagement of Third Parties (e.g. professional practices and procurement rules).

1.3 Roles and Responsibilities

The **Business Owner** has ultimate responsibility for managing and mitigating the bribery risks associated with Third Parties and must:

- confirm the legitimate need for the goods and/or service provided by the Third Party
- identify whether a Third Party falls within the scope of this Guideline
- ensure that the Due Diligence Coordinator (DDC) is provided with all necessary information to fulfill the requirements outlined in this Guideline
- validate the information captured in the Executive Summary and decide on the engagement of the Third Party
- ensure that the Agreement covers the content of the clauses listed in Section 2.2.1
- monitor the Third Party in adherence to the contract and in accordance with the measures identified in the Executive Summary
- define an audit plan, if necessary, for the Third Party in consultation with LCO and Legal

Procurement shall appoint DDCs in the relevant market, where possible cross-divisionally, and shall communicate the appointment.

The **DDC** is responsible for:

- Performing the due diligence or ensuring that it is performed for all new Third Parties or existing Third Parties who fall within the scope of this Guideline by virtue of the provision of a new service (see sections 2.1.1 and 2.1.2)

- Supporting the Business Owner in making an informed decision about the engagement of the Third Party (see section 2.1.3)
- Monitoring and performing any subsequent assessments after the Third Party has been engaged (see section 2.2.2)

If the Third Party is domiciled in a different country to the Novartis contracting entity, the DDC of the contracting entity may decide to request support from the DDC of the country in which the Third Party is domiciled. If such a request is made, the DDC in that country is obliged to provide support.

The **Local Compliance Officer** (LCO) is responsible for advising the Business Owner and the DDC. The LCO must approve any decision to pursue the engagement of any Third Party that is classified as medium or high risk.

Legal is responsible for supporting the Business Owner, as requested, when engaging the Third Party, including but not limited to the overall adequacy of the contract and inclusion of all necessary clauses.

The **Head Legal** of the local division or unit must approve any decision to pursue the engagement of any Third Party that is classified as high risk.

Group Integrity & Compliance (Group I&C) provides resources supporting the rollout of this Guideline (e.g., guidance, communication toolkits). They are responsible for keeping a central repository of these resources. A database of appointed DDCs is also maintained by Group I&C.

1.4 Third Parties Subject to this Guideline

A Third Party is subject to this Guideline if they engage in any of the activities specified below:

- Sell or resell or assist in selling or reselling Novartis products, through demand generation and/or active promotion of a Novartis product
- Act on behalf of Novartis or assist Novartis in dealing with government agencies to obtain permits, licenses, visas, regulatory approvals, pricing, reimbursement, participation in tenders, etc.
- Act on behalf of Novartis or assist Novartis in dealing or interacting with health care professionals
- Conduct clinical trials on behalf of Novartis

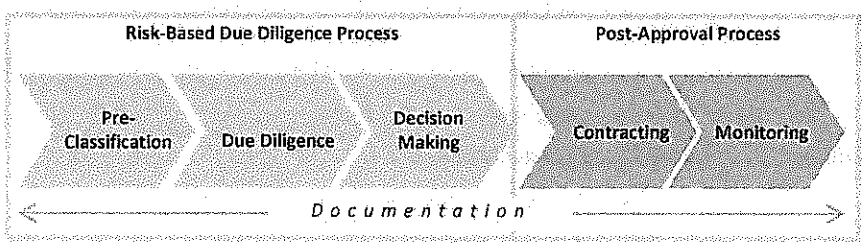
Further guidance to support the identification of Third Parties that fall within the scope of this Guideline can be found in Annex 6.

Due diligence on Third Parties that are selected as mandatory global providers for one or more of the activities listed above must be undertaken at the global level. Local organizations engaging such mandatory global providers for the activities that are subject to global due diligence are not required to perform a separate due diligence.

2 Anti-Bribery Third Party Risk Management

The management of Third Parties requires the identification, assessment, mitigation and monitoring of the risk associated with the engagement of Third Parties.

The following risk based due diligence and post-approval processes must be implemented to ensure that the risk is adequately managed:



2.1 Risk Based Due Diligence Process

2.1.1 Pre-classification of Third Party

Before the commencement of the due diligence, the Third Party must be pre-classified as "low", "medium" or "high" risk using the Novartis Risk Classification Methodology as per the Responsible Procurement Risk Assessment Process. This provides an indication of the risk-adjusted efforts required for each step of the management of the Third Party (e.g., due diligence, decision making, contracting and monitoring). Risk pre-classification is based on risk-related factors such as the geography, the type of services provided and background of Third Party.

2.1.2 Due Diligence

The purpose of the due diligence is to:

- Confirm the pre-classification through the collection and verification of due diligence process relevant information relating to the Third Party
- Identify and assess specific areas of elevated risk and seek to mitigate those risks

For all Third Parties, information on the Third Parties' business, ownership & management, government relations, compliance with laws, licenses, registrations, and certifications (such as licenses to trade) and commercial references must be collected. An essential component of this exercise is the full and accurate completion of the Novartis Anti-Bribery "Questionnaire for Third Parties" (Questionnaire) by the Third Party.

Depending on the Third Party risk pre-classification, the following due diligence activities must be completed.

Risk Classification	Minimum Activities Required
Low	Basic Due Diligence: • Verification of Questionnaire responses • Global screening of Third Party (sanctions and watch lists, etc.) • Conduct adverse internet & media search of Third Party in local language(s) and/or English
Medium	Mid-Level Due Diligence: • All low-risk due diligence activities plus: • Screening of key individuals [sanctions and watch lists, Politically Exposed Person list (PEP), etc.] • Conduct adverse internet and media searches of key individuals in the local language(s) and/or English
High	Enhanced Due Diligence: • All low and medium-risk due diligence activities plus: • Local public database searches focusing on in-country public records including litigation, regulatory, criminal, bankruptcy and directorship role of the Third Party • Verification of references collected in Questionnaire

Group I&C identifies external vendors that will provide the activities listed above.

Where the outcome of the due diligence is unclear due to conflicting or inadequate information, the DDC must conduct further investigation. This may require communication with the Third Party to clarify and validate the information collected, or to gather additional information. The DDC should discuss and align with Legal and/or the Local Compliance Officer as to whether further investigation by Global Security is needed.

Where Red Flags have been identified, mitigating and monitoring measures (if available) must be proposed to address the associated risks.

To conclude the due diligence, the DDC must prepare an Executive Summary of the information collected and verified during the due diligence; the Executive Summary must include:

- a final risk classification (i.e., low, medium or high risk)
- any Red Flags identified
- any proposed mitigating measures and monitoring activities

In order to support an informed decision, the DDC must send the Executive Summary to the Business Owner. In cases where the Third Party is classified as medium or high risk the Executive Summary shall also be sent to the LCO (for medium and high risk) and the Head Legal (for high risk only) of the local division or unit.

2.1.3 Decision Making

The Business Owner is responsible for deciding whether or not to engage the Third Party based on the results of the concluded due Diligence. For Third Parties that are classified as medium risk, the LCO has to approve the engagement. For Third Parties that are classified as high risk, the LCO and the Head Legal of the local division or unit have to approve the engagement.

Depending on the risk classification of a Third Party, the following functions and roles must be involved:

Risk Classification	**Decision**	**Consultation**	**Escalation in case of disagreement about**	
			Risk Classification, Mitigation and/or Monitoring	**Third Party Engagement**
Low Risk	Business Owner	DDC	LCO	-
Medium Risk	Business Owner & LCO	DDC	*Regional Compliance Officer (RCO) & next level manager of the Business Owner*	-
High Risk	Business Owner, LCO & Head Legal of the local division or unit	DDC	*Regional Compliance Officer (RCO) & Divisional Country Head*	

Legal, Finance, Integrity & Compliance, and other functions should be consulted by the Business Owner as appropriate.

The decision concerning the engagement of a Third Party must be documented in the Executive Summary. The concluded Executive Summary must be signed by the representatives of the functions involved.

Where Red Flags have been identified during the due diligence that could not be fully resolved (e.g. due to incomplete information), the Business Owner can only proceed if the other functions involved in decision making approve the engagement, and specific monitoring measures are documented in the Executive Summary.

Any due diligence that has been concluded may later be used by other Business Owners (from the same or another Novartis division or unit), provided that (i) the nature of the service remains the same (ii) the due diligence is not older than 3 years, and (iii) there is no Material Change to the Structure of the Third Party and there are no grounds to believe that the risk classification of the Third Party has increased.

A new due diligence may be conducted for any Third Party that failed to be approved after a prior Novartis due diligence if there are reasonable grounds to believe that the risk associated with the Third Party has decreased.

2.2 Post Approval Process

2.2.1 Contracting

Before a Third Party can be engaged by Novartis, or receive any payment from Novartis, a written contract or another written document with a similar legally binding effect (hereinafter referred to as "Agreement") must be concluded and must have come into effect. The Agreement must clearly describe the subject matter (e.g. goods and/ or services to be performed), and the terms of remuneration.

Clauses that address the following concepts must be included in each Agreement with a Third Party:

- An unequivocal statement that they will not promise, offer, pay, cause to pay, accept payment or induce payment or take any action that could be considered a bribe, and any such action will be grounds for immediate termination
- An unequivocal statement, agreeing to comply with the law, including those related to bribery and corruption such as the US Foreign Corrupt Practices Act, UK Bribery Act
- No sub-contracting of the services without Novartis prior written consent
- No assignment of the Agreement without Novartis prior written consent
- Obligation to inform Novartis of any Material Change in the Structure of the Third Party
- The right to terminate the Agreement upon occurrence of any of the following events (to the extent permitted under local law):
    - If the Third Party breaches the "Compliance with Law" clause
    - In the event of any material omission or misrepresentation of information provided by the Third Party in the due diligence
    - In the event of a material delay (at least thirty days) or failure to provide a Compliance Confirmation (where applicable)

  The termination right should be immediate where permitted under local law.

For Third Parties that pose a medium or high risk, the following additional concepts should be included in the Agreement:

- Right to audit the Third Party
- Refusal by the Third Party to be audited may result (subject to local law) in immediate termination of the Agreement by Novartis
- Responsibility to deliver during the term of the Agreement a Compliance Confirmation for each calendar year. The Compliance Confirmation shall be delivered during the first quarter of the year following the end of the calendar year to which the Compliance Confirmation relates
- Responsibility to provide training to the personnel of the Third Party or assign responsibility for such training to Third Party personnel according to the *Compliance Training Guideline for Externals Part 2: Companies and External Service Providers*

Examples of clauses that capture the aforementioned concepts are included in Annex 4 of this Guideline. Legal counsel shall have the authority to draft their preferred contract language which still adequately addresses the above concepts. Furthermore, some of these concepts may be covered by appropriate language in the Novartis Supplier Code if the Novartis Supplier Code is referenced in the Agreement with the Third Party.

2.2.2 Monitoring

The Third Party must be monitored on an on-going basis by the Business Owner and the respective DDC. The monitoring must be appropriate to the risk classification.

(a.) Event Triggered Monitoring Activities:
In instances where there is a change in circumstances (e.g., a Material Change to the Structure of a Third Party or newly identified Red Flags), the impact on the decision to continue to engage the Third Party and any possible mitigating and monitoring measures must be assessed. The Executive Summary must be updated accordingly.

This requires that the DDC and Business Owner work closely to inform each other of any relevant information that they become aware of that may have a negative impact on the risk classification of the Third Party.

(b.) Renewal of the Due Diligence:
The due diligence process must be renewed in line with the Novartis contract life and in any case at least every three years.

(c.) Pre-Defined Monitoring Activities:
An annual "Compliance Confirmation" shall be provided to Novartis by all Third Parties classified as medium and high risk. An example of such confirmation is included in Annex 5 of this Guideline.

The Business Owner in consultation with the LCO and Legal must define, if necessary, an appropriate audit plan for the Third Party.

3 Sub-Contracting and Assignment of Rights and Obligations

Any subcontracting of the services contracted by Novartis is subject to prior written approval in line with the Decision Making process defined in section 2.1.3. The risk classification of the Third Party applies to its sub-contractor.

Clauses that are materially equivalent to those that have been inserted into the Agreement with the Third Party as a result of applying section 2.2.1 should be included in the contract between the Third Party and its sub-contractor.

The requirements relating to sub-contracting also apply to any assignment of rights or obligations by the Third Party.

4 Record Keeping

Documentation related to the engagement of the Third Party must be retained to demonstrate that Novartis has taken reasonable precautions to avoid involvement in corrupt activities or with corrupt actors by providing evidence of credible due diligence, decision making, contracting and monitoring. The relevant documents should at a minimum include:

Due Diligence Process Documentation:

- Completed "Questionnaire for Third Parties" including any documentation provided by the Third Party
- Results of the Basic, Mid-Level or Enhanced Due Diligence
- Results of investigations performed by Global Security, if requested
- Completed "Due Diligence Checklist"
- Executive Summary of due Diligence
- Decision by the Business Owner, by the LCO (for medium or high risk Third Parties), and by Head Legal of the local division or unit (for high risk Third Parties); this should be shared across business units / divisions through the DDC

Contract Related Documentation:

- Agreement (e.g., Contract, Purchase Order, and evidence of relevant documentation required by Procurement)
- Documentation to support the conclusion that services and goods are priced at no more than market value (e.g., a fair market value analysis or the results of a procurement bidding process)
- Evidence of the transfer of value and/or proof the services or products were delivered (e.g. invoices)

Monitoring Related Documentation (as applicable based on Guideline):

- Documentation of training as defined by the Compliance Training Guideline for Externals Part 2: Companies and External Service Providers
- Evidence of an annual "Compliance Confirmation" by any medium or high risk Third Party
- Evidence of the results of any Third Party Audit, where performed
- Evidence of any additional local monitoring, where performed

All relevant documents should be made available at country level.

5 Implementation

5.1 Training

Associates must familiarize themselves with this Guideline. They must be trained in line with the Novartis-wide compliance training curriculum and the *Integrity & Compliance Training for Novartis Internal Associates Framework Guideline*. Additional training requirements may be defined in local company procedures.

Group I&C and/or divisional I&C provide the respective training tools.

The local compliance organization performs training about this Guideline. Procurement provides training about the systems and tools used to execute this Guideline.

5.2 Breach of this Guideline

Breaches of this Guideline will not be tolerated and can lead to disciplinary and other actions up to and including termination of employment.

5.3 Responsibilities with regard to the implementation of this Guideline

Subject to local adaption, every Novartis manager must implement this Guideline within his or her area of functional responsibility, lead by example, and provide guidance to the Associates reporting to him or her.

All Associates are responsible for adhering to the principles and rules set out in this Guideline.

The owner of this Anti-Bribery Third Party Guideline is Group I&C. They will prepare a high-level plan for the rollout of this Guideline which shall also define roles and responsibilities.

Any questions should be addressed to a representative from Integrity & Compliance or Legal.

Annexes

1. Questionnaire for Third Parties
2. Due Diligence Checklist
3. Executive Summary
4. Sample Clauses
5. Sample Compliance Confirmation
6. Guidance to support the identification of Third Parties that fall within the scope of the Anti-Bribery Third Party Guideline

NOVARTIS

Novartis Global Policy

Professional Practices Policy (P3)

Novartis Global Policy

March 1st, 2018

Version GIC 102V1.EN

NOVARTIS

Contents

1 Introduction

Purpose

Novartis' vision is to be a trusted leader in changing the practice of medicine. Consistent with this vision, Novartis is committed to the same high standard of ethical business conduct wherever it does business. Novartis has therefore adopted a single set of ethical principles that should be applied in daily decision-making by all Novartis Associates in any customer interaction and professional practice-related activity, including those not specifically covered by this Policy or related documents.

Scope and applicability

This Policy applies to all Novartis Associates as well as all professional practice-related activities conducted by third parties on behalf of Novartis. All such activities must be conducted in accordance with local laws, regulations and industry codes, which may be more stringent than the requirements outlined in this Policy.

This Policy serves as the foundation for P3 Guidelines ("Guidelines") and local standard operating procedures ("SOPs") all of which provide additional requirements for expected behaviors. As a result, this Policy should be read and applied in conjunction with the Guidelines and other references included in Section 5 of this document.

This Policy is effective as of March 1, 2018 and must be implemented by all Novartis affiliates. It replaces the existing versions of the divisional Professional Practices Policies.

The owner of this Professional Practices Policy (P3) is Group Integrity & Compliance

2 Principles

Put patients first

All interactions with our customers must ultimately benefit patients by enhancing the standard of care, raising awareness about diseases and their treatment options, or otherwise contributing to the ethical delivery of healthcare.

We will treat patient information with respect, protect confidentiality, where required obtain informed consent, and be transparent with patients at all times.

We must protect patient safety. If an Associate becomes aware of a product-related risk or complaint (e.g., adverse event, manufacturing defect or product failure) related to Novartis products (approved or investigated) it must be reported in a timely manner.

Fund responsibly

External funding, including grants, donations and sponsorships, must only be given to legitimate organizations and provided in a way that protects our reputation, aligns with society's expectations, and is consistent with the Novartis Mission to discover new ways to improve and extend people's lives.

The same rules apply for external in kind support.

Act with clear intent

As trusted partners in healthcare, all of our activities must have clear and transparent objectives that are accurate, truthful, not misleading, and appropriate for their intended context.

Novartis may conduct promotional and non-promotional activities throughout the product lifecycle. These activities ensure that products are developed to meet the needs of patients, to advance scientific understanding of disease, including disease management and treatment outcomes, and to discuss the appropriate use of products.

Non-promotional activities should never be conducted in a way that are intended or perceived to be promotional.

Engage appropriately

Associates must not offer, approve, or provide anything of value with the intent or consequence of inappropriately influencing or rewarding our customers for the use of Novartis products.

Novartis may choose to engage healthcare professionals or other customers to provide necessary and legitimate services to help us research, develop, and/or promote our products. Any compensation must be for a bona fide service, consistent with fair market value, properly documented and accounted for, and disclosed where required.

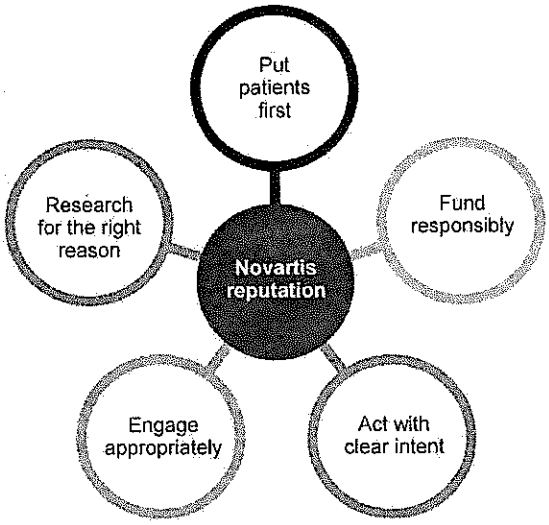
Allowable items of value, when provided to customers, must be modest, reasonable, infrequent, free from actual and perceived conflicts of interest, and disclosed where required.

Research for the right reason

Research and development must only be conducted to address valid medical or scientific questions aimed at enhancing patient care. We must always respect and protect the rights, safety and well-being of patients and animals and safeguard the integrity and validity of the data obtained.

Research and development activities must follow established ethical and scientific standards and be conducted by qualified investigators.

Research and development activities must never be promotional in nature.



3 Policy

3.1 Clinical Research

Novartis must conduct clinical **research for the right reasons**. Research must be conducted only if it is scientifically valid and designed to answer relevant medical, scientific, or health economic questions. It must follow the *Novartis Position on Clinical Study Transparency* and the *Novartis Quality Manual*.

Novartis Associates must always **put patients first** and protect their safety; if an Associate becomes aware of an adverse event related to any study or product, he/she must report it according to *Novartis Global Adverse Event Reporting Standard*.

Novartis supports the publication of study results in a timely manner and must not withhold or suppress data. We must protect confidential and/or patentable information, and personal information. Where required by local laws, regulations and/or industry codes, Novartis must disclose and report any payments or transfer of value made to HCPs and/or their institutions for research studies and third party medical writing support for publications. All publications must follow *Novartis Guidelines for the Publication of Results from Novartis-Sponsored Research*.

3.2 Pricing and Market Access

Novartis may interact with individuals, including HCPs, involved in recommending or deciding product reimbursement or purchase of Novartis products. However, these **interactions must not interfere with their independent judgment** or be perceived as improperly influencing them. Interactions may include proactive discussions to understand the needs of governments, payers and public health organizations (e.g., budgetary impact of new therapies) or responding to specific request for information (e.g., providing economic data or pipeline information that is in the public domain). All such discussions must be truthful and accurate. If these interactions are with public officials they may be subject to additional laws, regulations and industry codes. Engagement of HCPs for professional services who are formulary committee members must be disclosed according to local laws, regulations and industry codes. Discounts, rebates and other payments must be accurately and appropriately recorded in our books and records.

3.3 Pre-Approval Communication and Scientific Exchange

Products must only be **promoted consistent with approved labeling**.

Novartis supports the right of the scientific community and the public to be informed concerning scientific and medical progress. Therefore, where allowed by local laws, regulations and industry codes, Novartis may exchange scientific information. This may include communications at scientific events, public disclosure of information to investors/ shareholders, governments, reimbursement agencies or their agents and public health organizations.

Novartis may receive unsolicited requests for information on unapproved drugs and indications (off-label) from HCPs, patient organizations, and other stakeholders. Only the Medical function may provide such information in response to these requests. Novartis Associates who receive unsolicited requests for off-label information must forward such requests to the Medical function. The response provided by the Medical function, including any materials, must be accurate, not misleading, not promotional in nature, related solely to the subject matter of the request, and in compliance with local laws, regulations and industry codes. The Medical function should maintain written documentation of unsolicited requests and responses.

Novartis Medical Scientific Liaisons (MSLs) may interact with HCPs throughout the lifecycle of a product for the purpose of exchanging scientific information. Interactions must not be promotional in any way, and must have **clear intent and transparent objectives**.

3.4 Promotional Interactions

Upon receipt of marketing authorization, Novartis may interact with customers, either directly or via a third party, to promote Novartis products, related features, and benefits. All interactions must have **clear intent, transparent objectives,** and must not interfere with the independence of customers.

Products must only be promoted consistent with approved labeling, as approved by the local regulatory authorities. Anyone promoting a Novartis product must be trained and have sufficient knowledge of the product to provide full and accurate product information.

Any materials used for purposes of the interaction must be approved in accordance with the *P3 Guideline on Promotional and Non-Promotional Materials* and local laws, regulations and industry codes.

3.5 Promotional Content

Novartis may produce and disseminate content (printed, electronically, and orally) to inform, educate, or promote its products. All content **must be accurate, fair, balanced, truthful and not misleading**, based on adequate substantiation and consistent with the scope of the relevant product's marketing authorization. Content must be reviewed, approved and updated, as required in accordance with the *P3 Guideline on Promotional and Non-Promotional Materials* and local laws, regulations and industry codes.

3.6 Items of Medical Utility and Cultural Acknowledgements

Novartis must **engage appropriately with all customers**. Where permitted by local laws, regulations, and industry codes, items of medical utility and cultural acknowledgements may be offered or provided to HCPs if such items are modest, reasonable in value, offered on an occasional basis and according to the *P3 Guideline on Items of Medical Utility and Cultural Acknowledgements*.

Gifts (including personal gifts) or promotional aids, whether branded or unbranded, must not be provided to HCPs or their family members. This includes payments in cash or cash equivalents (such as gift certificates). Items made available to HCPs for use during Novartis meetings (such as pens and note pads) must not include any Novartis product or company branding.

Novartis Associates must not use their own personal funds to provide gifts to HCPs.

3.7 Samples, Demonstration and Evaluation Devices

Where permitted by local laws, regulations, and industry codes, free samples of Novartis pharmaceutical products may be provided to HCPs authorized to prescribe that product in order **to enhance patient care** or provide experience with the product. Pharmaceutical samples must be permanently labeled as samples, and managed with systems of control and accountability. They must never be resold or otherwise misused.

Over the counter (OTC) product samples may be distributed directly to customers where permitted by local laws, regulations, and industry codes.

Demonstration and evaluation devices may be provided free of charge to an HCP or HCO for a limited and agreed-upon duration. Devices provided must be labeled appropriately and must not be provided prior to receipt of marketing authorization for their intended use in that market. Title to the device must remain with Novartis for the entire duration of the evaluation and devices must not be stored at any HCP or HCO facility when not under evaluation.

3.8 Events

Novartis may organize events or fund events organized by third parties throughout the product lifecycle with the objective to provide scientific information or educate customers about our products or applicable disease areas. All events must have clear objectives, be **funded responsibly** and aligned with Novartis' mission, in a way that meets societal expectations.

Events must have **clear purpose and be transparently conducted.** If the purpose of the event is non-promotional we must not use materials with brand colors and logos or any promotional content, and avoid any perceptions of disguised promotion.

Common types of events organized or funded by Novartis are:

- Promotional **speaker programs** to educate HCPs on Novartis products or applicable disease areas.
- **Scientific meetings** to facilitate legitimate scientific debate, gain or provide scientific or medical educational information
- **Disease awareness programs** to increase knowledge and education about diseases and their management.
- **Investigator meetings** to initiate, update, or close-out Novartis sponsored or supported studies. Such meetings must be managed in accordance with the requirements of the relevant investigator study.
- Novartis **site visits** for customers or regulatory authorities. Such visits must be coordinated with the local site management.
- **Third party congress or symposia** to provide medical education.

Novartis Associates should organize events in accordance with the *P3 Guideline on Events and Professional Meetings.*

3.9 Venue, Travel, and Hospitality

All events, meetings, or activities must be held in a venue appropriate for scientific or educational exchange and in accordance with local laws, regulations, and industry codes. Novartis must avoid venues that may be perceived as extravagant or applying inappropriate influence. For Novartis-organized events, refreshments and/or meals incidental to the main purpose of the event may be provided, however no entertainment or other leisure/social activities should be provided or paid for by Novartis. Interactions with public officials may be subject to additional laws, regulations and industry codes.

Where permitted locally, Novartis may fund HCPs to attend events in their country of practice (or home country). However, Novartis does not fund HCPs to attend international events with the exception of HCPs who are providing a service to Novartis. International travel may be funded only under certain circumstances where HCPs are engaged by Novartis to provide professional services. In all instances, we must ensure that event funding does not interfere with HCP independence.

3.10 Fees for Service

Novartis may engage with HCPs and HCOs for professional services, either directly or via a third party. Such services may include the engagement of HCPs as **speakers for promotional speaking programs, scientific standalones, or other events, consulting engagements**, **advisory boards** and/or **market research**. Irrespective of direct engagement or via a third party, Novartis is responsible for **engaging appropriately** and without the intent, perception or consequence of inappropriately influencing HCPs or HCOs for the use of our products.

All engagements must be based on a legitimate need for the service. Any HCP or HCO engaged by Novartis must have the necessary experience and/or capabilities to provide the services. The engagement must be confirmed in a written agreement signed by both parties before commencing any services. Compensation for services must be reasonable and at fair market value in relation to the services rendered. Engagement of HCPs who are public officials may be subject to additional laws, regulations and industry codes.

Cross-country engagements of HCPs must be approved by qualified Novartis Associates from the HCP's practicing country for compliance with local laws, regulations and industry codes. Compensation for services must be paid into the HCP's practicing country.

Novartis Associates must follow the *P3 Guideline on HCP and HCO Engagement.*

3.11 Interactions with Patients and Patient Organizations

Novartis may interact with patients, caregivers, and patient organizations to understand their perspective and provide knowledge regarding diseases, treatments, and its care. All interactions must be ethical, transparent, non-promotional, and consistent with Novartis' mission and **maintain the independence of the patient and patient organizations**.

Novartis must treat **patient information with respect and protect confidentiality**. We must not accept any patient or caregiver information from third parties unless the patient or caregiver has provided explicit consent for the provision of the information to Novartis.

In most markets, interactions with patients are non-promotional activities and must not be used for, or mixed with, promotional purposes. Promotion of prescription-only products to patients (direct-to-consumer promotion, "DTC") is not allowed in most countries. Where such promotion is allowed, it must strictly follow the applicable local laws, regulations and industry codes. Advertisements for patient recruitment in public media, where permitted, must not be misused for promotion of a product.

Novartis may engage with patients or patient organization for services, such as participation in **patient advisory boards**. All engagements must be based on a legitimate need for the service and confirmed in a written agreement signed by both parties before commencing any services. Compensation for services must be reasonable in relation to the services rendered.
Novartis may also provide financial and other support to patients and patient organizations. Such support may be in the form of **Patient Support Programs** ("PSPs"), **Patient Assistance Programs** (PAPs), funding to support/establish patient organizations, etc.

Novartis Associates must follow the *P3 Guideline on Interactions with Patients and Patient Organizations*.

3.12 External Funding

Novartis may provide funding or other support to external organizations. This includes **grants, donations**, funding for medical education such as **preceptorship programs,** and **sponsorships.** We must **fund responsibly,** in a manner that maintains our reputation, aligns with our mission to discover new ways to improve and extend people's lives, advance medical or scientific knowledge, and supports communities where Novartis Associates live and work.

External funding or support must only be given to legitimate organizations, never to individuals, and in accordance with the *P3 Guideline on External Funding*. It must have a clear and defined purpose. Funding must be reasonable and legitimate in light of the activity being funded and properly tracked, documented, reported, and accounted for, as required by local laws, regulations and industry codes. Where applicable, funding must follow the *Novartis Anti-Bribery Policy*.

4 Definitions

Adverse Event

An adverse event is any unfavorable medical occurrence or unintended sign (including an abnormal laboratory finding), symptom, disease or injury temporally associated with the use of a medical device, medicinal or investigational product, in patients, users, or other persons, whether or not it is considered to be related to or due to the product.

Customer

Defined broadly as:

- Patients and patient organizations
- Healthcare partners, including but not limited to, healthcare professionals, healthcare organizations, payers, third party distributors/wholesalers, suppliers, intermediaries
- Non-HCP Retailers.

Caregiver

Someone who participates in or makes medical decisions for a patient. Examples of caregivers include parents or legal guardians, spouses or partners, adult children, relatives, or other friends.

Disease Awareness Programs

A program intended to provide information, awareness, or education regarding health and diseases and their management to the general public, potential patients, or HCPs.

Over the Counter (OTC) Product

A product marketed for use by consumer without the intervention of a HCP in order to obtain the product.

Cultural Acknowledgements

An inexpensive item, not related to the practice of medicine (also referred to as 'Courtesy Gift'), involving the HCP or their immediate family members to acknowledge significant national, cultural or religious holidays or events.

Donation

Benefit granted by Novartis to legitimate organizations for an altruistic and specified purpose, where Novartis does not expect to receive any benefit, consideration or service in return.

Event

A conference, congress, symposium, or any other meeting of a scientific, educational, or professional nature organized or funded partially or fully by Novartis or a third party to disseminate knowledge enhancing information, increase knowledge of Novartis products, provide scientific, educational and/or professional information.

Gifts

Benefits of any kind given to someone as a sign of appreciation or friendship without expectation of receiving anything in return.

Grant

Independently requested contribution conveyed to a legitimate organization for a specified purpose without agreement or intent to receive any tangible benefit (a measurable or quantifiable and objective benefit).

Healthcare Organizations (HCOs)

Any legal entity (such as a company, partnership, or healthcare institution), whether public or private, that offer/provide Medical Services to patients and may prescribe, order, dispense, recommend, purchase, supply, administer, lease, and use Novartis products, and all members of their office staff, and medical associations or organizations.

Examples of HCOs include: physician practices, hospitals (including university hospitals), ambulatory surgical centers, pharmacies, clinics, nursing facilities, managed care entities, group purchasing organizations (GPOs), specialty pharmacies, medical societies, and businesses owned by an individual or group of HCPs.

Healthcare Professional (HCP)

Any member, student, or researcher of the medical, dental, optometry, opticianry, pharmacy, or nursing profession or any other person, social workers, clinical psychologists, formulary committee members, and pharmacy & therapeutics (P&T) committee members who in the course of his or her professional activities provides medical services and may prescribe, order, dispense, recommend, purchase, supply, administer, lease, or use pharmaceutical products and/or medical technologies, and all members of their office staff.

Items of Medical Utility

Items given to HCPs that (1) are intended for the direct education of HCPs or patients, or are for use by patients to assist them in the administration of their treatment or management of their conditions, and (2) do not have value to HCPs outside of the scope of their practice and educational need.

Medical Services

Performing or ordering any examination, test, or procedure to diagnose or treat any medical or health-related issue, or filling a prescription for a pharmaceutical or device product that is eligible for payment by someone (whether payor is public or private) other than a patient/consumer.

Patient

Any person who may receive a prescription for, and/or are treated with a pharmaceutical product and/or medical technology for his or her individual needs.

Patient Organization

Independent organization which has the goal of providing direct support to people affected by an illness or advocating for, among other things, patients' rights, disease awareness and patient information in one or more therapeutic areas. Such organizations are often established by patients, their family members and caregivers but may also include Health Care Professionals (HCPs), volunteers and policy makers among their membership or leadership.

Patient Support Program

A program that involves direct or indirect interactions with a patient or patient's caregiver implemented by Novartis or a third-party on behalf of Novartis. Examples include helping patients manage medication administration and adherence, provide disease management support or provide or arrange for financial assistance for patients who cannot afford medications.

Pharmaceutical Samples

Free pharmaceutical products supplied to HCPs authorized to prescribe that product in order to enable HCPs and their patients to gain experience in dealing with the product.

Promotional Aid

Non-monetary items that are branded or include minimal information intended to promote Novartis or its products. Examples of Promotional Aids include pens, mousepads, and microfiber cloths.

Public Official

- Any elected or appointed officer or employee of a government or government department, government agency, or of a company owned or partially owned by a government. Medical and scientific personnel qualify as public officials when they work at a hospital, clinic, university or other similar facility owned or partially owned by a government.
- Any elected or appointed officers or employees of public international organizations, such as the United Nations

Received

- Any person acting in an official capacity for or on behalf of a government or a government department, government agency, or of a public international organization
- Politicians and candidates for a political office
- Any other person who is considered to be a public official according to applicable laws, regulations and industry codes

Research and development activities

Activities conducted to obtain scientific and clinical knowledge in order to address unmet medical needs. These activities include clinical and non-clinical studies, exploratory early stage research, investigator meetings, studies in human subjects or involving human/patient data, and animals or biological materials.

Scientific Exchange

Collection, publication, distribution and communication of scientific knowledge (knowledge related to, derived from or used in science for sharing), which may include information concerning a Novartis product.

Sponsorship

Agreement by which Novartis, for the mutual benefit of Novartis and the sponsored party, provides funding to establish an association between the Novartis' image, brands, or services and a sponsored event, activity, or organization.

5 References

- P3 Guideline on Items of Medical Utility and Cultural Acknowledgements
- P3 Guideline on Market Research
- P3 Guideline on Interactions with Patients and Patient Organizations
- P3 Guideline on External Funding
- P3 Guideline on Events and Professional Meetings
- P3 Guideline on HCP and HCO Engagements
- P3 Guideline on Promotional and Non-Promotional Materials
- Novartis Anti-Bribery Policy
- Novartis Position on Clinical Study Transparency
- Novartis Guideline for the Publication of Results from Novartis-Sponsored Research
- Novartis Quality Manual
- Novartis Global Adverse Event Reporting Standard
- Novartis Third Party Guideline

6 Implementation

Training

Associates must familiarize themselves with this Policy and the relevant Guidelines referred to in this Policy. Associates must be trained in line with the Novartis-wide compliance training curriculum. Additional training requirements for Associates and third parties conducting business on behalf of Novartis may be defined in local SOPs.

Third parties

Third parties involved in conducting activites covered by this Policy and on behalf of Novartis are expected to comply with this Policy, applicable laws and to adhere to ethical business practices. Novartis Associates contracting third parties are ultimately responsible for how third parties conduct these activities on behalf of Novartis.

Breach of this policy

Failure to comply with this Policy may lead to disciplinary and other actions, up to and including termination of employment.

Reporting potential misconduct/non-retaliation

Any Associate with knowledge of suspected misconduct must report his or her suspicion promptly in accordance with the Business Practices Office (BPO) process. Associates who report potential misconduct in good faith or who provide information or otherwise assist in any inquiry or investigation of potential misconduct will be protected against retaliatory action.

Exceptions

No exceptions can be granted from compliance with applicable laws, regulations and industry codes. The Compliance Leadership Team (CLT) will review exceptions related to this Policy.

Responsibilities

It is the responsibility of every Novartis Manager to adhere to this Policy within his or her area of functional responsibility, lead by example, and provide guidance to the Associates reporting to him or her. All Associates are responsible for adhering to this Policy.