सत्यमेव जयते

INDIA NON JUDICIAL

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Description	:	M O U
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First Party	:	BRS HEALTH AND RESEARCH INSTITUTE PVT LTD
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MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (the "MoU") is made and executed on 9th day of August Month, year Two Thousand and Nineteen 09/08/2019) at Mangalore.

BY AND BETWEEN

FATHER MULLER CHARITABLE INSTITUTIONS KANKANADY MANGALORE 575 002

BRS Health & Research Institute Pvt. Ltd. Mother & Child Hospital UDUPI

Statutory Alert:

1. The authenticity of this Stamp Certificate should be verified at "www.shcilestamp.com". Any discrepancy in the details on this Certificate and as available on the website renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
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BRS HEALTH AND RESEARCH INSTITUTE PRIVATE LIMITED, a private limited company incorporated under the provisions of Companies Act, 1956, having its registered office at No G17 North Block Manipal Centre, Dickenson Road Bangalore – 560042, represented by its Authorized Signatory - **Mr. Prashanth Mallya.**

(Hereinafter referred to as the **'Hospital'**, which expression, unless repugnant to the context hereof shall include its holding Company, subsidiaries, associates, affiliates, shareholders and directors) of the **ONE PART.**

AND

FATHER MULLER MEDICAL COLLEGE, a unit of Father Muller Charitable Institutions which is a trust/ society registered under Societies Registration act XX1 of 1860, having its office at Mangalore, represented by its Authorized Signatory – **Rev.Fr. Richard Aloysius Coelho**

(Hereinafter referred to as the **'College'**, which expression, unless repugnant to the context hereof shall include its associates, affiliates and directors) of the **OTHER PART.**

WHEREAS, Hospital is engaged in providing specialized medical care services in the areas of maternity, childcare and other allied services with its existing hospital located at Kavi Muddanna Marg, Udupi.

WHEREAS, College is conducting academic classes for medical students and as part of curriculum of students, College wishes to send Post Graduate students on monthly rotational basis to Hospital.

WHEREAS, Hospital and College on mutual acceptance agreed to enter into this MoU to record the terms and conditions of association.

NOW THIS MOU WITNESSETH as follows and the parties hereto hereby mutually agree with each other as follows:

1. SCOPE

   a. College will send one second year Post Graduate Student to Hospital on monthly rotational basis for getting experience in obstetrics and gynecologic procedures (including family planning procedures) for their learning under supervision of Hospital consultants and to be part of daily labor room and elective OT.

   b. The postgraduate is expected to take part in labor room activities, procedures, OT cases (obstetric and gynecologic cases), family planning procedure (i.e., concurrent sterilisations, post partum sterilisations, IUCD insertion, PPIUCD insertion and laparoscopic sterilizations) and doing minor procedures like MTPs and D&C's.

FATHER MULLER CHARITABLE INSTITUTIONS * MANGALORE 575 002

BRS Health & Research Institute Pvt. Ltd. Mother & Child Hospital UDUPI

c. The students will be under supervision and guidance of the duty consultants and shall not be held legally responsible.

d. The Hospital shall provide Duty Room to students who are coming from College under this MoU during the term of their assignment in Hospital. The College shall ensure that the Students shall follow the rules, regulations and bylaws of Hospital while they are in the Premises of Hospital.

e. The timing for Students to perform their assignment is 8 am to 8 pm daily (Monday to Saturday and alternate Sundays). Other alternate Sundays shall be considered off duty hours for the students.

f. The Students attendance shall be recorded on daily basis.

g. The Students are allowed to have canteen facility at Hospital.

h. Students shall do daily night rounds by 8pm for wards and inform the cases to the senior consultant.

i. The Hospital and College shall nominate Single Point of Contact (i.e., the Medical Suprintendent) for implementation of this MoU.

j. During the term of assignment, the Students shall not be allowed to go out of the Hospital Premises without prior written approval of the Medical Superintendent.

k. During the period of assignment of Students at Hospital, the Students shall not involve any activities which is in violation of rules of Hospital and Hospital shall not be responsible for any activities they undertake in violation of the rules of Hospital.

l. The students must maintain a log book mentioning the activities performed during the assignment period with them (i.e. one month) and get the same signed by Medical Superintendent at the end of the assignment period.

m. Violation of any rules of Hospital by Students shall be treated as breach of terms of this MoU and in such situation Hospital reserves the right to cancel assignment of such student with Hospital. The Hospital shall not be responsible for any accidents which is not attributable to Hospital.

2. CONSIDERATION

a) There is no consideration involved in this MoU.

FATHER MULLER CHARITABLE INSTITUTIONS * KANKANADY MANGALORE 575 002

BRS Health & Research Institute Pvt. Ltd. * Mother & Child Hospital UDUPI

3. TERM & TERMINATION

a) This MoU shall valid for a period of 24 months from the date of signing, unless terminated earlier.

b) This MoU shall be terminated by either party by giving 30 days prior written notice (**"Notice Period"**) to the other Party.

4. REPRESENTATIONS & WARRANTIES

a) The College represents and warrants to Hospital that, the College has full right to enter into and fully perform this MoU, and entering into this MoU with the Hospital will not in any way infringe upon or violate any applicable law, rule or regulation, any contract with a third party or any rights of any third person.

b) The College shall share all the information's of students to Hospital along with the necessary supporting certificates.

c) Each party (Defaulting Party) will indemnify other party and each party shall be responsible for any and all claims, demands, actions, suits or proceedings, liabilities, losses, costs, expenses, taxes, legal fees or damages asserted or incurred against other party by any person or customer on account of acts of commission or omission by the Defaulting Party in connection with this MoU.

IN WITNESS WHEREOF, the parties hereto have signed and executed this Memorandum of Understanding on the date first mentioned hereinabove in the presence of the following witnesses;

For BRS Health & Research Institute Pvt. Ltd.,

Authorized Signatory

For Father Muller Medical College

Authorized Signatory

FATHER MULLER INSTITUTIONAL ETHICS COMMITTEE

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

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

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/2893/2016 *Date* : 03.05.2016

To,
Dr. Ramesh Bhat M
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.

Study Protocol No: 605-12

Protocol Title: A double blind, Randomized, placebo controlled, parallel group, prospective Multicentre clinical trial for evaluation of efficacy and safety of fixed dose combination of Minoxidil (5 %) + Finasteride (0.1%) Liquid solution in comparison with Minoxidil (5%) Lipid solution and Finasteride (0.1%) lipid solution in adult male patients with Androgenetic alopecia.

Subject: Ethics Committee Approval of the Essential documents for the above mentioned Clinical trial.

Dear Dr. Ramesh Bhat,

The Father Muller Institutional Ethics Committee, Father Muller Medical College reviewed and discussed your application to conduct the clinical trial 605-12 entitled "A double blind, Randomized, placebo controlled, parallel group, prospective Multicentre clinical trial for evaluation of efficacy and safety of fixed dose combination of Minoxidil (5 %) + Finasteride (0.1%) Liquid solution in comparison with Minoxidil (5%) Lipid solution and Finasteride (0.1%) lipid solution in adult male patients with Androgenetic alopecia" on 16.04.2016.

The following documents are:

Sr. No.	Document	Version No. & Date	No. of Copies
01	Study Protocol	02 Dated 31 Jul 2015	01
02	DCGI Acknowledgement copy	Dated 17-Dec-15	01
03	Investigator's Brochure	01 Dated 4 Feb-15	01
04	Informed Consent Document in English	02 Dated 1 Sep 2015	01
05	Informed Consent Document in Hindi translated on 27-Nov-15	02 Dated 1 Sep 2015	01
06	Back translation of Informed Consent Document in English from Hindi on 28-Nov-15	02 Dated 1 Sep 2015	01
07	Informed Consent Document in Kannada translated on 07-Dec-15	02 Dated 1 Sep 2015	01
08	Back translation of Informed Consent Document in English from Kannada on 7-Dec-15	02 Dated 1 Sep 2015	01
09	Informed Consent Document in Malayalam translated on 28-Nov-15	02 Dated 1 Sep 2015	01
10	Back translation of Informed Consent Document in English from Malayalam on 28-Nov-15	02 Dated 1 Sep 2015	01
11	**Translation certificates** and **Back Translation certificates** of Informed Consent Document from English to Hindi, Hindi to English, English to Kannada, Kannada to English, English to Malayalam & Malayalam to English	-----	01
12	Patient Diary Card in English	01 Dated 9 Nov 2015	01
13	Patient Diary Card in Hindi translated on 27-Nov-15	01 Dated 9 Nov 2015	01
14	Back translation of Patient Diary Card in English from Hindi on 28-Nov-15	01 Dated 9 Nov 2015	01
15	Patient Diary Card in Kannada translated on 07-Dec-15	01 Dated 9 Nov 2015	01
16	Back translation of Patient Diary Card in English from Kannada on 07-Dec-15	01 Dated 9 Nov 2015	01
17	Patient Diary Card in Malayalam translated on 28-Nov-15	01 Dated 9 Nov 2015	01
18	Back translation of Patient Diary Card in English from Malayalam on 28-Nov-15	01 Dated 9 Nov 2015	01

Sr. No.	Document	Version No. & Date	No. of Copies
19	Translation and Back Translation certificates of Patient Diary Card: English to Hindi, Hindi to English, English to Kannada, Kannada to English, English to Malayalam & Malayalam to English	-----	01
20	Subject Self Assessment Score in English	01 Dated 9 Nov 2015	01
21	Subject Self Assessment Score in Hindi translated on 27-Nov-15	01 Dated 9 Nov 2015	01
22	Back translation of Subject Self Assessment Score in English from Hindi on 28-Nov-15	01 Dated 9 Nov 2015	01
23	Subject Self Assessment Score in Kannada translated on 07-Dec-15	01 Dated 9 Nov 2015	01
24	Back translation of Subject Self Assessment Score in English from Kannada on 07-Dec -15	01 Dated 9 Nov 2015	01
25	Subject Self Assessment Score in Malayalam translated on 28-Nov-15	01 Dated 9 Nov 2015	01
26	Back translation of Subject Self Assessment Score in English from Malayalam on 28-Nov -15	01 Dated 9 Nov 2015	01
27	Translation and Back Translation certificates of Subject Self Assessment Score: English to Hindi, Hindi to English, English to Kannada, Kannada to English, English to Malayalam & Malayalam to English	-----	01
28	Draft Clinical Trial Agreement	Draft	01
29	Investigator Undertaking	Dated 18 Aug 2015	01
30	CV & Medical Registration Certificate of Investigator	-----	01

The following members of the Ethics Committee were present at the meeting held on **16.04.2016 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. Shiva Shanker	Ph.D	Joint Secretary (Scientist)	Yes
3.	Mr. Eric Sequeira	BABL	Vice Chairperson (Advocate)	No
4.	Rev. Dr. Leo D' Souza	M. Sc, Ph.D	Member(Theologian)	No
5.	Mrs. Rameela Shekar	MSW, M. Phil, (PSW), PGDHRM, Ph.D	Member (Sociology)	No
6.	Dr. P J Kurian	MD	Member (Homeopathy)	Yes

7.	Prof. Irene T.R. Alvares	M. Sc	Member (Nursing)	Yes
8.	Dr. Ashok Shenoy	MD	Member (Pharmacologist)	No
9.	Dr. Varadaraj Shenoy	MD, DCH	Member (Pediatrician)	Yes
10.	Mrs. Veena Manoj	MA, B.Ed	Member (Lay person)	No
11.	Mr. Sudeep M J Pais	MPT	Member (Physiotherapist)	Yes
12.	Dr. Jayaram Shetty	BVSc, MVSc	Member (Veterinion)	No
13.	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
14.	Dr. B. Sanjeev Rai	MD, DCH, MBA	Secretary (Clinician)	Yes
15.	Dr. John Mathai	MD	Member (Clinician)	Yes
16.	Ms. Bindiya Shetty	MSW	Member (Counsellor)	No

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 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

GENERAL **MEMORANDUM OF UNDERSTANDING (MoU)** FOR

Health Services

BETWEEN

Father Muller Medical College and Hospital

AND

Confederation of Real Estate Developers Association of India,

MANGALORE

Father Muller Medical College and Hospital, Kankanady, Mangalore and The Confederation of Real Estate Developers Association of India, Mangalore establish this General Agreement to foster cooperation in providing health care to construction workers.

Father Muller Medical College and Hospital will provide health care facilities, outpatient and inpatient services at concession charges and free care where applicable to construction workers and their nuclear families, of real estate developers under the ambit of CREDAI Mangalore.

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.

1. This is not considered to be a contract creating a legal and financial relationship between the parties. Rather, it is designed to facilitate and develop a relationship between Father Muller Medical College and Hospital and CREDAI Mangalore to improve the health status and provide quality health care to construction workers.

2. 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.

3. This Agreement should be reviewed every three years to evaluate the progress and the quality of the mutual cooperation. The Agreement may be extended for an additional three-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.

4. Father Muller Medical College and Hospital will provide outpatient services i.e investigations/procedures in all general specialties at 30% concession and for inpatients at 50% concession, medications will be given at a 10% concession as applicable in the Father Muller health card however concessions will not apply to super specialties and OT materials will also

FATHER MULLER MEDICAL COLLEGE KANKANADY MANGALORE 575 002

Rev. Fr Richard Coelho
Administrator
Father Muller Medical College Hospital

For Confederation of Real Estate Developers Association of India

President / Secretary / Treasurer

not entail any concessions. Concessions will be given to super speciality patients on a case to case basis at the discretion of the Administrator, FMMCH.

5. FMMCH will facilitate free of cost some basic health check up including but not restricted to blood test, urine test etc at the time of registration.

6. FMMCH will also consider as and when possible on site checking of workers health by Mobile Checkup Vans at the CREDAI Mangalore member sites.

7. Both parties will meet once a quarter to review the functional aspects of this MOU.

8. This Agreement may be terminated by either party with minimum of 90 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.

9. Both parties 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.

10. All disputes or differences 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 Father Muller Medical College and CREDAI Mangalore.

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 Mr David Sequeira, P.R.O. Father Muller Medical College Hospital, Father Muller Road, Kankanady. Mangalore-575002. Mobile number: 9008820155, E mail: davidsequeira58@gmail.com and for CREDAI Mangalore- Mr Rajshekhar, Manager, CREDAI Mangalore, Empire Mall, MG Road, Mangalore-575003. Mobile: 8970825277. Email: mangalorecredai@gmail.com

.....

For Confederation of Real Estate Developers Association of India

President / Secretary / Treasurer

Rev Fr Richard Coelho

Administrator FMMCH

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

Rev. Fr Richard Coelho
Administrator
Father Muller Medical College Hospital

Mr. Dharmendra B Mehta

President, CREDAI- Mangalore

for **Confederation of Real Estate Developers Associations of India, Mangalore.**

FATHER MULLER MEDICAL COLLEGE
KANKANADY
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

ದಿನಾಂಕ : 16–01–2010 ರಂದು ರಾಜ್ಯ ಆರೋಗ್ಯ ಮತ್ತು ಕುಟುಂಬ ಕಲ್ಯಾಣ ಸಂಸ್ಥೆ ಮಾಗಡಿರಸ್ತೆ, ಬೆಂಗಳೂರು, ಇಲ್ಲಿ ನಡೆಸಲಾದ ವಿವಿಧ ವೈದ್ಯಕೀಯ ಕಾಲೇಜುಗಳ ಪ್ರಾಧ್ಯಾಪಕರು, ಎಲ್ಲಾ ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ/ ಪ್ರಾಥಮಿಕ ಆರೋಗ್ಯ ತರಬೇತಿ ಕೇಂದ್ರಗಳ ಪ್ರಾಂಶುಪಾಲರು ಮತ್ತು ರಾಜ್ಯ ಆರೋಗ್ಯ ಮತ್ತು ಕುಟುಂಬ ಕಲ್ಯಾಣ ಸಂಸ್ಥೆಯ ನಿರ್ದೇಶಕರು ಹಾಗೂ ಉಪನಿರ್ದೇಶಕರು ಸಭೆಯಲ್ಲಿ ವೈದ್ಯಾಧಿಕಾರಿಗಳಿಗೆ ಎಸ್.ಬಿ.ಎ. ತರಬೇತಿ ನೀಡುವ ಕ್ರಿಯಾ ಯೋಜನೆ ಬಗ್ಗೆ ಚರ್ಚಿಸಿದ ಮತ್ತು ಪ್ರಗತಿ ಪರಿಶೀಲನಾ ಸಭೆಯ ನಡವಳಿಗಳು.

ಸಭೆಯಲ್ಲಿ ಹಾಜರಿದ್ದವರು.

1. ಡಾ|| ಅಜಿತ್ ಪಾಯಿಕರ್ ಧನಂಜಯ, ನಿರ್ದೇಶಕರು – ರಾಜ್ಯ ಆ.ಕು.ಕ ಸಂಸ್ಥೆ, ಬೆಂಗಳೂರು
2. ಡಾ|| ಜರುಣಾ ರುದ್ರಪ್ಪ, ಸಹ ನಿರ್ದೇಶಕರು/ಅನ್ಯಹೊಣೆ – ರಾಜ್ಯ ಆ.ಕು.ಕ ಸಂಸ್ಥೆ, ಬೆಂಗಳೂರು
3. ಡಾ|| ಎಂ.ಮಂಜುಳ, ಉಪ ನಿರ್ದೇಶಕರು – ರಾಜ್ಯ ಆ.ಕು.ಕ ಸಂಸ್ಥೆ, ಬೆಂಗಳೂರು
4. ಡಾ|| ಆಶಾ ಪಾಪೇಟಿ, ಸಹಾ ನಿರ್ದೇಶಕರು/ಪ್ರಭಾರ – ರಾಜ್ಯ ಆ.ಕು.ಕ ಸಂಸ್ಥೆ, ಬೆಂಗಳೂರು
5. ಡಾ|| ಎಂ. ಸುಜಾತ, ಉಪ ನಿರ್ದೇಶಕರು – ರಾಜ್ಯ ಆ.ಕು.ಕ ಸಂಸ್ಥೆ, ಬೆಂಗಳೂರು
6. ಡಾ|| ಶ್ರೀನಿವಾಸ, ಉಪ ನಿರ್ದೇಶಕರು – ರಾಜ್ಯ ಆ.ಕು.ಕ ಸಂಸ್ಥೆ, ಬೆಂಗಳೂರು
7. ಡಾ|| ಮಲ್ಲಿಕಾರ್ಜುನ ಮರಾಡಿಕೆ, ಉಪ ನಿರ್ದೇಶಕರು – ರಾಜ್ಯ ಆ.ಕು.ಕ ಸಂಸ್ಥೆ, ಬೆಂಗಳೂರು
8. ಡಾ|| ಎಂ.ಸೆಲ್ವರಾಜನ್, ಉಪ ನಿರ್ದೇಶಕರು – ರಾಜ್ಯ ಆ.ಕು.ಕ ಸಂಸ್ಥೆ, ಬೆಂಗಳೂರು
9. ಡಾ|| ಗಂಟಿ ಶಂಕರಪ್ಪ, ಉಪ ನಿರ್ದೇಶಕರು – ರಾಜ್ಯ ಆ.ಕು.ಕ ಸಂಸ್ಥೆ, ಬೆಂಗಳೂರು
10. ಡಾ|| ಶ್ರೀಕಾಂತ್ ಖಾರ್ಗಿ, ಉಪ ನಿರ್ದೇಶಕರು – ರಾಜ್ಯ ಆ.ಕು.ಕ ಸಂಸ್ಥೆ, ಬೆಂಗಳೂರು
11. ಶ್ರೀ. ಹೆಚ್.ಪಿ.ಗುರುರೆಡ್ಡಿ, ಲೆಕ್ಕ ಅಧಿಕಾರಿಗಳು – ರಾಜ್ಯ ಆ.ಕು.ಕ ಸಂಸ್ಥೆ, ಬೆಂಗಳೂರು
12. ಶ್ರೀ. ಎಂ.ಶಿವಮಲ್ಲಪ್ಪ, ಸಹಾಯಕ ಆಡಳಿತ ಅಧಿಕಾರಿಗಳು – ರಾಜ್ಯ ಆ.ಕು.ಕ ಸಂಸ್ಥೆ, ಬೆಂಗಳೂರು
13. ಶ್ರೀ. ಎಸ್. ಶ್ರೀಧರನ್, ಲೆಕ್ಕ ಅಧೀಕ್ಷಕರು – ರಾಜ್ಯ ಆ.ಕು.ಕ ಸಂಸ್ಥೆ, ಬೆಂಗಳೂರು
14. ಶ್ರೀಮತಿ. ಕೆ.ಜಿ.ಜಗದಾಂಬಿಕೆ, ಆಪ್ತ ಸಹಾಯಕರು. – ರಾಜ್ಯ ಆ.ಕು.ಕ ಸಂಸ್ಥೆ, ಬೆಂಗಳೂರು
15. ಡಾ|| ಸಿ.ಎಸ್.ರಗಟಿ, ಪ್ರಾಂಶುಪಾಲರು – ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ಬೀದರ್
16. ಡಾ|| ಪಿ.ಟಿ.ವಿಜಯ್‌ಕುಮಾರ್, ಪ್ರಾಂಶುಪಾಲರು – ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ಚಿತ್ರದುರ್ಗ
17. ಡಾ|| ಹೆಚ್. ಗಿರಿಧರ್, ಪ್ರಾಂಶುಪಾಲರು – ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ಹುಬ್ಬಳ್ಳಿ
18. ಡಾ|| ಚಂದ್ರಾಜೀ ಅರಸ್, ಪ್ರಾಂಶುಪಾಲರು – ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ರಾಮನಗರ
19. ಡಾ|| ಎಂ.ಆರ್.ನಾಯಕ್, ಪ್ರಾಂಶುಪಾಲರು – ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ಸೂರತ್ಕಲ್(ಮಂಗಳೂರು)
20. ಡಾ|| ಒ.ಪಿ.ಪುರಿಪಾಲ್, ಪ್ರಾಂಶುಪಾಲರು – ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ಧಾರವಾಡ
21. ಡಾ|| ಎಂ.ಆರ್. ದಂಡಿನ, ಪ್ರಾಂಶುಪಾಲರು – ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ಕಾರವಾರ
22. ಡಾ|| ಡಿ.ಚಾಂಬೂಗನ್, ಪ್ರಾಂಶುಪಾಲರು – ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ಬಳ್ಳಾರಿ
23. ಡಾ|| ಟಿ.ನರಸಮ್ಮ, ಪ್ರಾಂಶುಪಾಲರು – ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ಗುಲ್ಬರ್ಗ
24. ಡಾ|| ಟಿ. ಜಗದೀಶ್ವರಿ, ಪ್ರಾಂಶುಪಾಲರು – ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ಶಿವಮೊಗ್ಗ
25. ಡಾ|| ವಿರೂಪಾಕ್ಷ ರೆಡ್ಡಿ, ಪ್ರಾಂಶುಪಾಲರು – ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ರಾಯಚೂರು
26. ಡಾ|| ನಾಗಲೀಕರ, ಪ್ರಾಂಶುಪಾಲರು. – ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ಬೆಳಗಾಂವಿ
27. ಡಾ|| ಅರುಣಾ, ಪ್ರಾಂಶುಪಾಲರು. – ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ಬಿಜಾಪುರ
28. ಡಾ|| ಕಲ್ಪನಾ. ಬಿ.ಎಲ್. ಪ್ರಾಂಶುಪಾಲರು – ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ಚಿಕ್ಕಮಗಳೂರು
29. ಡಾ|| ಹೇಮಲತಾ. ಎಂ.ಸಿ. ಪ್ರಾಂಶುಪಾಲರು – ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ಹಾಸನ
30. ಡಾ|| ಕುಮಾರಗೌಡ, ಪ್ರಾಂಶುಪಾಲರು – ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ಕೋಲಾರ
31. ಡಾ|| ಡಿ.ಮಹಾದೇವಯ್ಯ, ಪ್ರಾಂಶುಪಾಲರು – ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ಮೈಸೂರು
32. ಡಾ|| ಹೆಚ್.ಹೆಚ್.ಕೃಷ್ಣ ನಂದಾ, ಪ್ರಾಂಶುಪಾಲರು – ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ಮಂಡ್ಯ

33.	ಶ್ರೀ. ಬಸವರಾಜ, ಎಫ್.ಡಿ.ಎ.	– ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ಮಡಿಕೇರಿ
34.	ಡಾ॥ ಎಂ. ತಿಮ್ಮಾರೆಡ್ಡಿ, ಪ್ರಾಂಶುಪಾಲರು	– ಆ.ಕು.ಕ. ತರಬೇತಿ ಕೇಂದ್ರ, ಬೆಂಗಳೂರು
35.	ಡಾ॥ ಹೆಚ್.ಎಸ್. ಚಂದ್ರಮ್ಮ, ಪ್ರಾಂಶುಪಾಲರು	– ಆ.ಕು.ಕ. ತರಬೇತಿ ಕೇಂದ್ರ, ಮೈಸೂರು
36.	ಡಾ॥ ಶೈಲಜಾ. ಪಾಟೀಲ, ಪ್ರಾಂಶುಪಾಲರು	– ಆ.ಕು.ಕ. ತರಬೇತಿ ಕೇಂದ್ರ, ಹುಬ್ಬಳ್ಳಿ.
37.	ಡಾ॥ ಎಂ.ಸುಲೋಚನ, ಪ್ರಾಂಶುಪಾಲರು	– ಆ.ಕು.ಕ. ತರಬೇತಿ ಕೇಂದ್ರ, ಗುಲ್ಬರ್ಗ
38.	ಡಾ॥ ಧನಂಜಯ. ಬಿ.ಎಸ್, ಅಸಿಸ್ಟಂಟ್ ಪ್ರೊಫೆಸರ್	– ಎಸ್.ಎಸ್.ಎಂ.ಸಿ. ತುಮಕೂರು.
39.	ಡಾ॥ ಅಗಸಿಮನಿ, ಪ್ರೊಫೆಸರ್	– ಜೆ.ಜೆ.ಎ.ಎಂ.ಸಿ. ದಾವಣಗೆರೆ.
40.	ಡಾ॥ ಎಲ್.ಹೆಚ್.ರಾಠೋಡ, ಪ್ರೊಫೆಸರ್	– ಆಲ್‌ಅಮಿನ್ ಕಾಲೇಜ್, ಬಿಜಾಪುರ.
41.	ಡಾ॥ ಬಿ.ಆರ್. ದೇಸಾಯಿ, ಪ್ರೊಫೆಸರ್	– ಜೆ.ಎನ್.ಎಂ.ಸಿ. ಬೆಳಗಾಂವಿ.
42.	ಡಾ॥ ಎಂ.ಕೆ. ಸ್ವಾಮಿ, ಪ್ರೊಫೆಸರ್	– ಜೆ.ಎನ್.ಎಂ.ಸಿ. ಬೆಳಗಾಂವಿ.
43.	ಡಾ॥ ರಾಮಲಿಂಗಪ್ಪ, ಪ್ರೊಫೆಸರ್	– ಕಿಮ್ಸ್, ಹುಬ್ಬಳ್ಳಿ.
44.	ಡಾ॥ ಯು.ಎಸ್. ಹಂಗರಗಾ, ಪ್ರೊಫೆಸರ್	– ಕಿಮ್ಸ್, ಹುಬ್ಬಳ್ಳಿ.
45.	ಡಾ॥ ಟಿ. ಚಂದ್ರಲೇಖರ್, ಪ್ರೊಫೆಸರ್	– ವಿಮ್ಸ್, ಬಳ್ಳಾರಿ.
46.	ಡಾ॥ ಸುರೇಶ್, ಪ್ರೊಫೆಸರ್	– ವಿಮ್ಸ್, ಬಳ್ಳಾರಿ.
47.	ಡಾ॥ ಹೆಚ್.ಸಿ.ಲೋಕೇಶ್‌ಚಂದ್ರ, ಪ್ರೊಫೆಸರ್	– ಐ.ಎಂ.ಸಿ. & ಆರ್.ಐ. ಮೈಸೂರು.
48.	ಡಾ॥ ಎಸ್. ರಾಧಾಮನಿ, ಪ್ರೊಫೆಸರ್	– ಐ.ಎಂ.ಸಿ. & ಆರ್.ಐ. ಮೈಸೂರು.
49.	ಡಾ॥ ಇಂದಿರಾ, ಪ್ರೊಫೆಸರ್	– ಐ.ಆರ್.ಎಂ.ಸಿ. ಗುಲ್ಬರ್ಗಾ.
50.	ಡಾ॥ ಧನಂಜಯ, ಪ್ರೊಫೆಸರ್	– ಎಸ್.ಎಸ್.ಎಂ.ಸಿ. ತುಮಕೂರು.
51.	ಡಾ॥ ಸುಜಯಾ, ಪ್ರೊಫೆಸರ್	– ಫಾದರ್ ಮುಲ್ಲಾ ಕಾಲೇಜ್, ಮಂಗಳೂರು.
52.	ಡಾ॥ ಪಿ.ಟಿ.ಜಾಧವ್, ಪ್ರೊಫೆಸರ್	– ಆಲ್‌ಅಮಿನ್ ಕಾಲೇಜ್, ಬಿಜಾಪುರ.
53.	ಡಾ॥ ಸೋಮೆಶ್ವರ, ಪ್ರೊಫೆಸರ್	– ವಿಮ್ಸ್, ಬಳ್ಳಾರಿ.
54.	ಡಾ॥ ನಾಗೇಂದ್ರಗೌಡ, ಪ್ರೊಫೆಸರ್	– ಬಿ.ಎಂ.ಸಿ.ಹೆಚ್. ಚಿತ್ರದುರ್ಗ.
55.	ಡಾ॥ ಸಬೀತಾಬಾಯಿ, ಪ್ರೊಫೆಸರ್	– ಬಿ.ಎಂ.ಸಿ.ಹೆಚ್. ಚಿತ್ರದುರ್ಗ.
56.	ಡಾ॥ ಸುಭಾಸ್ ರೆಡ್ಡಿ, ಪ್ರೊಫೆಸರ್	– ನವೋದಯ ಕಾಲೇಜ್, ರಾಯಚೂರು.
57.	ಡಾ॥ ಗಾಯತ್ರಿ, ಪ್ರೊಫೆಸರ್	– ಐ.ಆರ್.ಎಂ.ಸಿ, ಗುಲ್ಬರ್ಗಾ.
58.	ಡಾ॥ ನಂದಗೋಪಾಲ್, ಪ್ರೊಫೆಸರ್	– ಎಸ್.ಎಸ್.ಎಂ.ಸಿ. ತುಮಕೂರು.
59.	ಡಾ॥ ಕಮಲಾ, ಪ್ರೊಫೆಸರ್	– ಬಿ.ಎಂ.ಸಿ. ಚಿತ್ರದುರ್ಗ.
60.	ಡಾ॥ ಸೋಮೇಗೌಡ, ಪ್ರೊಫೆಸರ್	– ಬಿ.ಎಂ.ಸಿ. & ಆರ್.ಐ, ಬೆಂಗಳೂರು.
61.	ಡಾ॥ ಹೇಮಲತಾ, ಪ್ರೊಫೆಸರ್	– ಡಿ.ಯು.ಎಂ.ಸಿ. ಕೋಲಾರ.

ರಾಜ್ಯ ಆರೋಗ್ಯ ಮತ್ತು ಕುಟುಂಬ ಕಲ್ಯಾಣ ಸಂಸ್ಥೆಯ ಉಪನಿರ್ದೇಶಕರಾದ ಡಾ॥ ಮಂಜುಳ, ಮತ್ತು ಡಾ॥ ಸುಜಾತ, ಇವರು ಆಗಮಿಸಿದ್ದವರನ್ನು ಸ್ವಾಗತಿಸುವ ಮೂಲಕ ಸಭೆಯನ್ನು ಪ್ರಾರಭಿಸಲಾಯಿತು.

ಡಾ॥ ಉಷಾ ವಾಸುನಕರ್ ಧನಂಜಯ, ನಿರ್ದೇಶಕರು, ರಾಜ್ಯ ಆರೋಗ್ಯ ಮತ್ತು ಕುಟುಂಬ ಕಲ್ಯಾಣ ಸಂಸ್ಥೆ, ಇವರು ಎಸ್.ಆರ್.ಹೆಚ್.ಎಂ. ಯೋಜನೆಯು 2005 ರಿಂದ ಜಾರಿಗೆ ಬಂದಿದ್ದರು, ಐ.ಎಂ.ಆರ್ ಮತ್ತು ಐ.ಎಂ.ಆರ್. ಸುಧಾರಣೆಮಾಡುವಲ್ಲಿ ಸಾಧ್ಯವಾಗಿಲ್ಲದ ಕಾರಣ ವೈದ್ಯಕೀಯ ಕಾಲೇಜುಗಳ ಮುಖಾಂತರ ವೈದ್ಯಾಧಿಕಾರಿಗಳಿಗೆ ಎಸ್.ಬಿ.ಎ. ತರಬೇತಿ ನಡೆಸುವುದು ಅತ್ಯವಶ್ಯವಾಗಿರುತ್ತದೆಂದು ಅಭಿಪ್ರಾಯ ಪಟ್ಟರು.

ಡಾ॥ ಸ್ವಾಮಿ, ಪ್ರಾಧ್ಯಾಪಕರು, ಜೆ.ಎಸ್.ಎಂ.ಸಿ. ಬೆಳಗಾಂವಿ, ಇವರು ತರಬೇತಿಯ ಬಗ್ಗೆ ವಿವರವಾಗಿ ತಿಳಿಸಿದರು. ಈ ಎಸ್.ಬಿ.ಎ. ತರಬೇತಿಯು ಗುಣಮಟ್ಟದ್ದಾಗಿರಬೇಕು. ಭಾರತ ಸರ್ಕಾರದ ತರಬೇತಿಯ ಮಾರ್ಗಸೂಚಿಯ ಪ್ರಕಾರವೇ ತರಬೇತಿ ಕೊಡಬೇಕಾಗಿರುತ್ತದೆ ಎಂದು ಎಲ್ಲರೂ ಅಭಿಪ್ರಾಯ ವ್ಯಕ್ತಪಡಿಸಿದರು.

ಡಾ॥ ಮಂಜುಳ, ಉಪನಿರ್ದೇಶಕರು, ಇವರು ಜೆ.ಎಸ್.ಎಂ.ಸಿ, ಬೆಳಗಾಂವಿಯಲ್ಲಿ ನಡೆದ ಟಿ.ಓ.ಟಿ. ಕಾರ್ಯಕ್ರಮದಲ್ಲಿ 13 ವೈದ್ಯಕೀಯ ಕಾಲೇಜುಗಳಿಂದ ತಜ್ಞರು ಭಾಗವಹಿಸಿದ್ದರು. ಪ್ರಸ್ತುತ ಈ ಕಾಲೇಜುಗಳ ಮುಖಾಂತರ ನಾವು ಎಸ್.ಬಿ.ಎ. ತರಬೇತಿಯನ್ನು ಪ್ರಾರಂಭಿಸಬಹುದೆಂದು ತಿಳಿಸಲಾಗಿ, ಕಾಲೇಜಿನ ಎಲ್ಲಾ ಪ್ರಾದ್ಯಾಪಕರು ತರಬೇತಿಗೆ ಸಹಕರಿಸುವುದಾಗಿ ತಿಳಿಸಿದರು.

ಎಲ್ಲಾ ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ/ ಪ್ರಾದೇಶಿಕ ಆರೋಗ್ಯ ಮತ್ತು ಕುಟುಂಬ ಕಲ್ಯಾಣ ತರಬೇತಿ ಕೇಂದ್ರಗಳ ಪ್ರಾಂಶುಪಾಲರುಗಳು ಅವರಿಗೆ ಸಂಬಂಧಪಟ್ಟ ಜಿಲ್ಲೆಗಳ ಆರೋಗ್ಯ ಮತ್ತು ಕುಟುಂಬ ಕಲ್ಯಾಣ ಅಧಿಕಾರಿಗಳ ಜೊತೆ ಚರ್ಚಿಸಿ, ಮುಖ್ಯವಾಗಿ 24/7 ಪ್ರಾಥಮಿಕ ಆರೋಗ್ಯ ಕೇಂದ್ರ/ ಸಮುದಾಯ ಆರೋಗ್ಯ ಕೇಂದ್ರಗಳ ವೈದ್ಯಾಧಿಕಾರಿಗಳಿಗೆ ಫೆಬ್ರುವರಿ–2010ರ ಮೊದಲನೇ ವಾರ ಒಂದು ಕ್ರಿಯಾ ಯೋಜನೆ ಮಾಡಿ, ಕನಿಷ್ಠ ಪಕ್ಷ ಫೆಬ್ರುವರಿ 3ನೇ ವಾರದೊಳಗೆ ತರಬೇತಿ ಪ್ರಾರಂಭ ಮಾಡಲು ಸೂಚಿಸಿದರು.

ಪ್ರಾಂಶುಪಾಲರು, ಎಸ್.ಬಿ.ಎ. ತರಬೇತಿಗೆ ಈ ಕೆಳಗೆ ನಮೂದಿಸಿದ ವೈದ್ಯಕೀಯ ಕಾಲೇಜುಗಳಿಗೆ ನಿಯೋಜಿಸಬೇಕೆಂದು ಕ್ರಿಯಾ ಯೋಜನೆ ಮಾಡಲಾಯಿತು.

ವೈದ್ಯಕೀಯ ವಿದ್ಯಾಲಯಗಳ ಹೆಸರು ಮತ್ತು ಸಹಭಾಗಿತ್ವ ಜಿಲ್ಲೆಯ ಹೆಸರುಗಳು ಹಾಗೂ ತರಬೇತಿ ಕೇಂದ್ರಗಳ ಹೊಣೆಗಾರಿಕೆ

ಕ್ರ ಸಂ.	ವಿದ್ಯಾಲಯಗಳ ಹೆಸರು	ಸಹಭಾಗಿತ್ವ ಜಿಲ್ಲೆಯ ಹೆಸರುಗಳು	ತರಬೇತಿ ಕೇಂದ್ರಗಳ ಹೊಣೆಗಾರಿಕೆ
1.	ದೇವರಾಜ್ ಅರಸ್ ವೈದ್ಯಕೀಯ ವಿದ್ಯಾಲಯ, ಕೋಲಾರ.	1) ಕೋಲಾರ, 2) ಚಿಕ್ಕಬಳ್ಳಾಪುರ,	ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ಕೋಲಾರ.
2.	ಸಿದ್ದಾರ್ಥ ವೈದ್ಯಕೀಯ ವಿದ್ಯಾಲಯ, ತುಮಕೂರು.	3) ತುಮಕೂರು	ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ತುಮಕೂರು.
3.	ವಿಮ್ಸ್ ಬಳ್ಳಾರಿ.	4) ಬಳ್ಳಾರಿ, 5) ಕೊಪ್ಪಳ.	ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ಬಳ್ಳಾರಿ
4.	ಆಲ್ ಅಮೀನ್ ವೈದ್ಯಕೀಯ ವಿದ್ಯಾಲಯ, ಬಿಜಾಪುರ.	6) ಬಿಜಾಪುರ	ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ಬಿಜಾಪುರ.
5.	ನಿಜಲಿಂಗಪ್ಪ ವೈದ್ಯಕೀಯ ವಿದ್ಯಾಲಯ, ಬಾಗಲಕೋಟೆ.	7) ಬಾಗಲಕೋಟೆ.	ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ಬಿಜಾಪುರ.
6.	ಜೆ.ಎಸ್.ಎಂ.ಸಿ. ಬೆಳಗಾಂವಿ.	8) ಬೆಳಗಾಂವಿ.	ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ಬೆಳಗಾಂವಿ.
7.	ನಪ್ರೋದಯ ವೈದ್ಯಕೀಯ ವಿದ್ಯಾಲಯ, ರಾಯಚೂರು.	9) ರಾಯಚೂರು.	ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ರಾಯಚೂರು.
8.	ಜೆ.ಜೆ.ಎಂ.ಸಿ. ದಾವಣಗೆರೆ.	10) ದಾವಣಗೆರೆ, 11) ಹಾವೇರಿ, 12) ಹಾಸನ.	ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ಚಿತ್ರದುರ್ಗ & ಹಾಸನ.
9.	ಬಸವೇಶ್ವರ ವೈದ್ಯಕೀಯ ವಿದ್ಯಾಲಯ, ಚಿತ್ರದುರ್ಗ.	13) ಚಿತ್ರದುರ್ಗ, 14) ಶಿವಮೊಗ್ಗ, 15) ಚಿಕ್ಕಮಗಳೂರು.	ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ಚಿತ್ರದುರ್ಗ,
10.	ಫಾದರ್ ಮುಲ್ಲರ್, ವೈದ್ಯಕೀಯ ವಿದ್ಯಾಲಯ, ಮಂಗಳೂರು.	16) ದಕ್ಷಿಣ ಕನ್ನಡ, 17) ಉಡುಪಿ, 18) ಮಡಿಕೇರಿ	ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ಸುರತ್ಕಲ್ (ಮಂಗಳೂರು)

ಕ್ರ ಸಂ.	ವಿದ್ಯಾಲಯಗಳ ಹೆಸರು	ಸಹಭಾಗಿತ್ವ ಜಿಲ್ಲೆಯ ಹೆಸರುಗಳು	ತರಬೇತಿ ಕೇಂದ್ರಗಳ ಹೊಣೆಗಾರಿಕೆ
11.	ಕಿಮ್ಸ್, ಹುಬ್ಬಳ್ಳಿ	19) ಧಾರವಾಡ, 20) ಗದಗ, 21) ಉತ್ತರ ಕನ್ನಡ	ಆ.ಕು.ಕ.ತ.ಕೇಂದ್ರ, ಹುಬ್ಬಳ್ಳಿ.
12.	ಎಂ.ಆರ್.ಎಂ.ಸಿ. ಗುಲ್ಬರ್ಗಾ	22) ಗುಲ್ಬರ್ಗಾ, 23) ಬೀದರ್,	ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ಗುಲ್ಬರ್ಗಾ, ಬೀದರ್,
		24) ಯಾದಗಿರಿ	ಆ.ಕು.ಕ.ತ.ಕೇಂದ್ರ, ಗುಲ್ಬರ್ಗಾ
13.	ಎಂ.ಎಮ್.ಸಿ. ಮೈಸೂರು.	25) ಮೈಸೂರು, 26) ಚಾಮರಾಜನಗರ, 27) ಮಂಡ್ಯ	ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ, ಮೈಸೂರು,
14.	ವಾಣಿ ವಿಲಾಸ, ಆಸ್ಪತ್ರೆ, ಬಿ.ಎಂ.ಸಿ. ಬೆಂಗಳೂರು.	28) ಬೆಂಗಳೂರು ಗ್ರಾಮೀಣ 29) ರಾಮನಗರ, 30) ಬೆಂಗಳೂರು ನಗರ	ಆ.ಕು.ಕ.ತ.ಕೇಂದ್ರ, ಬೆಂಗಳೂರು

ಇನ್ನುಳಿದ ವೈದ್ಯಕೀಯ ಕಾಲೇಜಿನ ಸ್ತ್ರೀರೋಗ ಹಾಗೂ ಪ್ರಸೂತಿ ವಿಭಾಗದ ತಜ್ಞರಿಗೆ, ಮಕ್ಕಳ ತಜ್ಞರಿಗೆ ಹಾಗೂ ಕಮ್ಯೂನಿಟಿ ಮೆಡಿಸಿನ್ ವಿಭಾಗದ ಪ್ರಾಧ್ಯಾಪಕರಿಗೆ 2 ದಿನದ ಟಿ.ಓ.ಟಿ. ತರಬೇತಿಯನ್ನು ಜೆ.ಎನ್.ಎಂ.ಸಿ. ಬೆಳಗಾಂವಿ ಇಲ್ಲಿ ನಡೆಸಿಕೊಡಲು ಕೋರಲಾಯಿತು.

ವೈದ್ಯರಿಗೆ ಮಾಡಬೇಕಾದ ಈ ಎಸ್.ಬಿ.ಎ. ತರಬೇತಿಯ ಕ್ರಯಾ ಯೋಜನೆ ಬಗ್ಗೆ ಚರ್ಚಿಸಲು ಬಂದಂತಹ ಎಲ್ಲಾ ವೈದ್ಯಕೀಯ ಕಾಲೇಜುಗಳ ಪ್ರಾಧ್ಯಾಪಕರುಗಳಿಗೆ ಡಾ॥ ಶಂಕರಪ್ಪ, ಉಪನಿರ್ದೇಶಕರು, ಅಭಿನಂದನೆ ಸಲ್ಲಿಸಿದರು.

ನಂತರ ಮಧ್ಯಾಹ್ನ ಎಲ್ಲಾ ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ/ ಪ್ರಾದೇಶಿಕ ಆರೋಗ್ಯ ಮತ್ತು ಕುಟುಂಬ ಕಲ್ಯಾಣ ತರಬೇತಿ ಕೇಂದ್ರಗಳ ಪ್ರಾಂಶುಪಾಲರುಗಳ ಸಭೆ ಮುಂದುವರೆಸಿ, ಪ್ರಗತಿ ಪರಿಶೀಲನೆ ಮಾಡಲಾಗಿ ಸಂಜೆ 5-00 ಗಂಟೆಗೆ ಸಭೆಯನ್ನು ಮುಕ್ತಾಯಗೊಳಿಸಲಾಯಿತು.

ನಿರ್ದೇಶಕರು,
ರಾಜ್ಯ ಆರೋಗ್ಯ ಮತ್ತು ಕುಟುಂಬ
ಕಲ್ಯಾಣ ಸಂಸ್ಥೆ, ಬೆಂಗಳೂರು-23.
24/01/10

ಪ್ರತಿಯನ್ನು :

1. ಪ್ರಾಂಶುಪಾಲರು, ಎಲ್ಲಾ ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ/ಆರೋಗ್ಯ ಮತ್ತು ಕುಟುಂಬ ಕಲ್ಯಾಣ ತರಬೇತಿ ಕೇಂದ್ರ.
2. ಸಂಬಂಧಿಸಿದ ಪ್ರಾಧ್ಯಾಪಕರು, ಎಸ್.ಎಂ.ಸಿ. ದಾವಣಗೆರೆ/ಜೆ.ಜೆ.ಎಂ.ಸಿ. ದಾವಣಗೆರೆ/ಆಲ್ ಅಮಿನ್ ಕಾಲೇಜ್, ಬಿಜಾಪುರ/ ಜೆ.ಎನ್.ಎಂ.ಸಿ. ಬೆಳಗಾಂವಿ/ಕಿಮ್ಸ್ ಹುಬ್ಬಳ್ಳಿ/ವಿಮ್ಸ್ ಬಳ್ಳಾರಿ/ಎಂ.ಎಂ.ಸಿ. & ಆರ್.ಯ, ಮೈಸೂರು/ ಎಂ.ಆರ್.ಎಂ.ಸಿ. ಗುಲ್ಬರ್ಗಾ/ಎಸ್.ಎಸ್.ಎಂ.ಸಿ. ತುಮಕೂರು/ಫಾದರ್ ಮುಲ್ಲಾ ಕಾಲೇಜ್, ಮಂಗಳೂರು/ ಬಿ.ಎಂ.ಸಿ, ಚಿತ್ರದುರ್ಗ/ಬಿ.ಎಂ.ಸಿ. & ಆರ್.ಐ, ಬೆಂಗಳೂರು/ಡಿ.ಯು.ಎಂ.ಸಿ. ಕೋಲಾರ/ಸಪ್ತೋದಯ ಕಾಲೇಜ್, ರಾಯಚೂರು.

ಕೆ.ಡಿ.

ಕರ್ನಾಟಕ ಸರಕಾರ

ಸಂಖ್ಯೆ:ಜಿತಕೇಸು:22:2009-2010

ಪ್ರಾಂಶುಪಲರ ಕಛೇರಿ,
ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ ಸುರತ್ಕಲ್
ದ.ಕ.ಮಂಗಳೂರು:ದಿನಾಂಕ 18-2-2010

ಇವರಿಗೆ

ಜಿಲ್ಲಾ ಆರೋಗ್ಯ ಮತ್ತು ಕುಟುಂಬ
ಕಲ್ಯಾಣಾ ಅಧಿಕಾರಿ,
ದಕ್ಷಿಣ ಕನ್ನಡ/ಉಡುಪಿ/ಮಡಿಕೇರಿ.

ಮಾನ್ಯರೇ,

ವಿಷಯ: ಸ್ಕಿಲ್ಡ್ ಬರ್ತ್ ಅಟೆಂಡೆಂಟ್(ಎಸ್.ಬಿ.ಎ) ಕುರಿತು
ಪ್ರಾ.ಆ.ಕೇಂದ್ರ/ಸ.ಆ.ಕೇಂದ್ರಗಳಲ್ಲಿ ಕೆಲಸ ನಿರ್ವಹಿಸುತ್ತಿರುವ
ವೈದ್ಯಾಧಿಕಾರಿಯವರ ತರಬೇತಿ ಏರ್ಪಡಿಸುವ ಬಗ್ಗೆ,

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ಮೇಲಿನ ವಿಷಯಕ್ಕೆ ಸಂಬಂಧಿಸಿದಂತೆ, ರಾಷ್ಟ್ರೀಯ ಗ್ರಾಮೀಣ ಆರೋಗ್ಯ ಅಭಿಯಾನದ ಅಡಿಯಲ್ಲಿ ತಾಯಿಂದಿರ ಮರಣ, ಶಿಶುಮರಣ ತಡೆಗಟ್ಟಲು ಆದ್ಯತೆ ನೀಡಲಾಗಿದೆ. ಇದಕ್ಕೆ ಪೂರಕವಾಗಿ ಹೆರಿಗೆ ನಿರ್ವಹಣೆ ಬಗ್ಗೆ ಕೌಶಲ್ಯತೆ ಆಧಾರಿತ ತರಬೇತಿಯನ್ನು ಈಗಾಗಲೇ 24X7 ಪ್ರಾ.ಆಕೇಂದ್ರ ಹಾಗೂ ಸಮುದಾಯ ಆರೋಗ್ಯ ಕೇಂದ್ರಗಳಲ್ಲಿ ಕೆಲಸ ನಿರ್ವಹಿಸುತ್ತಿರುವ ಶುಶ್ರೂಷಕರಿಗೆ 21 ದಿನಗಳು (18 ಕೆಲಸದ ದಿನಗಳು) ತರಬೇತಿಯನ್ನು ಜರುಗಿಸಲಾಗುತ್ತಿದೆ. ಅದೇ ರೀತಿ ಪ್ರಾ.ಆ.ಕೇಂದ್ರಗಳು ಹಾಗೂ ಸಮುದಾಯ ಆರೋಗ್ಯ ಕೇಂದ್ರಗಳಲ್ಲಿ ಕೆಲಸ ನಿರ್ವಹಿಸುತ್ತಿರುವ ವೈದ್ಯಾಧಿಕಾರಿಗಳಿಗೆ ಎಸ್.ಬಿ.ಎ ತರಬೇತಿ ನೀಡುವಂತೆ ನಿರ್ದೇಶಕರು, ರಾಜ್ಯ ಆರೋಗ್ಯ ಮತ್ತು ಕು.ಕ ಸಂಸ್ಥೆ ಬೆಂಗಳೂರು ಇವರು ಸೂಚನೆ ನೀಡಿರುತ್ತಾರೆ. ಅದರಂತೆ ತಮ್ಮ ಜಿಲ್ಲೆಯ ಅಧೀನದಲ್ಲಿ ಕೆಲಸ ನಿರ್ವಹಿಸುತ್ತಿರುವ ವೈದ್ಯಾಧಿಕಾರಿಗಳ ತರಬೇತಿ ಏರ್ಪಡಿಸುವರೇ ದಕ್ಷಿಣ ಕನ್ನಡ ಜಿಲ್ಲೆ ಮಂಗಳೂರು ಇಲ್ಲಿನ ಫಾದರ್ ಮುಲ್ಲರ್ಸ್ ವೈದ್ಯಕೀಯ ಆಸ್ಪತ್ರೆಯನ್ನು ಗುರ್ತಿಸಲಾಗಿರುತ್ತದೆ. ತರಬೇತಿ ಅವಧಿ 10 ದಿನಗಳಾಗಿರುತ್ತದೆ. ಈ ತರಬೇತಿಯನ್ನು ಯಶಸ್ವಿಯಾಗಿ ಜರುಗಿಸಲು ಹಾಗೂ ಕಾರ್ಯ ಯೋಜನೆ ತಯಾರಿಸಲು ದಿನಾಂಕ 23-2-2010ರಂದು 3-00 ಗಂಟೆಗೆ ಸರಿಯಾಗಿ ಕೌನ್ಸಿಲ್ ಹಾಲ್ ಫಾದರ್ ಮುಲ್ಲರ್ಸ್ ವೈದ್ಯಕೀಯ ಆಸ್ಪತ್ರೆ ಕಂಕನಾಡಿ ಮಂಗಳೂರು ಇಲ್ಲಿ ಸಭೆ ನಡೆಸಲು ಉದ್ದೇಶಿಸಲಾಗಿದೆ. ಆದ್ದರಿಂದ ತಮ್ಮ ಜತೆ ಆರ್.ಸಿ.ಹೆಚ್ ಅಧಿಕಾರಿಯವರನ್ನು ಈ ಸಭೆಗೆ ಕರೆದುಕೊಂಡು ಬರುವಂತೆ ಈ ಮೂಲಕ ವಿನಂತಿಸಲಾಗಿದೆ.

ಸಭೆಗೆ ಬರುವಾಗ ತಮ್ಮ ಆಧೀನದಲ್ಲಿ ಕೆಲಸ ನಿರ್ವಹಿಸುತ್ತಿರುವ 24X7 ಪ್ರಾ.ಆ.ಕೇಂದ್ರ ಸಮುದಾಯ ಆರೋಗ್ಯ ಕೇಂದ್ರದಲ್ಲಿ ಕೆಲಸ ನಿರ್ವಹಿಸುತ್ತಿರುವ ವೈದ್ಯಾಧಿಕಾರಿ ಪಟ್ಟಿಯನ್ನು ತರುವಂತೆ ಈ ಮೂಲಕ ವಿನಂತಿಸಲಾಗಿದೆ.

ಹೆಚ್ಚಿನ ಮಾಹಿತಿಗಾಗಿ ಡಾ: ಸುಜಯರಾವ್. ಪ್ರಸೂತಿ ಶಾಸ್ತ್ರವಿಭಾಗ ಫಾದರ್ ಮುಲ್ಲರ್ಸ್ ಆಸ್ಪತ್ರೆ ಮಂಗಳೂರು. ಫೋನ್ ನಂಬ್ರ. 9880490423 ಸಂಪರ್ಕಿಸಬಹುದಾಗಿದೆ.

ತಮ್ಮ ವಿಶ್ವಾಸಿ,

ಪ್ರಾಂಶುಪಾಲರು,
ಜಿಲ್ಲಾ ತರಬೇತಿ ಕೇಂದ್ರ ಸುರತ್ಕಲ್
ಮಂಗಳೂರು(ದ.ಕ)

ಪ್ರತಿಯನ್ನು: ಡಾ: ಸುಜಯ ರಾವ್ ಪ್ರಸೂತಿ ಶಾಸ್ತ್ರ ವಿಭಾಗ, ಫಾದರ್ ಮುಲ್ಲರ್ಸ್ ಆಸ್ಪತ್ರೆ,
ಕಂಕನಾಡಿ ಮಂಗಳೂರು ಇವರಿಗೆ ಮಾಹಿತಿಗಾಗಿ ಒಪಿಸಲಾಗಿದೆ
ಮಾನ್ಯ ನಿರ್ದೇಶಕರು, ರಾಜ್ಯ ಆರೋಗ್ಯ ಮತ್ತು ಕು.ಕ.ಸಂಸ್ಥೆ ಮಾಗಡಿ ರಸ್ತೆ,

ARMC IVF
(A Unit of Repro Health Care Mangalore Pvt. Ltd.)
Kavery Building, Falnir, Mangalore - 575002, Karnataka, India.
Ph : 0824-2430350 / 2430351, www.armcivf.com, email:info@armcivf.com
Also at : KOZHIKODE, THRISSUR, PALAKKAD, KANNUR, DUBAI & QATAR

Memorandum of understanding for Establishing a satellite clinic at FATHER MULLER HOSPITAL

This agreement is made on ..5th.. day of ..Jan..14 between 2015

ARMC IVF FERTILITY CENTRE (FIRST PARTY)
Kavery building, Falnir
Mangalore 575002
(Hereinafter referred as "ARMC")

AND

FATHER MULLER HOSPITAL (SECOND PARTY)
KANKANADY
MANGALORE
(Hereinafter referred as the "FMH")

Purpose of this Agreement:

WHEREAS the First Party M/S ARMC IVF FERTILITY CENTER (ARMC) is a well established infertility centre at Mangalore, having plans to expand across south India and represented by Dr.Kunjimoideen, is willing to associate with the second party Father Muller Medical College Hospital for establishing a satellite clinic for offering infertility services at Mangalore

NOW THE AGREEMENT WITNESS AS FOLLOWS.

1. Both parties (ARMC&FMH) agree to establish a satellite clinic in the second party's premises for the benefit of patients.
2. ARMC will provide the necessary technical Man Power to run the clinic
3. Second Party agreed to provide the necessary infrastructure and the supportive staff for effectively running the satellite clinic.
4. ARMC Faculty will share their knowledge in academic sessions of FMMCH.
5. Depending upon the success of satellite clinic over a period of ONE YEAR, decision will be taken to establish a fully fledged centre at FMH. The terms will be finalized during that time.
6. This agreement shall enter into effects as of ..... and shall remain in force for an initial period of one year and it shall be automatically renewed annually thereafter, unless terminated as set forth below.
7. Either party may terminate this agreement at any time by giving to the other party not less than 30 days prior written notice.
8. Both the parties will be responsible to full fill any statutory norms to operate the clinic in FMH Premises.

Signed on behalf of

For ARMC IVF MANGALORE
UNIT OF [illegible] HEALTH CARE
MANGALORE PVT. LTD.

ARMC, MANGALORE

Managing Director / Director

Signed on behalf of

FMH MANGALORE

Rev. Fr Richard Coelho
Administrator
Father Muller Medical College Hospital
Father Muller Road
Kankanady, Mangalore-575 002

WITNESS

1.

Dr. Uday kumar K.
MS. FMMCH

2.

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,
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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
FATHER MULLER CHARITABLE INSTITUTIONS
Father 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.

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

सत्यमेव जयते

Certificate No.	:	IN-KA36094144442913N
Certificate Issued Date	:	30-Mar-2015 10:31 AM
Account Reference	:	NONACC (FI)/ kacrsfl08/ MANGALORE1/ KA-DK
Unique Doc. Reference	:	SUBIN-KAKACRSFL0822310985382358N
Purchased by	:	DIRECTOR F M C I
Description of Document	:	Article 12 Bond
Description	:	MEMORANDUM OF UNDERSTANDING
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	DIRECTOR F M C I
Second Party	:	DISTRICT PROGRAM MANAGER
Stamp Duty Paid By	:	DIRECTOR F M C I
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

ATHMANANDA MULTIPURPOSE CO-OP. SOCIETY LTD. MANGALORE
Authorised Signature "Bendoorwell"

Please write or type below this line

MEMORANDUM OF UNDERSTANDING (MOU) BETWEEN DISTRICT HEALTH AND FAMILY WELFARE SOCIETY (R) (BLINDNESS CONTROL DIVISION) AND PARTICIPATING NON GOVERNMENT ORGANIZATION

1. Preamble :

1.1. WHEREAS the Union Cabinet has approved continuation of National Program for Control of Blindness, hereafter referred to as NPCB, for implementation in all the States of the Country during the 11th Plan (2007-2012);

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

1.2. WHEREAS the Cabinet has also agreed to follow the strategies of "Vision 2020 : The Right to Sight" in NPCB as per Plan of Action developed for the country.

1.3. WHEREAS NPCB aims to reduce prevalence of blindness by implementing various activities through State and District Blindness Control Societies established in all the districts of the country;

1.4. Whereas the NPCB seeks to involve eye care facilities in Government, Non-Government and Private sectors having capacity to perform various activities under National Programme for Control of Blindness;

1.5. AND WHEREAS schemes for Non-Government Organizations (hereafter referred as NGO) providing eye care services are implemented as per pattern of assistance approved by the Cabinet;

1.6. NOW THEREFORE the signatories of Memorandum of Understanding (MOU) have agreed as set out herein below :

2. Parties of MOU :

This MOU is an agreement between District Health and Family Welfare Society (R.) (Blindness Control Division) of Dakshina Kannada of the State of Karnataka; hereafter called District Health and Family Welfare Society (R.) (Blindness Control Division) and Father Muller Charitable Institutions.

3. Duration of MOU :

This MOU will be operative from the date of its signing by the parties and remain in force till **31st March 2016**. MOU can be renewed through mutual agreement by the parties.

4. Commitments of NGO :

Through this MOU the NGO agrees to provide following services under National Programme for Control of Blindness :

Sl.No.	Activities	Yes / No
a)	Screening of population in all the villages / townships in the area allotted to the NGO and preparation of village wise blind registers.	Yes
b)	Identification of cases fit for cataract surgery, motivation thereof and transportation to the base hospital	Yes
c)	Pre-operative examination and investigation as required	Yes
d)	Performance of cataract surgery preferably IOL implantation through ECCE / IOL, Small Incision Cataract Surgery (SICS) or Phaco-emulsification of patients identified in allotted areas, self motivated walk-in cases and those referred by DH&FWS (BCD)	Yes

e)	Post-operative care including management of complications, if any and post-operative counseling regarding use of glasses;	Yes
f)	Follow-up services including refraction and provision of glasses, if required providing best possible correction.	Yes
g)	Submission of cataract surgery records of operated cases.	Yes
h)	Eye operation for poor and deserving patients other than cataract surgery	Yes

5. Commitments of District Health and Family Welfare Society (Blindness Control Division) :

Through this MOU, the DH & FWS (BCD) agrees to provide following support to participating NGO to facilitate service delivery :

Clause	Clause of Agreement	Yes / No
5.1	Issue Certificate of Recognition about participation in NPCB	
5.2	Undertake random verification of operated cases not exceeding 5% before discharge of patients;	
5.3	Sanction cost of free cataract operations performed by the NGO as per GOI guidelines indicated in para 6 below within one month of submission of claim along with Cataract Surgery Records;	
5.4	Make payment of the sanctioned amount to the NGO on monthly/quarterly basis;	
5.5	Regularly disseminate literature, guidelines or any other relevant information to participating NGO)	

6. Grant-in-aid to NGO for this scheme is governed by the following table :

(Rupees per operation)

	Items	ECCE/IOL	SICS/PHACO
a.	Drugs and consumables	250	250
b.	Sutures	100	0
c.	Spectacles	125	125
d.	Transport/POL	150	150
e.	Organization & Publicity	125	125
f.	IOL, Viscoelastics & additional Consumables	250	350
	Total	**1000**	**1000**

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

7. Grant-in-aid to NGO for the Scheme other than Cataract Surgery :

1.	Diabetic Retinopathy	Rs.1,500.00
2.	Glaucoma	Rs.1,500.00
3..	Keratoplasty	Rs.5,000.00
4.	Squint	Rs.1,500.00
5.	Retinopalty of Prematurity	Rs.5,000.00
6.	Retinoblastoma	Rs.1,000.00
7.	Congenital Ptosis	Rs.1,000.00
8.	Intraocular Trauma in children	Rs.1,000.00
9.	Low vision	Rs. 500.00

8. Termination of MOU :

Commitments agreed to by the Parties are meant for prevention and control of blindness and therefore MOU should generally not be suspended or terminated. However, both parties can decide to suspend or terminate the MOU.

Signed this day, the **1st of April 2015.**

Dist. Programme Manager
DIST. BLINDNESS CONTROL SOCIETY
Dakshina Kannada District
Mangalore.

.....

For and on behalf of
District Health and Family Welfare Society (BCD)

.....

For and on behalf of NGO

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

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

Dr. Jaya Prakash Alva

Dean

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

Dr. Swapan Bhattacharya Feb 10, 2015

Director

Dr. M. B. Saidutta

Dean (Alumni Affairs & Institutional Relations)

Date-10/02/2015

Memorandum Of Understanding (MOU)

Between

Department of Community Medicine, Father Muller Medical College, Kankanady, Mangalore 575 002 (Henceforth referred to as First party)

And

St. Aloysius College (Autonomous), Light House Hill Road Mangalore 575 003 (Henceforth referred as Second party)

The First party is in the profession of imparting medical education. The second party looking for someone to impart basic medical education to its student is willing to tie up with the first party for the same under the following terms.

Terms:

1) The First party will provide the following services to the Second party
   a) Health Education
   b) First Aid Training
   c) Other medical and health related activities
2) The resource personal will be arranged by the first party while the activities will be carried out on the premises of the second party.
3) The topics, timing and participants for the above mentioned activities will be discussed and mutually decided by both parties in consultation with each other.
4) The Second Party will intimate to the First Party a minimum of 7 working days prior to the training to be conducted.
5) If the first party is unable to conduct a health related activity, the second party is free to make alternate arrangements with any other entity it deems fit.
6) Either party is free to terminate this MOU by giving its intention to do so in writing to the other party.
7) The validity of this MOU shall be for one year from the date of signing the same. However it shall be extended by mutual consent.

This MOU is signed on Eighth of July 2016 by the authorized officials from the first party and second party and will remain in effect until modified or terminated by any one of the parties by mutual consent.
In the absence of mutual agreement, this MOU shall terminate at the end of one year of signing of the MOU

First party

Signature

Name (Brig (Dr) Hemant Kumar)

Position Head & Deptt.

Date 08 July 2016.

Professor and HOD
Community Medicine Department
Fr. Muller Medical College

Second party

Signature

Name Rev. Fr. Swebert D'Silva

Position : Principal

Date : 12 July 2016

Principal
ST. ALOYSIUS COLLEGE (AUTONOMOUS)

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 : DIST. GANDHINAGAR-382 428. (GUJ.)
ચિરાગ લક્ષ્મણભાઈ સ્વાદીયા
લા. નં. એસ.બી. /૩૦૦/૩૦૧/૧૯૯૬
અમદાવાદ નારણપુરા વિસ્તાર નાં સબંદી
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. 100

તારીખ: 13 માહે 07 2016

નામ : TORRENT PHARMACEUTICALS LIMITED

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

આઈ.ડી. પ્રુફ

ચિરાગ લક્ષ્મણભાઈ સ્વાદીયા

લા. નં. એસ.બી./300/301/1999

અમદાવાદ નારણપુરા વિસ્તાર નાં સહિંદી

લેનારની સહીઓ

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".

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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".

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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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 FATHER 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 Karnataka

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Certificate No.	:	IN-KA23582287189721O
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Stamp Duty Paid By	:	DIRECTOR FMCI
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

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MEMORANDUM OF UNDERSTANDING (MOU) BETWEEN DISTRICT HEALTH AND FAMILY WELFARE SOCIETY (R) (BLINDNESS CONTROL DIVISION) AND PARTICIPATING NON GOVERNMENT ORGANIZATION

1. Preamble :

1.1. WHEREAS the Union Cabinet has approved continuation of National Program for Control of Blindness, hereafter referred to as NPCB, for implementation in all the States of the Country during the 11th Plan (2007-2012);

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

Statutory Alert:

1. The authenticity of this Stamp Certificate should be verified at "www.shcilestamp.com". Any discrepancy in the details on this Certificate and as available on the website renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

1.2. WHEREAS the Cabinet has also agreed to follow the strategies of "Vision 2020 : The Right to Sight" in NPCB as per Plan of Action developed for the country.

1.3. WHEREAS NPCB aims to reduce prevalence of blindness by implementing various activities through State and District Blindness Control Societies established in all the districts of the country;

1.4. Whereas the NPCB seeks to involve eye care facilities in Government, Non-Government and Private sectors having capacity to perform various activities under National Programme for Control of Blindness;

1.5. AND WHEREAS schemes for Non-Government Organizations (hereafter referred as NGO) providing eye care services are implemented as per pattern of assistance approved by the Cabinet;

1.6. NOW THEREFORE the signatories of Memorandum of Understanding (MOU) have agreed as set out herein below :

2. Parties of MOU :

This MOU is an agreement between District Health and Family Welfare Society (R.) (Blindness Control Division) of Dakshina Kannada of the State of Karnataka; hereafter called District Health and Family Welfare Society (R.) (Blindness Control Division) and Father Muller Charitable Institutions.

3. Duration of MOU :

This MOU will be operative from the date of its signing by the parties and remain in force till **31st March 2017**. MOU can be renewed through mutual agreement by the parties.

4. Commitments of NGO :

Through this MOU the NGO agrees to provide following services under National Programme for Control of Blindness :

Sl.No.	Activities	Yes / No
a)	Screening of population in all the villages / townships in the area allotted to the NGO and preparation of village wise blind registers.	Yes
b)	Identification of cases fit for cataract surgery, motivation thereof and transportation to the base hospital	Yes
c)	Pre-operative examination and investigation as required	Yes
d)	Performance of cataract surgery preferably IOL implantation through ECCE / IOL, Small Incision Cataract Surgery (SICS) or Phaco-emulsification of patients identified in allotted areas, self motivated walk-in cases and those referred by DH&FWS (BCD)	Yes

e)	Post-operative care including management of complications, if any and post-operative counseling regarding use of glasses;	Yes
f)	Follow-up services including refraction and provision of glasses, if required providing best possible correction.	Yes
g)	Submission of cataract surgery records of operated cases.	Yes
h)	Eye operation for poor and deserving patients other than cataract surgery	Yes

5. Commitments of District Health and Family Welfare Society (Blindness Control Division) :

Through this MOU, the DH & FWS (BCD) agrees to provide following support to participating NGO to facilitate service delivery :

Clause	Clause of Agreement	Yes / No
5.1	Issue Certificate of Recognition about participation in NPCB	
5.2	Undertake random verification of operated cases not exceeding 5% before discharge of patients;	
5.3	Sanction cost of free cataract operations performed by the NGO as per GOI guidelines indicated in para 6 below within one month of submission of claim along with Cataract Surgery Records;	
5.4	Make payment of the sanctioned amount to the NGO on monthly/quarterly basis;	
5.5	Regularly disseminate literature, guidelines or any other relevant information to participating NGO)	

6. Grant-in-aid to NGO for this scheme is governed by the following table :

(Rupees per operation)

	Items	ECCE/IOL	SICS/PHACO
a.	Drugs and consumables	250	250
b.	Sutures	100	0
c.	Spectacles	125	125
d.	Transport/POL	150	150
e.	Organization & Publicity	125	125
f.	IOL, Viscoelastics & additional Consumables	250	350
	Total	**1000**	**1000**

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

7. Grant-in-aid to NGO for the Scheme other than Cataract Surgery :

1.	Diabetic Retinopathy	Rs.1,500.00
2.	Glaucoma	Rs.1,500.00
3..	Keratoplasty	Rs.5,000.00
4.	Squint	Rs.1,500.00
5.	Retinopalty of Prematurity	Rs.5,000.00
6.	Retinoblastoma	Rs.1,000.00
7.	Congenital Ptosis	Rs.1,000.00
8.	Intraocular Trauma in children	Rs.1,000.00
9.	Low vision	Rs. 500.00

8. Termination of MOU :

Commitments agreed to by the Parties are meant for prevention and control of blindness and therefore MOU should generally not be suspended or terminated. However, both parties can decide to suspend or terminate the MOU.

Signed this day, the **1st of April 2016.**

Dist. Programme Manager
DIST. BLINDNESS CONTROL SOCIETY
Dakshina Kannada District
Mangalore.

.....
For and on behalf of
District Health and Family Welfare Society (BCD)

.....
For and on behalf of NGO

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

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

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Certificate No.	:	IN-KA31307534445393O
Certificate Issued Date	:	27-Oct-2016 11:47 AM
Account Reference	:	NONACC (FI)/ kacrsfl08/ DERALAKATTE/ KA-DK
Unique Doc. Reference	:	SUBIN-KAKACRSFL08123107534931540
Purchased by	:	K S HEGDE MEDICAL ACADEMY DERALAKATTE MANGALORE
Description of Document	:	Article 12 Bond
Description	:	M O U
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	K S HEGDE MEDICAL ACADEMY DERALAKATTE MANGALORE
Second Party	:	FATHER MULLER MEDICAL COLLEGE HOSPITAL MANGALORE
Stamp Duty Paid By	:	K S HEGDE MEDICAL ACADEMY DERALAKATTE MANGALORE
Stamp Duty Amount(Rs.)	:	200 (Two Hundred only)

Authorised Signatory
For Vijaya [illegible] Society Ltd
[illegible]

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MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (herein after referred to as "MOU") is made and executed on this date November **1, 2016** *at Mangalore*

Dean
K. S. Hegde Medical Academy
DERALAKATTE, POST NITHYANANDA NAGAR
MANGALORE - 575 018

Administrator
Father Muller Medical College Hospital
Fr. Muller Road, Kankanady
MANGALORE-575002
Karnataka State

BY AND BETWEEN

K. S. Hegde Medical Academy, Deralakatte, Mangalore (a constituent college of Nitte University) situated at Nithyananda Nagar, Deralakatte, Mangalore – 575018 represented by Prof. (Dr.) B. Satheesh Kumar Bhandary, Dean (hereinafter referred to as "KSHEMA") which term unless repugnant to the context thereof, shall mean and include its successors-in-interest and permitted assigns, of the FIRST PART

AND

Father Muller Medical College Hospital, Mangalore (a unit of Father Muller Charitable Institutions) situated at Father Muller Road, Kankanady, Mangalore – 575002 represented by Rev Fr. Richard Coelho, Administrator (hereinafter referred to as "FMMCH") which term unless repugnant to the context thereof, shall mean and include its successors-in-interest and permitted assigns, of the SECOND PART

"KSHEMA" and "FMMCH" are individually and collectively referred to as "Party" and "Parties" respectively.

WHEREAS

- *KSHEMA centre for Genetic Services, a division of K. S. Hegde Medical Academy is a diagnostic genetic laboratory delivering specialized testing facilities in the field of Pediatrics, Obstetrics and Gynecology, Oncology & Pathology*
- *KSHEMA offers Inter Laboratory Quality Control specialized genetics diagnostic services on request from similar health care facilities.*
- *FMMCH owns and operates a hospital, requires services of the type offered by KSHEMA.*
- *FMMCH desires to obtain services from KSHEMA and KSHEMA is willing to provide such services to FMMCH, in accordance with the terms and conditions set forth within.*

Wherefore, it is agreed between the Parties as under:

1. Term

1. This agreement shall be a valid for a period of three years from the date of execution of this agreement. This agreement shall come into effect from November 1, 2016. However either party will renew this agreement for further period of three years with mutual consent.

2. Objective

1. The objective of this MOU is to establish a written document framing a basic understanding under which both the parties shall be governed for conducting diagnostics and monitoring tests on the samples received from FMMCH.

Dean
Medical Academy

Administrator
Father Muller Medical College Hospital
Fr. Muller Road, Kankanady
MANGALORE-575002
Karnataka State

4. Scope of Work

4.1 During the term hereof or the extended term as the case may be KSHEMA shall provide the services to FMMCH for all the tests requested by FMMCH. The list of tests annexed to this agreement as **Annexure 1**

4. **Role and Responsibilities of K. S. Hegde Medical Academy**

4.1 KSHEMA shall conduct tests/investigations as per duly filled request form sent by FMMCH. The testing and reporting shall be carried out conforming to prescribed high standards of quality.

4.2 KSHEMA shall provide reports of tests/ investigations through e-mail to reduce the Turn Around time (TAT) and then hard copy by courier.

4.3 KSHEMA shall conduct tests/investigations on the basis of samples received from FMMCH. The sample received from FMMCH shall be tested and reported as per **Annexure 1.**

5. **Roles and Responsibilities of Father Muller Medical College Hospital**

5.1 FMMCH shall be responsible for proper packing of samples and transportation in defined condition and temperature. KSHEMA will not be responsible for packing and transportation.

5.2 FMMCH shall be responsible for sending duly filled test requisition form, patient history, samples packing and labeling at required temperature in good condition to KSHEMA for test/ investigations.

5.3 FMMCH shall make payments to KSHEMA for services provided under this MOU within 15 days of receiving the invoices.

5.4 It is the responsibility of FMMCH to provide additional details requested by KSHEMA to conduct the test/ investigation.

6. **Force Majeure**

6.1 Any event beyond the control of KSHEMA which prevents it from complying with its obligation to FMMCH resulting in delay in reporting or most performing to test shall be subject to majeure. These include but not limited to unavailability of test kits, failure of test, incomplete patient / test details, problem sample, need for repeat sample/ testing, instrument or machinery breakdown, civil unrest, riots, change in or in the interpretation of laws, strikes, lockout or other labour problems, unavailability of supply, fire or explosion, act of terrorism and other natural calamities.

6.2 KSHEMA would make efforts to mitigate the impact of such Force Majeure conditions and ensure timely testing as feasible and inform FMMCH accordingly.

7. **Consideration:**

7.1 The billing shall be done on monthly basis at rates as per the **Annexure 1** starting from 1st to 31st of each month and FMMCH undertakes to clear all the outstanding payments within 15 days from the date of receiving the invoices.

Dean
K. S. Hegde Medical Academy
DERALAKATTE, POST NITHYANANDA NAGAR
MANGALORE - 575 018
KARNATAKA

Administrator
Father Muller Medical College Hospital
Fr. Muller Road, Kankanady
MANGALORE-575002
Karnataka State

7.2 Revision of tariff by KSHEMA will be intimated to FMMCH in writing, upon which the revised rate tariff shall be applicable from the date revision.

8. Termination and Consequences of Termination

8.1 Each of the parties makes the following representations and warranties to the other party hereto that the representing party has the full power and unrestricted authority to enter into this MOU. Entering this MOU and performing the obligations hereunder does not conflict with and is not prohibited under the terms of any other agreement, document, law, rule, regulation or court order to which the representing party is subject. Each of the parties has the full power and unrestricted authority to grant the licenses that are granted herein.

8.2 This MOU may be terminated on mutual consent or by either party with at least 30 days prior written notice without assigning any reasons.

8.3 All payments due, becoming due and payable to the Parties as on the date of termination, under the terms of this MOU shall continue to be due and payable to the Parties notwithstanding the termination hereof.

9. Confidentiality:

10.1 Each Party shall keep secret all Confidential Information, if any, transmitted to it or made available to it by the other Party and shall not pass such Confidential Information on, wholly or partly, to third parties without express written consent of the other Party.

10.2 The Parties shall not disclose the terms of this MOU or make any announcement in respect of the subject matter thereof without prior written consent of the other Party unless the disclosure is required by law or other regulatory authorities. In the event disclosure is required by law, rules or regulations, such disclosure shall be made after obtaining written permission of other party.

10.3 The Confidentiality obligations in this do not apply to disclose information that either Party in writing can prove that:

i. It was known at the time of disclosure to be free of any obligation to keep it confidential, as evidenced by written records.

ii. Became generally publicly known through authorized disclosure.

iii. The information was independently developed without access to or use of any confidential Information, as evidenced by written records, or

iv. The information was rightfully obtained from a third party who had the right to transfer or disclose it without violation of any confidentiality obligations.

10. Dispute Resolution and Governing Law

11.1 In case if any difference or dispute arises between the Parties herein, the Parties shall hold mutual discussions to resolve such difference and / or dispute in an amicable manner for the best interests of both Parties. Parties shall try to resolve the difference and / or dispute within 30 days or such extended time as agreed between the Parties. In case, any difference and / or dispute could not be resolved through mutual discussion then such difference and / or dispute between the Parties shall be referred to sole arbitrator

Dean
K. S. Hegde Medical Academy
DERALAKATTE, POST NITHYANANDA NAGAR
MANGALORE - 575 018
KARNATAKA

Administrator
Father Muller Medical College Hospital
Fr. Muller Road, Kankanady
MANGALORE-575002
Karnataka State

appointed by both the parties in accordance with the Arbitration and Conciliation Act, 1996. The venue of the arbitration shall be Mangalore. The award of the arbitration shall be final and binding between the Parties.

11. Limitation of Liability

12.1 To the fullest extent permitted by Applicable Law neither Party nor its affiliates shall be liable for any special, indirect, consequential, or incidental damages (including but not limited to damages for loss of business profits, business interruption, loss of business information, and the like) arising out of this MOU even if either Party has been advised of the possibility of such damages.

12.2 Miscellaneous:

Relationship: No provision of this MOU shall be deemed to constitute a partnership or joint venture between the Parties.

Further, each Party shall inform its employees that they shall not be treated as employees of the other Party for any purpose whatsoever and that they shall not exercise any rights or seek or be entitled to any benefits accruing to the regular employees of the other Party.

No provision of this MOU shall constitute either Party as the legal representative or agent of the other, nor shall either Party have the right or authority to assume, create or incur any liability or any obligation of any kind, express or implied, against or in the name of or on behalf of the other Party except as provided expressly under this Agreement.

12. Notices:

Any notice required or permitted to be given hereunder shall be in writing and shall be effectively served.

13.1.1 If delivered personally, upon receipt by the other party;

13.1.2 If sent by prepaid courier service, airmail or registered mail, within seven (7) days of being sent; or

13.1.3 If sent by facsimile or other similar means of electronic communication (with confirmed receipt), upon receipt of transmission notice by the sender.

13.1.4 Any notice required or permitted to be given hereunder shall be addressed as given in the title to this MOU.

13.1.5 Any party hereto may change any particulars of its address for notice, by notice to the other in the manner aforesaid.

Violation of terms:

The Parties agree that each party shall be entitled to an injunction, restraining order, right for recovery, suit for specific performance, or such other equitable relief as a court of competent jurisdiction may deem necessary or appropriate to restrain the other party from permitting any violation or enforce the performance of the covenants, obligations and representations contained in this MOU. These injunctive remedies are cumulative and are in addition to any other rights and remedies the Parties may have at law or in equity, including without limitation, a right for recovery of the amounts due under this Agreement and related costs and a right for damages.

Dean
K. S. Hegde Medical Academy
DERALAKATTE, POST NITHYANANDA NAGAR
MANGALORE - 575 018
KARNATAKA

Administrator
Father Muller Medical College Hospital
Fr. Muller Road, Kankanady
MANGALORE-575002
Karnataka State

IN WITNESS THEREOF the Parties have through their respectively duly authorized representatives, executed this MOU the day, month and year first hereinabove written.

Signed and delivered by KSHEMA K. S. Hegde Medical Academy	Signed and delivered by FMMCH Father Muller Medical College Hospital
(Sign) By: Prof. (Dr.) [illegible] Bhandary Title: Dean Dean K. S. Hegde Medical Academy NITTE (DU) PERALAKATTE, POST-NITHYANANDA NAGAR MANGALORE-575 018 KARNATAKA	(Sign) By: Rev Fr. Richard Coelho Title: Administrator Administrator Father Muller Medical College Hospital Kankanady Road, Kankanady MANGALORE-575002 Karnataka State
Witness1: (Sign) Name: DR. D. PRASHANTH SHETTY.	Witness1: (Sign) Name: Dr. SHIVASHANKARA A
Witness 2: (Sign) Name: Dr. Sucheetha Kumari. N.	Witness2: (Sign) Name: MS. LIDIA PAIS FINANCE OFFICER

****

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Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA003344871536070
Certificate Issued Date	:	26-Aug-2016 10:26 AM
Account Reference	:	NONACC (FI)/ kaksfcl08/ KANKANADY/ KA-DK
Unique Doc. Reference	:	SUBIN-KAKAKSFCL08508928918926620
Purchased by	:	FATHER MULLER MEDICAL COLLEGE HOSPITAL
Description of Document	:	Article 12 Bond
Description	:	M O U
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	FATHER MULLER MEDICAL COLLEGE HOSPITAL
Second Party	:	KASTURBA HOSPITAL
Stamp Duty Paid By	:	FATHER MULLER MEDICAL COLLEGE HOSPITAL
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

SUGGI SOUHARDA CO-OP. LTD. Authorised Signatory MANGALURU - 575 002

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MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (herein after referred to as "MOU") is made and executed on this date **September 1st, 2016 till the date August 31st, 2017at Mangalore**

FATHER MULLER CHARITABLE INSTITUTIONS Kankanady Mangalore 575 002

First Party

Second Party

CHIEF OPERATING OFFICER & MEDICAL SUPERINTENDENT KASTURBA HOSPITAL, MANIPAL

Statutory Alert:

1. The authenticity of this Stamp Certificate should be verified at "www.shcilestamp.com". Any discrepancy in the details on this Certificate and
available on the website renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. The onus of checking the legitimacy is on the users of the certificate.

BY AND BETWEEN

Father Muller Medical College Hospital, Mangalore (a unit of Father Muller Charitable Institutions) situated at Father Muller Road, Kankanady, Mangalore – 575002 represented by Rev Fr. Richard Coelho, Administrator (hereinafter referred to as "FMMCH") which term unless repugnant to the context thereof, shall mean and include its successors-in-interest and permitted assigns, of the FIRST PART

AND Kasturba Hospital having its office at Madhavanagar, Manipal - 576104duly represented by Dr. (Col) M Dayananda, Medical Superintendent & COO (hereinafter referred to as "Kasturba")which term unless repugnant to the context shall mean and include its successors and permitted assigns) of the SECOND PARTY

"FMMCH" and "Kasturba" are individually and collectively referred to as "Party" and "Parties" respectively.

WHEREAS

1. Father Muller Medical College Hospital Laboratory, a division of Father Muller Medical College Hospital is a clinical laboratory delivering specialized testing facilities in the field of Biochemistry, Hematology, Histopathology and Microbiology.
2. FMMCH offers Inter Laboratory Quality Control specialized pathological diagnostic services on a per-request basis from similar health care facilities.
3. Kasturba owns and operates a hospital, requires services of the type offered by FMMCH.
4. Kasturba desires to obtain services from FMMCH and FMMCH is willing to provide such services to Kasturba, in accordance with the terms and conditions set forth within.

Wherefore, it is agreed between the Parties as under:

1. Term

1.1 This agreement shall be a valid for a period of one year from the date of execution of this agreement. This agreement shall come into effect from September 1st, 2016. However either party will renew this agreement for further period of one year with mutual consent.

2. Objective

2.1 The objective of this MOU is to establish a written document framing a basic understanding under which both the parties shall be governed for conducting diagnostics and monitoring tests on the samples received by Kasturba.

3. Scope of Work

3.1 During this one year term hereof or the extended term as the case may be FMMCH shall provide the services to Kasturba for all the tests (i.e. 2 samples per test for one year) requested by Kasturba. The list of tests annexed to this agreement as **Annexure 1**.

4. Role and Responsibilities of Father Muller Medical College Hospital

4.1 FMMCH shall conduct tests/investigations as per duly filled request form filled by Kasturba. The testing and reporting shall be carried out conforming to prevalent high standards of quality.

FATHER MULLER CHARITABLE INSTITUTIONS Kankanady Mangalore 575 002

CHIEF OPERATING OFFICER & MEDICAL SUPERINTENDENT MANIPAL

4.2 FMMCH shall provide reports of tests/ investigations through hard copy by courier.

4.3 FMMCH shall conduct tests/investigations on the basis of samples received from Kasturba. The sample received from Kasturba shall be tested and reported within two or three working days under normal circumstances. Reporting timeliness will be in accordance with prevalent quality standards.

5. Roles and Responsibilities of Kasturba

5.1 Kasturba shall be responsible for proper packing of samples and transportation in defined condition and temperature. Hospital will not be responsible for packing and transportation.

5.2 Kasturba shall be responsible for sending duly filled test requisition form, patient history, samples packing and labeling at required temperature in good condition to FMMCH for test/ investigations.

5.3 Kasturba shall make payments to FMMCH for services provided under this MOU within 15 days of receiving the invoices.

5.4 It is the responsibility of Kasturba to provide additional details requested by FMMCH to conduct the test/ investigation.

6. Force Majeure

6.1 Any delay in reporting the test/ investigation shall be subject to Force Majeure, such as unavailability of test kits, failure of test, incomplete patient / test details, problem sample, need for repeat sample/ testing, instrument or machinery breakdown, civil unrest, riots, change in or in the interpretation of laws, strikes, lockout or other labour problems, unavailability of supply, fire or explosion, act of terrorism and other natural calamities. FMMCH would make efforts to mitigate the impact of such Force Majeure conditions and ensure timely testing as feasible and inform Kasturba accordingly.

7. Consideration:

7.1 The billing shall be done on case to case basis and Kasturba undertakes to clear all the outstanding payments within 15 days from the date of receiving the invoices.

7.2 Revision of tariff by FMMCH will be intimated to Kasturba in writing, upon which the revised rate tariff shall be applicable from the date revision.

8. Termination and Consequences of Termination

8.1 Each of the parties makes the following representations and warranties to the other party hereto that the representing party has the full power and unrestricted authority to enter into this MOU. Entering this MOU and performing the obligations hereunder does not conflict with and is not prohibited under the terms of any other agreement, document, law, rule, regulation or court order to which the representing party is subject. Each of the parties has the full power and unrestricted authority to grant the licenses that are granted herein.

9. Termination and Consequences of Termination

9.1 This MOU may be terminated on mutual consent or by either party with at least 30 days prior written notice without assigning any reasons.

9.2 All payments due, becoming due and payable to the Parties as on the date of termination, under the terms of this MOU shall continue to be due and payable to the Parties notwithstanding the termination hereof.

10. Confidentiality:

10.1 Each Party shall keep secret all Confidential Information, if any, transmitted to it or made available to it by the other Party and shall not pass such Confidential Information wholly or partly to third parties without express written consent of the other Party.

MULLER CHARITABLE INSTITUTIONS Kankanady Mangalore

CHIEF OPERATING OFFICER & SUPERINTENDENT

10.2 The Parties shall not disclose the terms of this MOU or make any announcement in respect of the subject matter thereof without prior written consent of the other Party unless the disclosure is required by law or other regulatory authorities. In the event disclosure is required by law, rules or regulations, such disclosure shall be made after obtaining written permission of other party.

10.3 The Confidentiality obligations in this do not apply to disclose information that either Party in writing can prove that:

i. It was known at the time of disclosure to be free of any obligation to keep it confidential, as evidenced by written records.

ii. Became generally publicly known through authorized disclosure.

iii. The information was independently developed without access to or use of any confidential Information, as evidenced by written records, or

iv. The information was rightfully obtained from a third party who had the right to transfer or disclose it without violation of any confidentially obligations.

11. Dispute Resolution and Governing Law

11.1 In case if any difference or dispute arises between the Parties herein, the Parties shall hold mutual discussions to resolve such difference and / or dispute in an amicable manner for the best interests of both Parties. Parties shall try to resolve the difference and / or dispute within 30 days or such extended time as agreed between the Parties. In case, any difference and / or dispute could not be resolved through mutual discussion then such difference and / or dispute between the Parties shall be referred to sole arbitrator appointed by both the parties in accordance with the Arbitration and Conciliation Act, 1996. The venue of the arbitration shall be Mangalore. The award of the arbitration shall be final and binding between the Parties.

12. Limitation of Liability

12.1 To the fullest extent permitted by Applicable Law neither Party nor its affiliates shall be liable for any special, indirect, consequential, or incidental damages (including but not limited to damages for loss of business profits, business interruption, loss of business information, and the like) arising out of this MOU even if either Party has been advised of the possibility of such damages.

13. Miscellaneous:

Relationship: No provision of this MOU shall be deemed to constitute a partnership or joint venture between the Parties.

Further, each Party shall inform its employees that they shall not be treated as employees of the other Party for any purpose whatsoever and that they shall not exercise any rights or seek or be entitled to any benefits accruing to the regular employees of the other Party.

No provision of this MOU shall constitute either Party as the legal representative or agent of the other, nor shall either Party have the right or authority to assume, create or incur any liability or any obligation of any kind, express or implied, against or in the name of or on behalf of the other Party except as provided expressly under this Agreement.

Notices:

Any notice required or permitted to be given hereunder shall be in writing and shall be effectively served.

13.1.1 If delivered personally, upon receipt by the other party;

13.1.2 If sent by prepaid courier service, airmail or registered mail, within seven (7) days of being sent; or

13.1.3 If sent by facsimile or other similar means of electronic communication (with confirmed receipt), upon receipt of transmission notice by the sender.
13.1.4 Any notice required or permitted to be given hereunder shall be addressed as given in the title to this MOU.
13.1.5 Any party hereto may change any particulars of its address for notice, by notice to the other in the manner aforesaid.

Violation of terms:
The Parties agree that each party shall be entitled to an injunction, restraining order, right for recovery, suit for specific performance, or such other equitable relief as a court of competent jurisdiction may deem necessary or appropriate to restrain the other party from permitting any violation or enforce the performance of the covenants, obligations and representations contained in this MOU. These injunctive remedies are cumulative and are in addition to any other rights and remedies the Parties may have at law or in equity, including without limitation, a right for recovery of the amounts due under this Agreement and related costs and a right for damages.

IN WITNESS THEREOF the Parties have through their respectively duly authorized representatives, executed this MOU the day, month and year fist hereinabove written.

Signed and delivered by FMMCH Father Muller Medical College Hospital	Signed and delivered by Kasturba Kasturba Hospital, Madhavanagar, Manipal
(Sign) By: Rev Fr. Richard Coelho Title: Administrator Father Muller Medical College Hospital Father Muller Road Kankanady, Mangalore-575 002	(Sign) By:Dr. (Col) M.Dayananda Title:Medical Superintendent & COO CHIEF OPERATING OFFICER & MEDICAL SUPERINTENDENT KASTURBA HOSPITAL, MANIPAL
Witness1: (Sign) Name: LIDIA PAIS, FINANCE OFFICER	Witness1: (Sign) Name: Vijish V K, Asst. Manager - Quality, Kasturba Hospital, Manipal - 576 104
Witness 2: Jyothi Pinto (Sign) Name: Manager-HRD Fr. Muller Charitable Institutions Kankanady, Mangalore-575 002	Witness2: (Sign) Name: Dr. Sushma Belitkar OFFICER-IN-CHARGE CLINICAL LABORATORY KASTURBA HOSPITAL MANIPAL

ManipalHospitals
LIFE'S ON

MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (herein after referred to as "MOU") is made and executed on this, date 22nd November 2016 at Bangalore.

BETWEEN

Manipal Hospital, Bangalore a unit of Manipal Health Enterprises Private Limited situated at # 98, HAL airport road , Bangalore 560017, represented by **Mr. Pramod Alagharu, Regional Head-Operations** (hereinafter referred to as 'MANIPAL'), which expression unless repugnant to the context thereof, shall mean and include its successors-in-interest and permitted assigns, of the One Part;

AND

Father Muller Medical College Hospital, Father Muller Road, Kankanady, Mangalore - 575 002, represented by **Rev. Fr Richard Coelho, Administrator** (hereinafter referred to as "Client" which expression unless repugnant to the context shall mean and include its legal representatives, affiliate, subsidiary Company, administrators, executors, nominee and assigns of the Other Part;

"**Manipal**" and "**Client**" are individually and collectively referred to as "**Party**" and "**Parties**" respectively.

WHEREAS:

A. Department of Laboratory Medicine, a division of Manipal Hospital Bangalore is a clinical laboratory delivering specialized testing facilities in the field of Biochemistry, Transfusion Medicine services, Hematology, Histopathology, Microbiology, Molecular Pathology, Nephropathology and Medical Genetics services.

B. Manipal Hospital offers Inter Laboratory Comparison & as Referral Laboratories services on a per-request basis from similarly-situated health care facilities.

C. Client owns and operates a hospital, requires Services of the type offered by the Manipal Hospital.

D. Client desires to obtain Services from the Manipal Hospital and the Manipal Hospital is willing to provide such Services to Client, in accordance with the terms and conditions set forth herein.

FATHER MULLER MEDICAL COLLEGE ... MANGALORE

11 YEARS

NOW THEREFORE THE PARTIES TO THE MOU WITNESS AS UNDER:

1. Term

1.1 This agreement shall be valid for a period of two year from the date of execution of this agreement. Thus agreement shall come in to effect from 22nd November 2016. However either party will renew this agreement for further period of one year with mutual consent.

2. Objective:

2.1 The objective of this MOU is to establish a written document framing a basic understanding under which both the parties shall be governed for conducting diagnostics and monitoring tests on the samples received by the Client.

3. Scope of Work:

3.1 During the term hereof or the extended term as the case may be Manipal Hospital shall provide the services to Client for all test requested by Client. The list of the Tests annexed to this agreement as Annexure A.

4. Role and Responsibilities of Manipal Hospital.

4.1 Manipal Hospital shall conduct test/investigations, as per the duly filled request form filled by Client. The testing and reporting shall be carried out conforming to prevalent high standards of quality

4.2 Manipal Hospital shall provide reports of test/investigation conducted through E-mail. The hard copy of report may be couriered or collected by Client on specific request by the Client.

4.3 Manipal Hospital shall conduct test/investigation on the basis of samples received from Client. Upon receipt of the sample from the Client will be tested and reported within 2-3 working days under normal circumstances. Reporting timeliness will be in accordance with prevalent quality standards

4.4 For any query related to technical issues for Hospital other issues relating to billing will be handled by Lab Manager & Lab Officer (ph. No. 080-25023399).

5. Role and Responsibilities of Client:

5.1 Samples will be pickup by Manipal Hospital by - Department of laboratory Medicine with written Test Request Form

5.2 Client shall be responsible for proper packing of samples and transportation in defined condition and temperature. Hospital will not be responsible for packing and transportation.

5.3 Client shall be responsible for sending duly filled Test Requisition Form, Patient History, samples packing and labeling at required temperature in good condition to Manipal Hospital for test/investigation.

5.4 Client shall make payments to Manipal Hospital for services provided under this MOU within 10 days of receiving the invoices.

5.5 Its on responsibility of Client to provide additional details requested by Manipal Hospital to conduct the test/investigation.

6. **Force Majeure:**

6.1 Any delay in reporting the test/investigation shall be subject to Force Majeure, such as unavailability of test kits, failure of test, incomplete patient / test details, problem sample, sample lost in transit, need for repeat sample/testing, instrument or machinery breakdown, civil unrest, riots, change in or in the interpretation of laws, strikes, lockout or other labor problems, unavailability of supply, fire or explosion, act of terrorism and other natural calamities. In the event of repeat sample/testing requirement, MH would agree to repeat the test at its own cost. Manipal Hospitals would also make efforts to mitigate the impact of such Force Majeure conditions and ensure timely testing as feasible and inform the client accordingly.

7. **Consideration**

7.1 The billing shall be done on monthly basis starting from 1st to 31st of each month and Client undertakes to clear all the outstanding payments within 15 days from the date of receiving the invoices.

7.2 Consideration for the services is mentioned in **Annexure II.**

7.2 Revision of tariff by Manipal Hospital will be intimated to Client in writing, upon which the revised rate tariff shall be applicable from the date of Client accepting the same in writing.

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8. **Representations and Warranties of the Parties**

8.1 Each of the parties makes the following representations and warranties to the other party hereto that the representing party has the full power and unrestricted authority to enter into this MOU. Entering this MOU and performing the obligations hereunder does not conflict with and is not prohibited under the terms of any other agreement, document, law, rule, regulation or court order to which the representing party is subject. Each of the parties has the full power and unrestricted authority to grant the licenses that are granted herein.

9. **Termination and Consequences of Termination**

9.1 This MOU may be terminated on mutual consent or by either party with at least 30 days prior written notice without assigning any reasons.

9.2 All payments due, becoming due and payable to the Parties as on the date of termination, under the terms of this MOU shall continue to be due and payable to the Parties notwithstanding the termination hereof.

10. **Confidentiality**

10.1 Each Party shall keep secret all Confidential Information, if any, transmitted to it or made available to it by the other Party and shall not pass such Confirmation Information on, wholly or partly, to third parties without express written consent of the other Party.

10.2 The Parties shall not disclose the terms of this MOU or make any announcement in respect of the subject matter thereof without prior written consent of the other Party unless the disclosure is required by law or other regulatory authorities. In the event disclosure is required by law, rules or regulations, such disclosure shall be made after obtaining written permission of other party.

10.3 The Confidentiality obligations in this do not apply to disclosed information that either Party in writing can prove that:

i. It was known at the time of disclosure to be free of any obligation to keep it confidential, as evidenced by written records;
ii. Became generally publicly known through authorized disclosure;
iii. The information was independently developed without access to or use of any confidential Information, as evidenced by written records; or

iv. The information was rightfully obtained from a third party who had the right to transfer or disclose it without violation of any confidentiality obligations

11. Dispute Resolution and Governing Law

11.1 In case of any difference or dispute arises between the Parties herein, the Parties shall hold mutual discussions to resolve such difference and/or dispute in an amicable manner for the best interests of both Parties. Parties shall try to resolve the difference and / or dispute within 30 days or such extended time as agreed between the Parties. In case, any difference and / or dispute could not be resolved through mutual discussion then such difference and / or dispute between the Parties shall be referred to sole arbitrator appointed by both the parties in accordance with the Arbitration and Conciliation Act, 1996. The venue of the arbitration shall be Bangalore. The award of the arbitration shall be final and binding between the Parties.

12. Limitation of Liability

12.1 To the fullest extent permitted by Applicable Law neither Party nor its affiliates shall be liable for any special, indirect, consequential, or incidental damages (including but not limited to damages for loss of business profits, business interruption, loss of business information, and the like) arising out of this MOU even if either Party has been advised of the possibility of such damages.

13 Miscellaneous

Relationship:
No provision of this MOU shall be deemed to constitute a partnership or joint venture between the Parties.

Further, each Party shall inform its employees that they shall not be treated as employees of the other Party for any purpose whatsoever and that they shall not exercise any rights or seek or be entitled to any benefits accruing to the regular employees of the other Party.

No provision of this MOU shall constitute either Party as the legal representative or agent of the other, nor shall either Party have the right or authority to assume, create or incur any liability or any obligation of any kind, express or implied, against or in the name of or on behalf of the other Party except as provided expressly under this Agreement.

Notices:

Any notice required or permitted to be given hereunder shall be in writing and shall be effectively served

13.1.1 If delivered personally, upon receipt by the other Party;

13.1.2 If sent by prepaid courier service, airmail or registered mail, within five (5) days of being sent; or

13.1.3 If sent by facsimile or other similar means of electronic communication (with confirmed receipt), upon receipt of transmission notice by the sender.

13.1.4 Any notice required or permitted to be given hereunder shall be addressed to the address as given in the title to this MOU.

13.1.5 Any Party hereto may change any particulars of its address for notice, by notice to the other in the manner aforesaid.

Violation of Terms:

The Parties agree that each Party shall be entitled to an injunction, restraining order, right for recovery, suit for specific performance, or such other equitable relief as a court of competent jurisdiction may deem necessary or appropriate to restrain the other Party from committing any violation or enforce the performance of the covenants, obligations and representations contained in this MOU. These injunctive remedies are cumulative and are in addition to any other rights and remedies the Parties may have at law or in equity, including without limitation, a right for recovery of the amounts due under this Agreement and related costs and a right for damages.

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IN WITNESS WHEREOF the Parties have through their respectively duly authorized representatives, executed this MOU the day, month and year first hereinabove written.

Signed & Delivered by CLIENT **Father Muller Medical College Hospital**	*Signed & Delivered by MHEPL* **Manipal Health Enterprises Private Limited**
(Sign) Rev. Fr Richard Coelho By: **Rev. Fr Richard Coelho** Title: **Administrator** Father Muller Medical College Hospital Father Muller Road Kankanady, Mangalore-575 002	(Sign) By: **Mr. Pramod Alagharu** Title: **Regional Head**
Witness 1: (Sign) Name	Witness 1: (Sign) Name
Witness 2: (Sign) Name	Witness 2: (Sign) Name

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ANNEXURE II
(Consideration)

Manipal Hospital Laboratory will extend Institutional discount of 30% to M/S Father Muller Medical College Hospital on MRP for all tests other then the tests of Medical Genetics which is applicable a discount of 15% on MRP conducted in Manipal Hospital Genetics Laboratory.

FATHER MULLER MEDICAL COLLEGE HOSPITAL
KANKANADY
MANGALORE
575 002

[CLINICAL RESEARCH SERVICES ONLY]

AGREEMENT FOR CLINICAL TRIALS BY SITE

THIS MASTER AGREEMENT FOR CLINICAL TRIALS BY SITE(hereinafter referred to asthis "**Agreement**") is made on this 14 day of the month of Marchin 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,an institution registered under laws of Indiaand located at **Kankanady, Mangalore - 575 002, Karnataka, India**(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 Department of Dermatology, Venereology and Leprosy, Father Muller Medical College,Kankanady, Mangalore - 575 002,Karnataka, Indiawill 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**") attached hereto as Annexure 2; and

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

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

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

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; and

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

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 SITEagrees 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**").

3.2 The Study will besupervised 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 SITEshall instruct each Sub-investigator and team member to follow the direction of the SITEand 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. Institutionfurther 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. SITEfurther 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 andin 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. SITEshall 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

a) 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;

b) 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.

c) 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

SITEwill 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.

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

e) the Fees include all performance requirements of this Agreement; and

f) 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

a) 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 Purchase Order provided by SPONSOR.

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

c) SPONSOR will pay the Fees within45days of thereceipt of a correct and valid invoice or as per the milestones set in the agreement, subject to the satisfactory completion of associated Deliverables.

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

e) 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 SITEto 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 Itprepares, 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 SITEfor 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 SITEmaintains 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 SITEprepares 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 SITEretains 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 SITEfacilities 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 SITEhereby 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-center 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.

6.4Notwithstanding 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 SITEincluding 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 orderprior 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 SITEends 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 SITErelating 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 SITEexcept insofar as necessary to permit SITEto conduct the Study which is the subject of this Agreement. SPONSOR and SITEacknowledge 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 aregulatory 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**"), SITEshall 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 SITEterminate and SITEthereafter 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 individuallygrants 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 SITEmay, 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.

9.1.1. 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 Institutionfor 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 SITEand/or SITEstaff; (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 SITEany 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 SITEfor 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 SPONSORor SITE immediately upon written notice without any further action or notice by either Parties, in the event (a) SITEceases operations, is insolvent or unable to pay its debts when they become due; (b) of negligence or wilful misconduct by SITEor 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 SITEharmless 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**. Institutionshall be liablefor, and agrees to indemnify and hold the SPONSOR harmless from and against, any and all Losses caused by or attributable toSITE'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. Institutionshall maintain such coverage for the duration of this Agreement and if the policy is claims-made, for two (2) years thereafter.Institutionwill 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. SITEis 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 . Patrick Rodrigues

Director- Father Muller Charitable Institutions

Address: Father Muller Medical College Hospital,

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

Telephone: 0824-2238000

Attention: 0824-2238261

To PRINCIPAL INVESTIGATOR at:

Dr. Jacintha Martis

Address:Department of Dermatology, Venereology and Leprosy, Father Muller Medical College Hospital, Kankanady, Mangalore - 575 002, Karnataka, India

Telephone: 9845148112

To SPONSOR at:

Global Clinical Management

Dr. Reddy's Laboratories Limited,

Integrated Product Development ,

Bachupally, Quthubullapur Mandal

Survey No: 42, 45 and 46,

Hyderabad,

R R District– 500 090

Telangana, India

Telephone:+91 40 4879 6019

Attention:

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.

AGREED FOR AND ON BEHALF OF:

DR. REDDY'S LABORATORIES LIMITED,

Name: _____

Title: _____

Signature: _____

Date: _____

THEINSTITUTION,

Name: Rev. Fr. Patrick Rodrigues

Title: Director, Father Muller Charitable Institutions

Signature: _____

Date: _____

PRINCIPAL INVESTIGATOR,

Name: Dr. Jacintha Martis

Title: Professor, Department of Dermatology, Venereology and Leprosy

Father Muller Medical College Hospital

Signature: _____

Date: _____

ANNEXURE –1
STUDY

1. Title

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 Objective:

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%).

Secondary Objective:

To evaluate the efficacy, safety and local tolerability of Benzoyl peroxide (2.5%/5%), Zinc oxide and Polysiloxanes combination in comparison to Benzoyl Peroxide (2.5%/5%) in the treatment of moderate acne vulgaris.

Study Name:Acne-Benzoyl peroxide (2.5%/5%), Zinc oxide and Polysiloxanes

Study Site:List will be annexed

Protocol Number:DRL-INDG04-BPO/2016

Responsible Ethics Committee:List will be annexed

3. Study Fees

Annexure II

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 Consultation Charges	Rs. 2000 per patient	20	6 Visits	2,40,000
2	Research Assistant Charges**	Rs.12000 per month	-	6 months	72,000
3	Patient Conveyance	Rs.500 per patient	20	6 visits	60,000
4	Screening failures charges (assuming screening failures rate 5 patients) Consultation charges	Rs. 2000	05	-	10,000
5	Patient conveyance for screening failure patients	Rs.500 per patient	05	-	2,500
6	Fax, Telephone, Stationery, Courier etc.(Rs 1000 per month for 6 months)				6000
7	Institutional Overheads charges, if any				
	Total Cost of the Project for the 20* completed Patients**				3,90,500

2. Payment Schedule:

The agreed payment schedule is as follows.

Instalment	Milestone of Payment
1st	20% of estimated total as Advance payment
2nd	20% of estimated total after 5 patients are enrolled.
3rd	30% 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 and Patient Conveyance 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, they shall be 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, 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 Institutions branch, Mangalore
4. Bank Account No.: **02392160000136**
5. Statutory Details:

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

ANNEXURE - 2

PROTOCOL

MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (herein after referred to as "MOU") is made and executed on this date **December 1, 2017** at Mangalore

BY AND BETWEEN

Father Muller Medical College Hospital, Mangalore (a unit of Father Muller Charitable Institutions) situated at Father Muller Road, Kankanady, Mangalore – 575002 represented by Rev Fr. Rudolph Ravi D'sa, Administrator (hereinafter referred to as "FMMCH") which term unless repugnant to the context thereof, shall mean and include its successors-in-interest and permitted assigns, of the FIRST PART

AND

Metropolis Health care ltd. having its office at A J Hospital and Research Center Kuntikana, Mangalore, D.K- 575008 duly represented by Dr. Krishna Prasad HV, Chief of Lab Services and Consultant Pathologist (Hereinafter referred to as "METROPOLIS") which term unless repugnant to the context shall mean and include its successors and permitted assigns) of the SECOND PART

"FMMCH" and "METROPOLIS" are individually and collectively referred to as "Party" and "Parties" respectively.

WHEREAS

1. Father Muller Medical College Hospital Laboratory, a division of Father Muller Medical College Hospital is a clinical laboratory delivering specialized testing facilities in the field of Biochemistry, Hematology, Histopathology and Microbiology.
2. FMMCH offers Inter Laboratory Quality Control specialized pathological diagnostic services on a per-request basis from similar health care facilities.
3. KSHEMA owns and operates a hospital, requires services of the type offered by FMMCH.
4. KSHEMA desires to obtain services from FMMCH and FMMCH is willing to provide such services to METROPOLIS, in accordance with the terms and conditions set forth within.

Wherefore, it is agreed between the Parties as under:

1. Term

1.1 This agreement shall be a valid for a period of two years from the date of execution of this agreement. This agreement shall come into effect from December 1, 2017. However either party will renew this agreement for further period of one year with mutual consent.

2. Objective

2.1 The objective of this MOU is to establish a written document framing a basic understanding under which both the parties shall be governed for conducting diagnostics and monitoring tests on the samples received by METROPOLIS.

3. Scope of Work

3.1 During the term hereof or the extended term as the case may be FMMCH shall provide the services to METROPOLIS for all the tests requested by METROPOLIS. The list of tests annexed to this agreement as **Annexure 1**.

4. **Role and Responsibilities of Father Muller Medical College Hospital**

4.1 FMMCH shall conduct tests/investigations as per duly filled request form filled by METROPOLIS. The testing and reporting shall be carried out conforming to prevalent high standards of quality.

4.2 FMMCH shall provide reports of tests/ investigations through hard copy by courier.

4.3 FMMCH shall conduct tests/investigations on the basis of samples received from METROPOLIS. The sample received from METROPOLIS shall be tested and reported within two or three working days under normal circumstances. Reporting timeliness will be in accordance with prevalent quality standards.

5. **Roles and Responsibilities of METROPOLIS**

5.1 METROPOLIS shall be responsible for proper packing of samples and transportation in defined condition and temperature. Hospital will not be responsible for packing and transportation.

5.2 METROPOLIS shall be responsible for sending duly filled test requisition form, patient history, samples packing and labeling at required temperature in good condition to FMMCH for test/ investigations.

5.3 METROPOLIS shall make payments to FMMCH for services provided under this MOU within 15 days of receiving the invoices.

5.4 It is the responsibility of METROPOLIS to provide additional details requested by FMMCH to conduct the test/ investigation.

6. **Force Majeure**

6.1 Any delay in reporting the test/ investigation shall be subject to Force Majeure, such as unavailability of test kits, failure of test, incomplete patient / test details, problem sample, need for repeat sample/ testing, instrument or machinery breakdown, civil unrest, riots, change in or in the interpretation of laws, strikes, lockout or other labour problems, unavailability of supply, fire or explosion, act of terrorism and other natural calamities. FMMCH would make efforts to mitigate the impact of such Force Majeure conditions and ensure timely testing as feasible and inform METROPOLIS accordingly.

7. **Consideration:**

7.1 The billing shall be done on monthly basis starting from 1st to 31st of each month and METROPOLIS undertakes to clear all the outstanding payments within 15 days from the date of receiving the invoices.

7.2 Revision of tariff by FMMCH will be intimated to METROPOLIS in writing, upon which the revised rate tariff shall be applicable from the date revision.

8. **Termination and Consequences of Termination**

8.1 Each of the parties makes the following representations and warranties to the other party hereto that the representing party has the full power and unrestricted authority to enter into this MOU. Entering this MOU and performing the obligations hereunder does not conflict with and is not prohibited under the terms of any other agreement, document, law, rule, regulation or court order to which the representing party is subject. Each of the parties has the full power and unrestricted authority to grant the licenses that are granted herein.

9. **Termination and Consequences of Termination**

9.1 This MOU may be terminated on mutual consent or by either party with at least 30 days prior written notice without assigning any reasons.

9.2 All payments due, becoming due and payable to the Parties as on the date of termination, under the terms of this MOU shall continue to be due and payable to the Parties notwithstanding the termination hereof.

10. **Confidentiality:**

10.1 Each Party shall keep secret all Confidential Information, if any, transmitted to it or made available to it by the other Party and shall not pass such Confidential

Information on, wholly or party, to third parties without express written consent of the other Party.

10.2 The Parties shall not disclose the terms of this MOU or make any announcement in respect of the subject matter thereof without prior written consent of the other Party unless the disclosure is required by law or other regulatory authorities. In the event disclosure is required by law, rules or regulations, such disclosure shall be made after obtaining written permission of other party.

10.3 The Confidentiality obligations in this do not apply to disclose information that either Party in writing can prove that:

i. It was known at the time of disclosure to be free of any obligation to keep it confidential, as evidenced by written records.

ii. Became generally publicly known through authorized disclosure.

iii. The information was independently developed without access to or use of any confidential Information, as evidenced by written records, or

iv. The information was rightfully obtained from a third party who had the right to transfer or disclose it without violation of any confidentially obligations.

11. Dispute Resolution and Governing Law

11.1 In case if any difference or dispute arises between the Parties herein, the Parties shall hold mutual discussions to resolve such difference and / or dispute in an amicable manner for the best interests of both Parties. Parties shall try to resolve the difference and / or dispute within 30 days or such extended time as agreed between the Parties. In case, any difference and / or dispute could not be resolved through mutual discussion then such difference and / or dispute between the Parties shall be referred to sole arbitrator appointed by both the parties in accordance with the Arbitration and Conciliation Act, 1996. The venue of the arbitration shall be Mangalore. The award of the arbitration shall be final and binding between the Parties.

12. Limitation of Liability

12.1 To the fullest extent permitted by Applicable Law neither Party nor its affiliates shall be liable for any special, indirect, consequential, or incidental damages (including but not limited to damages for loss of business profits, business interruption, loss of business information, and the like) arising out of this MOU even if either Party has been advised of the possibility of such damages.

13. Miscellaneous:

Relationship: No provision of this MOU shall be deemed to constitute a partnership or joint venture between the Parties.

Further, each Party shall inform its employees that they shall not be treated as employees of the other Party for any purpose whatsoever and that they shall not exercise any rights or seek or be entitled to any benefits accruing to the regular employees of the other Party.

No provision of this MOU shall constitute either Party as the legal representative or agent of the other, nor shall either Party have the right or authority to assume, create or incur any liability or any obligation of any kind, express or implied, against or in the name of or on behalf of the other Party except as provided expressly under this Agreement.

Notices:
Any notice required or permitted to be given hereunder shall be in writing and shall be effectively served.
13.1.1 If delivered personally, upon receipt by the other party;
13.1.2 If sent by prepaid courier service, airmail or registered mail, within seven(7) days of being sent; or

13.1.3 If sent by facsimile or other similar means of electronic communication (with confirmed receipt), upon receipt of transmission notice by the sender.
13.1.4 Any notice required or permitted to be given hereunder shall be addressed as given in the title to this MOU.
13.1.5 Any party hereto may change any particulars of its address for notice, by notice to the other in the manner aforesaid.

Violation of terms:
The Parties agree that each party shall be entitled to an injunction, restraining order, right for recovery, suit for specific performance, or such other equitable relief as a court of competent jurisdiction may deem necessary or appropriate to restrain the other party from permitting any violation or enforce the performance of the covenants, obligations and representations contained in this MOU. These injunctive remedies are cumulative and are in addition to any other rights and remedies the Parties may have at law or in equity, including without limitation, a right for recovery of the amounts due under this Agreement and related costs and a right for damages.

IN WITNESS THEREOF the Parties have through their respectively duly authorized representatives, executed this MOU the day, month and year fist hereinabove written.

Signed and delivered by FMMCH	Signed and delivered by METROPOLIS
Father Muller Medical College Hospital	METROPOLIS HEALTH CARE LTD.
(Sign)	(Sign)
By: Rev Fr. Rudolph Ravi D'sa Title: Administrator	By: Dr. Krishna Prasad HV Title: Chief of Lab Services and Consultant Pathologist
Witness1: (Sign)	Witness1: (Sign)
Name: MRS. LIDIA PAIS	Name: Mr. Danil Pais
Witness 2: (Sign)	Witness2: (Sign)
Name: N. SHIVASHANKARA	Name: Pooja R. Shenoy

FATHER MULLER MEDICAL COLLEGE HOSPITAL KANKANADY MANGALORE 575 002

METROPOLIS HEALTHCARE LTD A.I. HOSPITAL & RESEARCH CENTRE

To:- Ophthalmology Dept

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Certificate No.	:	IN-KA11122819045680P
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Account Reference	:	NONACC (FI)/ kaksfcl08/ KANKANADY/ KA-DK
Unique Doc. Reference	:	SUBIN-KAKAKSFCL0870888458933235P
Purchased by	:	FR MULLER MEDICAL COLLEGE HOSPITAL
Description of Document	:	Article 12 Bond
Description	:	MOU
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	FR MULLER MEDICAL COLLEGE HOSPITAL
Second Party	:	DISTRICT HEALTH AND FAMILY WELFARE SOCIETY
Stamp Duty Paid By	:	FR MULLER MEDICAL COLLEGE HOSPITAL
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

MEMORANDUM OF UNDERSTANDING (MOU) BETWEEN DISTRICT HEALTH AND FAMILY WELFARE SOCIETY (R) (BLINDNESS CONTROL DIVISION) AND PARTICIPATING NON GOVERNMENT ORGANIZATION

1. Preamble :

1.1. WHEREAS the Union Cabinet has approved continuation of National Program for Control of Blindness, hereafter referred to as NPCB, for implementation in all the States of the Country during the 11th Plan (2007-2012);

In-charge Director
Father Muller Charitable Institutions
Kankanady, Mangalore - 575002

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1.2. WHEREAS the Cabinet has also agreed to follow the strategies of "Vision 2020 : The Right to Sight" in NPCB as per Plan of Action developed for the country.

1.3. WHEREAS NPCB aims to reduce prevalence of blindness by implementing various activities through State and District Blindness Control Societies established in all the districts of the country;

1.4. Whereas the NPCB seeks to involve eye care facilities in Government, Non-Government and Private sectors having capacity to perform various activities under National Programme for Control of Blindness;

1.5. AND WHEREAS schemes for Non-Government Organizations (hereafter referred as NGO) providing eye care services are implemented as per pattern of assistance approved by the Cabinet;

1.6. NOW THEREFORE the signatories of Memorandum of Understanding (MOU) have agreed as set out herein below :

2. Parties of MOU :

This MOU is an agreement between District Health and Family Welfare Society (R.) (Blindness Control Division) of Dakshina Kannada of the State of Karnataka; hereafter called District Health and Family Welfare Society (R.) (Blindness Control Division) and Father Muller Charitable Institutions.

3. Duration of MOU :

This MOU will be operative from the date of its signing by the parties and remain in force till **31st March 2018**. MOU can be renewed through mutual agreement by the parties.

4. Commitments of NGO :

Through this MOU the NGO agrees to provide following services under National Programme for Control of Blindness :

Sl.No.	Activities	Yes / No
a)	Screening of population in all the villages / townships in the area allotted to the NGO and preparation of village wise blind registers.	Yes
b)	Identification of cases fit for cataract surgery, motivation thereof and transportation to the base hospital	Yes
c)	Pre-operative examination and investigation as required	Yes
d)	Performance of cataract surgery preferably IOL implantation through ECCE / IOL, Small Incision Cataract Surgery (SICS) or Phaco-emulsification of patients identified in allotted areas, self motivated walk-in cases and those referred by DH &FWS (BCD)	Yes

e)	Post-operative care including management of complications, if any and post-operative counseling regarding use of glasses;	Yes
f)	Follow-up services including refraction and provision of glasses, if required providing best possible correction.	Yes
g)	Submission of cataract surgery records of operated cases.	Yes
h)	Eye operation for poor and deserving patients other than cataract surgery	Yes

5. Commitments of District Health and Family Welfare Society (Blindness Control Division) :

Through this MOU, the DH & FWS (BCD) agrees to provide following support to participating NGO to facilitate service delivery :

Clause	Clause of Agreement	Yes / No
5.1	Issue Certificate of Recognition about participation in NPCB	
5.2	Undertake random verification of operated cases not exceeding 5% before discharge of patients;	
5.3	Sanction cost of free cataract operations performed by the NGO as per GOI guidelines indicated in para 6 below within one month of submission of claim along with Cataract Surgery Records;	
5.4	Make payment of the sanctioned amount to the NGO on monthly/quarterly basis;	
5.5	Regularly disseminate literature, guidelines or any other relevant information to participating NGO)	

6. Grant-in-aid to NGO for this scheme is governed by the following table :

(Rupees per operation)

	Items	ECCE/IOL	SICS/PHACO
a.	Drugs and consumables	250	250
b.	Sutures	100	0
c.	Spectacles	125	125
d.	Transport/POL	150	150
e.	Organization & Publicity	125	125
f.	IOL, Viscoelastics & additional Consumables	250	350
	Total	**1000**	**1000**

In-charge Director
Father Muller Charitable Institutions
Kankanady, Mangalore - 575002

7. Grant-in-aid to NGO for the Scheme other than Cataract Surgery :

1.	Diabetic Retinopathy	Rs.1,500.00
2.	Glaucoma	Rs.1,500.00
3..	Keratoplasty	Rs.5,000.00
4.	Squint	Rs.1,500.00
5.	Retinopalty of Prematurity	Rs.5,000.00
6.	Retinoblastoma	Rs.1,000.00
7.	Congenital Ptosis	Rs.1,000.00
8.	Intraocular Trauma in children	Rs.1,000.00
9.	Low vision	Rs. 500.00

8. Termination of MOU :

Commitments agreed to by the Parties are meant for prevention and control of blindness and therefore MOU should generally not be suspended or terminated. However, both parties can decide to suspend or terminate the MOU.

Signed this day, the **1st of April 2017.**

Dist. Programme Manager
DIST. BLINDNESS CONTROL SOCIETY
Dakshina Kannada District
Mangalore

.....

For and on behalf of
District Health and Family Welfare Society (BCD)

.....

For and on behalf of NGO

In-charge Director
Father Muller Charitable Institutions
Kankanady, Mangalore-575002

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Unique Doc. Reference	:	SUBIN-KAKAKSFCL0830682254680676P
Purchased by	:	DIRECTOR FMCI
Description of Document	:	Article 12 Bond
Description	:	MOU
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	DIRECTOR FMCI
Second Party	:	MEDICAL OFFICER PHC PADIL
Stamp Duty Paid By	:	DIRECTOR FMCI
Stamp Duty Amount(Rs.)	:	20 (Twenty only)

Please write or type below this line

MEMORANDUM OF UNDERSTANDING

This memorandum of understanding is made on ..... **between :**
Father Muller Charitable Institutions, Fr Muller Road, Kankanady, Mangalore 575 002

and

The Medical Officer, Urban PHC, Padil, Mangaluru, Dakshina Kannada District.

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

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Unique Doc. Reference	:	SUBIN-KAKAKSFCL0839523518608858P
Purchased by	:	T PANNEERSELVAM
Description of Document	:	Article 4 Affidavit
Description	:	AFFIDAVIT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	T PANNEERSELVAM
Second Party	:	NA
Stamp Duty Paid By	:	T PANNEERSELVAM
Stamp Duty Amount(Rs.)	:	20 (Twenty only)

For Pranava Souharda Sahakari Ltd.

Authorised Signatories

Please write or type below this line

MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (MOU) sets for the terms and understanding between the Father Muller Medical College Hospital,. Father Muller Road, Kankanady, Mangalore-575 002, Karnataka (Party one) and the Chairman/ Principal/ Dean/ Medical Superintendent/ Medical Director/ CEO Karavali College of Pharmacy, Vamanjoor, Mangalore-575 028, Karnataka affiliated by AICTE, PCI, RGUHS and Govt (Party two) to Research Collaboration.

8/12/17

Background

Institutional Links provides additional impact for the development of research and innovation collaborations

Purpose

This MOU will reason to execute

1. **Joint Research in Discipline of Mutual Interest**
   Biological Screening of Novel Drugs
2. **Propose of research projects to various funding bodies**

Duration

- ✓ This MOU is at-will and may be modified by mutual consent of authorized officials from Father Muller Medical College Hospital and Karavali College of Pharmacy
- ✓ This MOU shall become effective upon signature by the authorized officials from the Father Muller Medical College Hospital and Karavali College of Pharmacy to achieve the beneficial objectives of research goal.
- ✓ The mutual agreement by the authorized officials from Father Muller Medical College Hospital and Karavali College of Pharmacy is to be effect at least for ten years of its endorsement by both the parties.

8/12/17

PRINCIPAL
KARAVALI COLLEGE OF PHARMACY
Vamanjoor, Mangalore

REV. FR RICHARD ALOYSIUS COELHO
Director
Father Muller Charitable Institutions
Fr Muller Road, Kankanady
MANGALORE-575002

KARAVALI COLLEGE OF PHARMACY * MANGALORE

Contact Information

Partner name: **Father Muller Medical College Hospital**

Partner representative: **Rev.Fr. Richard Coelho**

Position: **Director**

Address: Father Muller Road, Kankanady, Mangalore-575 002, Karnataka

12. 12. 2017 Date:

(Party one)

Father Muller Medical College Hospital

Partner name: **Karavali College of Pharmacy**

Partner representative: **Dr. V.B. Narayanasamy**

Position: **Principal**

Address: Vamanjoor, Mangalore-575 028, Karnataka

8/12/17 Date:

(Party two)

Karavali College of Pharmacy

PRINCIPAL
KARAVALI COLLEGE OF PHARMACY
Vamanjoor, Mangalore

KARAVALI COLLEGE OF PHARMACY * MANGALORE

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Certificate No.	:	IN-KA86603105003581Q
Certificate Issued Date	:	03-Feb-2018 11:43 AM
Account Reference	:	NONACC (FI)/ kaksfcl08/ KANKANADY/ KA-DK
Unique Doc. Reference	:	SUBIN-KAKAKSFCL08232203290091360
Purchased by	:	DIRECTOR FMCI
Description of Document	:	Article 12 Bond
Description	:	MOU
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	DIRECTOR FMCI
Second Party	:	ST JOSEPH INDUSTRIAL TRAINING CENTER
Stamp Duty Paid By	:	DIRECTOR FMCI
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Informed from Directors office - on 19/1 - with Fr. Andrew

----------Please write or type below this line----------

MEMORANDUM OF UNDERSTANDING

File

This memorandum of understanding is made between Father Muller Charitable Institution, (hereinafter referred to as "FMCI") Kankanady, Mangaluru- 575002 represented by its Director the present incumbent Rev Fr. Richard Aloysius Coelho, (term shall mean and include its successors and permitted assigns).

REV. FR RICHARD ALOYSIUS COELHO
Director
Father Muller Charitable Institutions
Kankanady

..2..

Correspondent
St Joseph's Industrial Training Institute
P.O. Box No. 502, Fr Muller Road
Jeppu, Mangaluru - 575 002

And

St. Joseph's Industrial Training Centre, (hereinafter referred to as SJITC) P.B. #502, Jeppu, Mangalore-575002 an educational Institution having its main/ administrative office at Jeppu, Mangalore and established/promoted by St. Joseph's Engineering Educational Trust, having its registered office St. Jeppu, Mangalore-575002 and represented by the Correspondent, the present incumbent Rev Fr. Andrew D'Costa (term shall mean and include its successors and permitted assigns).

WHERAS

FMCI is a charitable institution having various educational institutions as well as a Medical College Hospital. The Hospital has a Bio-medical Department which has Bio-medical Engineer and qualified staff for the procurement, installation and maintenance of all Bio-medical equipments related to the various clinical and non-clinical departments of the hospital dealing with patient care.

SJITC is an educational institution which among other things trains students in Medical Electronics and is looking for a Hospital which can provide hands-on experience/ internship or special training on Medical equipments in the Bio-medical Department.

SJITC having approached FMCI with a proposal to seek the training facilities at the Bio-medical Department of the FMCI and FMCI having agreed to provide the facilities to the students of SJITC on the terms and conditions mutually agreed as follows:-

I. PURPOSE OF AGREEMENT

1. The Purpose of this MOU/agreement is to develop academic and educational cooperation by establishing a collaborative program in training the students of Medical Electronics of SJITC and also to provide the students necessary practical knowledge of various Bio-medical equipments/ instruments by FMCI.

2. To collaborate, share information and technology to students of SJITC in order to develop the required skills and thereby create a centre of excellence to support this collaborative effort.

3. To support SJITC, in following activities:-
   - Assistance in the Laboratory /infrastructure Development of SJITC
   - Capability development of the students and trainers
   - To extend training assistance in Sponsored projects as and when possible
   - Recruiting passed out student in case of vacancies
   - Assisting students in their Publication.
   - To extend support of Product and Patent related matters.
   - Assisting in whatever possible way to conduct Workshops, Conclave, seminars, Events

II. IMPLEMENTATION

Training by way of Internship programme shall be given by FMCI in-house only with prior written permission and as per the schedule mutually agreed upon by both parties. Training shall include observational visits, hands-on experience wherever possible. During the training period of students, FMCI will provide equipments, support tools relating to Medical Electronics wherever possible. Training/Internship fees will be charged by FMCI per student after discussion with SJITC. The fees will have to be remitted within the time frame mutually agreed upon. Fees once paid will not be refunded.

FMCI shall provide staff from Bio-medical Department to SJITC if required to take classes at a specified timeframe. Remuneration for the same will have to be paid by SJITC as mutually agreed upon in writing.

Correspondent
St Joseph's Industrial Training Institute
P.O. Box No. 502, Fr Muller Road

III. DURATION AND RENEWAL OF AGREEMENT

This Memorandum of understanding will become effective from 1st February 2018 for a period of one year. It shall remain in force for a period of two years initially. The Parties may renew the MOU upon the terms to be decided mutually.

IV. AMENDMENTS

1. This Memorandum of Understanding may be amended by a written agreement signed by the representatives of both Institutions.
2. In the event of any unforeseen incident during collaborative activities in either institution both agree to negotiate a mutually acceptable solution.
3. Should any disagreement arise out of the application, interpretation or implementation of this agreement, the institutions shall endeavor to exercise best efforts to negotiate their differences.

V. INTELLECTUAL PROPERTY, CONFIDENTIALITY AND NON-DISCLOSURE

1. SJITC accept and agree that all tangible and intangible information obtained or disclosed to its staff or students including all details, documents, patient information and particulars and trade secrets (all of which are hereinafter referred to as confidential and / or proprietary information) or in the course of performance of Internship/training information received shall be treated as absolutely confidential and the staff/students of SJITC shall ensure that the same as secret/confidential and shall not disclose the same, at all in whole or in part to any person at any time or use such information for study purpose without prior permission of FMCI.

2. SJITC hereby unconditionally agree and undertake to ensure that they or their staff / employees shall not disclose or publish information/documentation or any information relating to FMCI or its business which they may come across in the normal course of performing their study/internship at FMCI.

VI. TERMINATION OF AGREEMENT

This agreement may at any time during its period of validity, be terminated by either party upon prior notice to the other in writing not lesser than ..02..... months before termination date, provided that such termination shall not affect the completion of any program or activity underway at the time the notice of termination is given.

Father Muller Charitable Institution

by _____

(Signature)

Name: REV. FR RICHARD ALOYSIUS COELHO

Title: Director

Date: _____

St Joseph ITI

by _____

(Signature)

Name: _____

Title: Correspondent
St Joseph's Industrial Training Institute
P.O. Box No. 592, Fr Muller Road
Jeppu, Mangaluru - 575 002

Date: _____

Witness:-

1. Jyothi Pinto
HR Manager
FMCI
Kankanady
Mangalore - 2

2. BLANY LOBO
OFFICE SUPDT.
ST JOSEPH'S ARY INDL INST
JEPPU, MANGALORE - 2

MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (hereinafter referred to as "MOU") is made and executed on this date 27th June 2018 at Mangaluru.

BY AND BETWEEN

St. Joseph Engineering College (hereinafter referred to as "SJEC") represented by Rev Fr Wilfred Prakash D'Souza, Director, St Joseph Engineering College, Vamanjoor, Mangaluru, which term unless repugnant to the context thereof, shall mean and include its successors-in-interest and permitted assigns, of the FIRST PART.

AND

Father Muller Medical College, Fr Muller Road, Kankanady, Mangaluru – 575002 (hereinafter referred to as "FMMC") duly represented by Rev Fr Richard Aloysius Coelho, Director, Father Muller Charitable Institutions, which term unless repugnant to the context shall mean and include its successors and permitted assigns) of the SECOND PART.

"SJEC" and "FMMC" are individually and collectively referred to as "Party" and "Parties" respectively.

WHEREAS

1. Term :

This agreement shall be a valid for a period of Five years from the date of execution of this agreement. This agreement shall come into effect from **1st July 2018**. However either party will renew this agreement for further period of five years with mutual consent.

2. Objective

The objective of this MOU is to establish a written document framing a basic understanding under which both the parties shall be governed for chemical management policies and procedures

3. Scope of Work

During the term hereof or the extended term as the case may be SJEC shall provide the services to FMMC for chemical management.

4. Role and Responsibilities of SJEC

1) The SJEC shall provide guidance and training to the staff of FMMCH for chemical management. The training will comprise of categorization and storage of chemicals, disposal of chemicals and chemical spill management.
2) The faculty from Chemistry Department of SJEC will visit FMMCH as and when requested, and as per the schedule mutually decided by both the parties.

5. Roles and Responsibilities of FMMC

1) Shall provide the necessary infrastructure and manpower support for the training and visits of faculty from SJEC
2) Honorarium for the visits of faculty from SJEC will be provided by FMMC as per the commitment. The honorarium is fixed at Rs.2,000/visit/faculty.

Signed on Behalf of SJEC

Name : **Rev Fr Wilfred Prakash D'Souza**

Designation : **Director**
St Joseph Engineering College,
Vamanjoor, Mangaluru

Date : 27-06-2018

Signed on Behalf of FMMC

Name : **Rev Fr Richard Aloysius Coelho**

Designation : **Director,**
Father Muller Charitable Institutions,
Fr Muller Road, Mangaluru

Date : 27-06-2018

GOVT. OF KARNATAKA
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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**

ગુજરાત गुजरात GUJARAT

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નંબર
તારીખ : 28 FEB 2018 રૂા.
માટે ૨૦૧૮
નામ : Cliantha Research Limited
Opp. Pushparaj Towers,
Nr. Judges Bunglows,
ઠેકાણું : Bodakdev, Ahmedabad-380054.
Ph.: +91 - 79 - 26853088-92
કે. [illegible] Fax: +91 - 79 - 26853093
લા. નં. એસ.બી. ૪૨૮, ૪૨૯/૧૯૯૯
એ-૪, સોના કુટિર, નેમનગર, અમદાવાદ ના સાટેનો
કેનારની સહી.....

CLINICAL TRIAL AGREEMENT

PROTOCOL CRL111735

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

CLIANTHA RESEARCH LIMITED, a part of Cliantha Group, a company incorporated under the Companies Act, 1956 having its Registered Office at Commerce House II, Opp. Pushpraj Towers, Near Judges Bungalows, Bodakdev, Ahmedabad-380 054, India (hereinafter referred to as **"CRO"** which expression, unless repugnant to the context or meaning thereof shall mean and include its affiliates, employees, assignees, subsidiaries, nominees, agents and successors-in-interest)

AND

Dr. Ramesh Bhat M. whose principal place of business is **Father Muller Medical College & Hospital, Father Muller Road , Kankanady , Mangalore 575002, Karnataka, India**

(hereinafter referred to as the **"Principal Investigator"** which expression, unless repugnant to the subject or context therein, shall mean and include his legal heirs, administrators, executors and assigns)

AND

Father Muller Charitable Institutions, Father Muller Road , Kankanady , Mangalore 575002, Karnataka, India (hereinafter referred to as the **"Institute"** which expression, unless repugnant to the subject or context therein, shall mean and include its authorized representative(s), administrators, executors, assigns & successors-in-interest)

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

Whereas, **Morningside Healthcare Ltd,** Morningside House, Unit C, Harcourt Way, Meridian Business Park, Leicester, LE19 1WP, UK, Tel# +44116045950

(Hereinafter referred to as the **"Sponsor"**) through its Agent CRO desires the Institution to study Drug Address

and the Institution is willing to perform a clinical study of the Study Drug (defined herein below); and

WHEREAS, the Study (defined below) is of mutual interest and benefit to the Sponsor, CRO, Institution and Principal Investigator and will further the investigational and research objectives of the Institution and Principal Investigator;

WHEREAS, the Principal Investigator and the Institution have the **qualified personnel and the facilities** equipped according to Good Clinical Practices (GCP) to undertake the Study (defined herein below);

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

1. THE STUDY AND THE PROTOCOL

The study of Clindamycin Phosphate 10 mg/g + Benzoyl Peroxide 50 mg/g Gel (Morningside Healthcare Ltd, UK) **(the "Study Drug") shall be conducted, under the direction of the Principal Investigator, in the treatment of patients ("Subjects") in accordance with this Agreement and the protocol identified as Protocol ID No. CRL111735 and entitled** "A Randomised, Double-blind, Multicentre, Parallel-group, Active & Placebo Controlled, Three Arm Clinical Study to Compare the Efficacy and Safety of Clindamycin Phosphate 10 mg/g + Benzoyl Peroxide 50 mg/g Gel (Morningside Healthcare Ltd, UK) versus DUAC® Once Daily 10 mg/g + 50 mg/g Gel (GlaxoSmithKline UK Limited) in Subjects with Acne Vulgaris." A copy of which is attached hereto as Exhibit A (the **"Protocol"**), including any subsequent duly authorized amendments, and which is hereby incorporated by reference (the **"Study"**). The Study will be monitored on behalf of the Sponsor by the CRO.

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

2. **THE STUDY SCHEDULE**

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

B. **Enrollment.** Principal Investigator will enroll atleast 40 to 50 (as per the randomization schedule) and **not more than 100 Subjects** (as per the randomization schedule) (the "Site Maximum") for the duration of enrollment. The Principal Investigator shall commence enrollment of the Subjects once all the contractual and regulatory obligations have been met. Enrollment of, and payment for, each Subject over the Site Maximum shall require prior written consent of the Sponsor. Notwithstanding the foregoing, the Institution immediately shall cease enrolling the Subjects upon receipt of notice from the Sponsor, or the Sponsor's designee, that, in the sole determination of the Sponsor:

i. the Complete Study enrollment has been achieved; or

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

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

C. **Study Documentation.** Case Report Forms ("CRFs") must be satisfactorily completed maximum within **three (3) days** of each Subject visit. If any tests are to be performed after the Subject visit, CRF shall be completed maximum within **three (3) days** of receipt of test results for each Subject, provided, however, that with respect to the last Subject enrolled at the Site, CRF for such Subject must be completed within **three (3) days** of such Subject's last visit to the Site. The Principal Investigator shall ensure the accuracy, completeness, legibility and timeliness of the data reported to the Sponsor in the CRFs and in all required reports. Safety data (Serious Adverse Event Report Forms) will be faxed / mailed to Sponsor and CRO within **twenty four (24) hours** of (i) the Subjects visit and (ii) receipt of the test results at, or from which, such event was reported, noted or recognized. Data Clarification Forms Queries ("DCFs") must be resolved within **two (2) days** of its receipt.

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

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

3. **PAYMENT**

A. **Budget and Payment Schedule:** CRO shall on behalf of the Sponsor reimburse the Institution all direct and indirect costs incurred by the Institution in accordance with the Budget and Payment Schedule, attached hereto as Exhibit B and incorporated herein by reference (the "**Budget and Payment Schedule**"). Payment shall be made by

cheque payable to **Payee Name: Father Muller Research Centre (PAN No: AAATFO345D)**. Payment shall be made within thirty (30) days after CRO has received invoice from the Principal Investigator. In addition, CRO shall reimburse directly the IEC / IRB for all costs associated with the Study.

B. **Payment of Costs Outside Budget and Payment Schedule.** Payment for any costs not specifically described in the Budget and Payment Schedule must be approved in advance in writing by the CRO's Project Manager.

C. **Payment Terms.** CRO shall have no obligation to make payments for any subject who is not qualified to participate in the protocol based on the inclusion and exclusion criteria described in the protocol. Queries pertaining to a subject's eligibility shall be addressed to and resolved by the sponsor's clinical and/or medical monitor identified in the protocol prior to entry of any such subject into the study.

The foregoing notwithstanding:

Upon submission of such documentation as may be requested, to the extent not already paid by CRO, CRO will pay the actual cost of completed visits in accordance with the Budget and Payment Schedule for the Subjects who are dropped from the Study or withdraw from the Study; provided, however, such costs were incurred at a time when, in the good faith judgment of CRO, none of the Institution, its employees or agents, or the Principal Investigator knew or could have reasonably determined that such Subject was not or would not be an Eligible and Evaluable Subject. **"Eligible and Evaluable Subjects"** are defined as Subjects who have satisfied all the Protocol requirements, including compliance with dosing regimen and visit schedule, and are eligible to be included in the statistical analysis for the Study; and Institution and Principal Investigator agree that all payments made under this Section are made solely for the performance of activities relating to the Study and for no other purpose.

D. **Payment Recipient and Mailing Address.** All cheques/online transfer shall be made payable to the entity / person mentioned in the Clause 3A.

The mailing address for checks shall be:

Address:
Dr. Ramesh Bhat M.
Department of Dermatology Venereology and Leprosy,
Father Muller Medical College & Hospital,
Father Muller Road , Kankanady ,
Mangalore 575002, Karnataka, India

The further details for the payments should be provided as

Cheque in the favor of	**Father Muller Research Centre** payable **at Mangalore**
PAN Number	**AAATF0345D**
Name of Bank	**Syndicate Bank**
Branch	**Father Muller Charitable Institution Branch, Mangalore**
Account No.	**02392160000136**
Branch Code	**0239**
IFSC Code	**SYNB0000239**

E. **Reimbursement.** Upon completion of the Study or earlier termination of this Agreement as provided herein, the Institution shall reimburse the CRO for any amounts that were paid by the CRO to the Institution which exceed the amounts to which the Principal Investigator was entitled for completed Subject visits under the Budget and Payment Schedule of this Agreement.

F. **Payments for Screen Failure:** Sponsor will pay only **INR 1000 only per Subject for screen failure**. The maximum ratio for screen failure Subjects shall be **5:1** i.e. maximum one screen failure per **Five** randomized Subjects. Subject discontinued/withdrawn after screening will be considered as screen failure and payment for screen failure will be provided as per above mentioned statement.

G. **Payment for Study Coordinator:** PI will make sure payment to study coordinator / involved study team to ensure that the Quality and deliverables of the Project are not affected at any phase of the study.

4. OBLIGATIONS OF THE INSTITUTION AND THE PRINCIPAL INVESTIGATOR

A. **IEC/IRB Approval.** The Principal Investigator shall be responsible, with the cooperation of the Institution and Sponsor, for obtaining approval from the IEC / IRB of the Protocol and the Subject's Informed Consent Form. The Principal Investigator shall provide the Sponsor or Sponsor's designee with written confirmation of the IEC / IRB's approval prior to the treatment of Subjects. If the IEC/IRB withdraws approval of the Study, at any time, the Principal Investigator shall be immediately notify the Sponsor and/or CRO, providing a written explanation of the circumstances leading to such withdrawal of approval, and the Principal Investigator shall cease the treatment of all Subjects under the Study.

B. **Performance of the Study.** The Principal Investigator shall conduct the Study solely at the Institution. Principal Investigator will personally conduct or supervise the investigation of the Study. Principal Investigator will ensure that all persons assisting in the performance of the Study are informed of their obligations with regard to the Study. Principal Investigator agrees to report promptly, in writing, any non-compliance

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

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

D. **Sponsor Visits.** The Sponsor's representatives may conduct periodic visits, at mutually acceptable times during normal business hours, to: (i) inspect and examine the Institution's facilities at which the Study is being conducted or was conducted; (ii) review the progress of the Study (including without limitation all source documents and data, and correspondence involving the IEC/IRB and applicable regulatory agencies); (iii) inspect and copy, at Sponsor's expense, any or all written and electronic data and work product relating to the Study; and (iv) collect financial billing and economic outcomes (including expense reports) provided that collection of such information is clearly described in the Informed Consent Form and appropriately authorized by the Subject and the IEC/IRB. The Principal Investigator and the Institution shall cooperate with the Sponsor and use reasonable efforts to promptly provide all of the information requested by the Sponsor.

The Institution and the Principal Investigator shall also cooperate with the Sponsor and with any regulatory agencies in the event of announced or unannounced monitoring, audit or inspection by such regulatory agencies. The Institution and the Principal Investigator shall notify the Sponsor by telephone of the intended or possible inspection within **twenty four (24) hours** of becoming aware of it; in addition, notice of the intended or possible inspection shall be sent to Sponsor within **forty eight (48) hours** of the telephonic notification. If a written response is required, the Institution and Principal Investigator shall permit representatives of the Sponsor to review and comment on such response prior to its being sent to the regulatory agencies. The Institution and Principal Investigator shall provide Sponsor with a copy of any report

received in connection with, or as a result of such inspection within **three (3) days** of its receipt.

E. Supplies.

a. The Sponsor or Sponsor's designee shall supply to the Principal Investigator, at no charge, sufficient quantity of the Study Drug to conduct the Study, as well as the materials, equipment and information which the Protocol specifies. The Principal Investigator acknowledges that the Study Drug is experimental in nature, and therefore shall use prudence and reasonable care in the use, handling, storage, transportation, disposition and containment of the Study Drug and any of its derivatives. Within **thirty (30) days** following the completion or termination of the Study, all unused Study Drugs, devices and other materials that were furnished to the Institution by or on behalf of Sponsor shall, at Sponsor's expense, be returned to Sponsor, or if Sponsor so directs destroyed in accordance with instructions provided by the Sponsor. The Sponsor shall solely own all rights, title and interest in the Study Drug, including any materials derived therefrom and all intellectual property rights therein. The transfer of physical possession of the Study Drug hereunder, and/or the possession or use of the Study Drug by the Principal Investigator, shall neither constitute nor be construed as a sale, lease, or offer to sell or lease the Study Drug or other transfer of title in or to the Study Drug. Further, the Principal Investigator shall use the Study Drug solely for the conduct of the Study and in accordance with the Protocol unless they obtain the prior written authorization of the Sponsor.

b. Any instruments, materials or other equipment supplied/provided by the CRO to the Principal Investigator shall be used solely for the purpose of conducting the Study and as per the Protocol/ Study requirements/ Study manuals under the Agreement. Also, any damage caused to the equipment supplied/provided by the CRO under the said Agreement or any repairing cost incurred in order to maintain the said equipment or repair the damage done while conducting the Study shall be borne solely by the Principal Investigator and no liability of the same shall be placed upon the CRO.

F. Study Records, Reports, and Data.

i. *Study Records.* The Principal Investigator and the Institution shall, in a timely manner, prepare and maintain complete and accurate Study records as set forth in the Protocol and as may otherwise be required by applicable law, rule, regulation and good clinical practice (**"Study Records"**). The Principal Investigator shall make all Study Records, including, without limitation, source documents, signed Informed Consents, laboratory data, Drug inventory records, available to representatives of the Sponsor at the Sponsor's request. Except as otherwise expressly provided for in the Protocol or elsewhere herein, all Study Records shall be retained by the Principal Investigator for a period of **fifteen (15) years** after the approval of the Study Drug for marketing or the formal discontinuation of the clinical development of the Study Drug or as per instruction given by CRO/ sponsor for the same. Thereafter, prior to the disposal of the Study Records, Principal Investigator (as applicable) shall give

the Sponsor not less than **sixty (60) days** prior express written notice thereof, and if the Sponsor requests in writing, the Principal Investigator shall transfer the Study Records to the Sponsor at Sponsor's expense. Study Records shall in no event be destroyed without Sponsor's prior written permission.

All the source documents pertaining to clinical conduct of the study shall be treated as confidential. All the Study Records shall be the sole and exclusive property of the Sponsor excluding the source data.

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

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

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

v. In case the Principal Investigator is no longer associated with the Institute, Institute Head or authorized designee will be responsible for maintenance and retention of study records.

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

5. CONFIDENTIALITY

A. **Confidential Information.** The term "Confidential Information" shall mean any and all information, data or know-how, trade secrets whether written or oral, technical or non-technical, as well as tangible materials including without limitation (i) financial, accounting, and business information, (ii) information relating to samples, compounds, procedures, Protocol, the Study Drug and all reports, documents, data and other information generated in connection with the Study or other information which the Institution or the Principal Investigator receives, directly or indirectly, from Sponsor and/or CRO and (iii) any other data or information that is generated by the Institution as required by the Protocol and/or this Agreement, including Case Report Forms, laboratory data and Study results, but not including the medical records of the Institution. Subject to the provisions of Clause 5(A)(*i*) through 5(A)(*iv*), the Parties

shall not disclose Confidential Information without prior written authorization from the Disclosing Party for any purpose other than those specified in this Agreement. The obligations of non-disclosure shall not apply to the following:

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

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

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

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

Disclosing Party: The term "Disclosing Party" shall mean the party disclosing Confidential Information to other party.

Receiving Party: The term "Receiving Party" shall mean the party receiving Confidential Information from the other Party.

B. Notwithstanding anything to the contrary in this Agreement, nothing herein shall (i) prevent the Institution from disclosing to the DCGI or any other appropriate regulatory agency Confidential Information (including Study results) that indicates that the administration or use of the Study Drug or device is associated with a serious risk of harm to the Subjects, provided that Institution furnishes at least fourteen (14) days advance written notice to the Sponsor and Sponsor fails during such time to either make the disclosure requested by Institution or to adequately demonstrate to the Institution that it has complied with all applicable disclosure requirements, or (ii) prevent Institution and/or Principal Investigator from informing the Subjects or potential Subjects of any adverse experiences or risks associated with the Study Drug or device.

C. **Non-Disclosure and Non-Use.** Except as otherwise expressly provided herein, for the term of this Agreement, and for a period of five (5) years thereafter, the Parties shall not disclose to any third party Confidential Information and shall not use for any purpose other than as expressly provided for herein any such Confidential Information, without the express written consent of the Disclosing Party. Without limiting the foregoing, the Parties shall disclose Confidential Information only to those employees of the respective Party who require such Confidential Information for the purposes of this Agreement and who are bound by an obligation of confidentiality and non-use no less stringent than set forth herein. Upon disclosing Confidential Information to any employee, the employing Party shall advise them of the confidential nature of the information, and shall require them to take all necessary and reasonable precautions to prevent the unauthorized disclosure thereof. In the event that the Parties are required to disclose Confidential Information pursuant to an order or requirement of a court,

administrative agency, or other governmental body, the Parties, as the case may be, may disclose the Confidential Information provided that the Receiving Party provides the Disclosing Party with reasonable advance notice thereof to enable the Disclosing Party to seek an appropriate protective order or to prevent the disclosure. In such a situation, the Receiving Party shall provide reasonable assistance to the other Party to obtain a protective order or to prevent disclosure.

D. **Medical Confidentiality.** Notwithstanding any of the foregoing, Sponsor shall maintain the confidentiality of all medical records, case history, test reports, fitness data and charts to which it may have access in accordance with all applicable federal, state and local confidentiality laws and regulations and its corresponding regulations issued under DCGI or other applicable regulations. Sponsor shall not use, disclose, maintain, store, or transmit any individually identifiable Subject information except as permitted by such laws

6. **Protection.** Without limiting the foregoing, the Parties shall maintain reasonable procedures to prevent accidental or other loss of any Confidential Information of the Disclosing Party, and shall use at least the same procedures and degree of care which each uses to protect its own confidential information, but in no case less than reasonable care. In the event of loss, disclosure or use of any Confidential Information in violation of this Agreement, the Receiving Party shall immediately notify the Disclosing Party. The Parties shall prevent the disclosure of medical records and private or personal information, whether confidential or not, to the extent required by applicable laws or regulations.

7. **PUBLICATION**

Subject to governing law, the Sponsor shall have the sole right to review, use, publish, and disclose any data, information, or results developed or arising out of the Study as the Sponsor, in its discretion, deems appropriate, including, without limitation, in submissions to the FDA and other governmental agencies. If Principal Investigator wants to publish his part, the prior written approval from Sponsor is required.

8. **OWNERSHIP OF MATERIALS, DATA, INVENTIONS, AND DISCOVERIES**

A. **Materials and Data.** The Sponsor shall solely own all right, title and interest in and to the Study Drug and any and all information, data or other materials delivered to the Institution or the Principal Investigator by or on behalf of the Sponsor as well as any derivatives, progeny, or improvements developed therefrom, and all intellectual property rights therein. Further, all data and work product arising out of or relating to the Study, including, without limitation, the Study Records, CRFs, reports, and specimens, and all intellectual property rights therein, shall be the sole property of the Sponsor. Accordingly, the Sponsor shall have, in its sole discretion, the right to publish, disclose, disseminate, and use, in whole or in part, the same for any and all purposes, including, without limitation, in and for submissions to the FDA or other regulatory agencies.

B. **Patents and Inventions.** All right, title and interest in and to, whether domestic or foreign any inventions or discoveries (collectively, **"Inventions"**) first conceived of and reduced to practice prior to the Effective Date of this Agreement by the Principal Investigator, Institution or CRO as expressed in protocols, lab notebooks, or other

written records, the know-how incidental thereto, and any patent applications and resulting patents derived there from shall be the exclusive property of that Party.

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

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

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

iv. Institution and / or the Principal Investigator shall promptly notify the Sponsor a full written description of any New Inventions or Discoveries described in either Clause 7(B)(*iii*) or 7(B)(*iv*) of which they become aware. Sponsor shall have a time-limited, first option to negotiate an exclusive, worldwide, royalty-bearing license to any Institution Invention. Any such exclusive license shall include a reasonable royalty based on Sponsor's and Institution's respective contributions to Institution Invention and other terms that are typical in licenses of similar technology. Sponsor shall advise Institution in writing of its interest in obtaining an exclusive license to any Institution Invention within sixty (60) days of Sponsor's receipt of notice of Institution Invention. If Sponsor fails to notify the Institution within sixty (60) days or provides notice that it elects not to obtain an exclusive license, then Sponsor's option shall expire with respect to that particular Institution Invention and Institution shall be free to dispose of its interest in accordance with its technology transfer policies. If Sponsor and Institution fail to reach agreement on the terms for an exclusive license of a particular Institution Invention within four (4) months after Sponsor provides notice that it wishes to exercise its option, then for a period of one (1) year thereafter, the Institution shall not offer to license the Institution Invention to any third party on materially better terms than those last offered to the Sponsor without first offering such terms to Sponsor, in which case Sponsor shall have a period of thirty (30) days to accept the offer.

C. **No Other Rights.** Except as expressly set forth herein, none of the Sponsor, the Principal Investigator, or the Institution transfers to any other Party hereto, by

relate to Principal Investigator's activities under this Agreement, the Principal Investigator shall notify the Sponsor immediately and the Sponsor shall have the right to terminate this Agreement immediately without further cost or liability.

B. **Of the Sponsor.** The Sponsor represents and warrants that (i) it has the legal authority and right to enter into this Agreement, (ii) it has no obligation to any other party that is in conflict with the Sponsor's obligations under this Agreement, and (iii) this Agreement has been duly executed and delivered by it and constitutes a valid, binding obligation enforceable against it in accordance with its terms.

Sponsor represents and warrants to Institution and Principal Investigator the following: (i) any Study Drug or device administered or used in carrying out the Protocol has been approved by the DCGI or FDA or by the other regulatory agencies if applicable for investigational use; and (ii) Sponsor has at all times complied with and will continue to comply with all DCGI or FDA and comparable foreign rules, regulations, requirements, and guidelines regarding administration, manufacture, and production of drugs and devices under regulatory control of the DCGI or FDA and/or comparable foreign agencies in connection with any drug or device administered or used pursuant to the Protocol. In particular, Sponsor shall comply with all DCGI or FDA reporting rules that require it to inform Institution and/or Principal Investigator of any serious and unexpected adverse experience associated with the Study Drug or device.

C. **No Other Representations or Warranties.** Except for the limited representations and warranties given in this Clause 8, none of the Sponsor, the Institution, or the Principal Investigator makes or receives any representations or warranties, express or implied, statutory or otherwise, and each expressly disclaims any implied warranties of merchantability, fitness for a particular purpose, or non-infringement.

D. **Of the Institution:** Institution will ensure that the Principal Investigator remits to the Sponsor all clinical data, including without limitation, case record forms, medical reports and the information generated during the performance of the Study. Institution will notify the Sponsor immediately if the Principal Investigator ceases to be employed by or associated with the Institution.

10. GOVERNING LAW

This Agreement shall be governed by and construed in accordance to the Laws of India. Disputes, if any, shall be arbitrated upon under the Arbitration and Conciliation Act, 1996 in English language and the venue shall be Ahmedabad, India. It is expressly agreed that the arbitral award shall be final and binding upon both the Parties hereto. However, the final jurisdiction shall lie with the courts of Ahmedabad, India. Each of the Parties hereby expressly submits to the jurisdiction of the courts of Ahmedabad, India.

11. INDEMNIFICATION

A. **Sponsor Indemnification.** The Sponsor shall defend, indemnify, and hold harmless the Institution and its trustees, officers, the Principal Investigator, employees and agents (the "**Institution Indemnities**") from and against any liability, loss, damage, or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the Institution Indemnities or any one of them in connection with any third party claims, suits, actions, demands, or judgments but only to the extent such

operation of this Agreement or otherwise, rights to any patent, copyright, trademark or other intellectual property right of any kind.

9. REPRESENTATIONS, WARRANTIES AND COVENANTS

A. Of the Principal Investigator. The Principal Investigator represents and warrants that (i) he has the legal authority and right to enter into this Agreement; (ii) he has no obligation to any third party that is in conflict with, or has the potential to conflict with, its obligations under this Agreement; (iii) he has and will maintain throughout the conduct of the Study, all training, information, licenses, approvals and certifications necessary for safely, adequately, and lawfully performing the Study; (iv) he will not enter into any agreement with any third party to directly or indirectly fund or support the Study without the express written consent of the Sponsor (excluding laboratory investigations, radiological investigations or any other requirement to fulfill Protocol criteria), and (v) this Agreement has been duly executed and delivered by it and constitutes a valid, binding obligation enforceable against it in accordance with its terms.

The Principal Investigator represents and warrants that no clinical study or trial in which he was involved was terminated for any reason prior to completion that was due, in whole or in part, to the Principal Investigator's non-compliance with the applicable protocol and/or safety requirements of the study or any applicable local, state or federal law. The Principal Investigator further represents and warrants that he has not received any written notice from the DCGI/FDA or NIH of any violation of any applicable federal law relating to clinical studies that has not been disclosed to the Sponsor and attached to this Agreement as an Exhibit hereto. For the purposes of the prior sentence, "written notice" shall include, but not be limited to, DCGI or FDA lists of Inspectional Observations (FDA Form 483), Notices of Adverse Findings, regulatory letters, warning letters, notices of intent to initiate clinical investigator disqualification proceedings under national regulations or under 21 C.F.R. 312.70 or 21 C.F.R. 812.119 or any similar regulation (**"Notice of Intent to Disqualify**"). The Principal Investigator further represents and warrants that he has never been disqualified from receiving investigational drugs or medical devices by the DCGI or FDA or NIH or any other federal governmental body. In the event that any of the foregoing events in this paragraph occur during the course of this Study, the Principal Investigator shall provide the Sponsor with a full written explanation of the circumstances of such an incident within ten (10) days of the occurrence of such an incident. If the Institution or the Principal Investigator becomes debarred as per the national or local regulations, this Agreement will immediately terminate. If the Principal Investigator receives a notice or threat of action with respect to its debarment or a Notice of Intent to Disqualify, the Sponsor shall have the right to terminate this Agreement immediately without further cost or liability. The Principal Investigator represents and warrants on his own behalf that he has not used, in any capacity, the services of any individual, corporation, partnership, or association which has been debarred, and neither shall use, in any capacity, the services of any individual, corporation, partnership, or association which has been debarred. In the event that the Principal Investigator becomes aware of the debarment or threatened debarment of any individual, corporation, partnership, or association providing services to the Principal Investigator which directly or indirectly

claims, suits, actions, demands or judgments arise from or are caused by the Study Drug and are not covered by insurance or self-insurance as set forth in Clause 11 and provided that the Study is conducted in accordance with (i) this Agreement and the Protocol; (ii) all written instructions provided by the Sponsor concerning the Study; (iii) all applicable federal, state, or local laws, rules, regulations, requirements, and policies; and (iv) the manner required of reasonable and prudent clinical investigators and physicians; and such loss does not arise out of the negligent or reckless conduct or omission or intentional misconduct or malfeasance of any Institution Indemnity, or any other person on the Institution's property or under its control, exclusive of the Sponsor's employees; and the Sponsor is notified within ten (10) working days of any complaint, claim, or injury relating to any loss for which indemnification and/or defense under this Agreement might be sought; and Principal Investigator and the Institution and its directors, officers, and employees fully cooperate with the Sponsor and its legal representatives in the investigation and defense of any claim or suit covered under this Agreement.

B. **Institution Indemnification.** The Institution shall defend, indemnify, and hold harmless the Sponsor and its affiliates and their respective directors, officers, employees, agents, successors, and assigns ("**Sponsor Indemnities**") from and against any and all third party liability, loss, damage, or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the Sponsor Indemnities or any one of them in connection with any third party claims, suits, actions, demands, or judgments to the extent such claims, suits, actions, demands, or judgments arise out of: (i) a failure to conduct the Study in accordance with this Agreement and the Protocol, all written instructions provided by the Sponsor concerning the Study, all applicable federal, state, or local laws, rules, regulations, requirements, and policies, and in the manner required of reasonable and prudent clinical investigators and physicians; and (ii) the negligent or reckless conduct or omission or intentional misconduct or malfeasance of any Institutional Indemnity, or any other person on the Institution's property or under its control, exclusive of the Sponsor's employees.

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

D. **Claims.** The indemnifying Party, at its own expense, shall have the exclusive right to manage claims, control investigation and litigation, and select counsel, including the right to compromise or settle any claims, actions, suits, demands, or judgments, provided that it shall not compromise or settle any such action with an admission of liability or wrongdoing by the indemnified Party without such Party's written consent.

E. **Representation.** In the event a claim or action is or may be asserted, the non-indemnifying Party shall have the right to select and obtain representation by separate legal counsel. If the non-indemnifying Party exercises such right, all costs and expenses incurred by the non-indemnifying Party for such separate counsel shall be fully borne by the non-indemnifying Party; provided, that without the Indemnifying Party's prior written consent, the non-indemnifying Party shall make no admission to,

or any settlement or agreement with, any person or party who is in any manner related to the liabilities for which indemnification may be sought by an non-indemnifying Party Indemnity.

F. **Subject Injury.** Subject shall be entitled to financial compensation as well as reimbursement of reasonable and necessary medical expenses from the Sponsor in case of subject injury or death during clinical trial in accordance with Rule 122DAB of Drugs and Cosmetics Rules, 1945 as may be amended from time to time.

12. INSURANCE

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

B. **Institution Insurance.** Institution and Principal Investigator shall maintain during the term of this Agreement, general liability insurance and professional liability insurance coverage sufficient to meet its indemnification obligations on appropriate conditions and will provide to Sponsor and CRO thirty (30) days prior written notice of cancellation of its coverage.

This Clause 11 shall survive termination of this Agreement.

13. TERM AND TERMINATION

A. **Term.** This Agreement shall begin on the Effective Date and shall remain in full force and effect until the completion of the Study and the submission of the Final Report pursuant to Clause 4(F)(*iv*), above, unless earlier terminated in accordance with this Agreement.

Termination

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

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

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

   c. the circumstances require termination of Study in order to protect the safety, rights, or welfare of Subjects enrolled in the Study. In the alternative, either Party may immediately dis-enroll any Subject to protect that Subject's safety, rights or welfare without terminating this Agreement, but shall promptly give the other Party written notice of the dis-enrollment.

ii. This Agreement may be terminated by either party, upon thirty (30) days prior written notice, if either of the following conditions occurs:

a. if either Party fails to comply with the terms of this Agreement within thirty (30) days of receipt of written notice, with opportunity to cure, from the other Party; or

b. if the Principal Investigator is unwilling or unable (for whatever reason) to act as Principal Investigator and no mutually acceptable replacement has been found in accordance with Clause 4C of this Agreement.

i. This Agreement may be terminated by either Party for any reason other than those listed in Clause 12(B) upon thirty (30) days prior written notice.

ii. Upon the effective date of termination, there shall be an accounting conducted by Institution, subject to verification by Sponsor. Within thirty (30) days after receipt of adequate documentation therefrom, Sponsor will make payment to Institution for.

a. all services properly rendered and monies properly expended by the Institution until the date of termination not yet paid for; and

b. Reasonable non-cancelable obligations properly incurred for the Study by Institution prior to the effective date of termination.

iii. Immediately upon receipt of a notice of termination, the Principal Investigator shall stop enrolling Subjects into the Study and shall cease conducting procedures on Subjects already enrolled in the Study as directed by Sponsor, to the extent medically permissible.

vi. **Immediate Termination by the Sponsor.** The Sponsor may terminate this Agreement, in whole or in part, effective immediately, upon written notice to the Principal Investigator; a) if the Sponsor, in its sole discretion, deems that the safety of the Subjects will be compromised by a delay in termination; or b) for any violation of the Study Schedule set forth in Clause 2) prior to the shipment of the Study Drug to the Institution.

vii. **Effect of Termination.** In the event this Agreement is terminated prior to completion of the Study, for any reason, the Principal Investigator shall a) notify the IRB that the Study has been terminated; b) cease enrolling Subjects in the Study; c) cease treating Subjects under the Protocol as directed by the Sponsor to the extent medically permissible and appropriate, and d) terminate, as soon as practicable, but in no event more than thirty (30) days after the effective date of termination, all other Study activities; provided, however, upon the Sponsor's request, the Institution and the Principal Investigator shall continue to collect data and prepare and complete CRFs for Subjects treated in the Study prior to termination. Within ninety (90) days from the effective date of any such termination, the Institution and the Principal Investigator shall provide to the Sponsor all data collected in connection with the Study, including, without limitation, Study reports and the Final Report described in Clause 4(F), above, and, except as otherwise provided herein, shall return to the Sponsor any and all materials and Confidential Information provided by the Sponsor for the conduct of the Study, at the Sponsor's expense, provided, however, that the Institution may retain one (1) copy of the Confidential

Information for record keeping purposes. The Sponsor shall remain liable for payment for any CRFs submitted prior to the effective date of termination, or within ninety (90) days thereafter, in compliance with the terms of this Agreement.

viii. **Survival.** Termination of this Agreement by either Party shall not affect the rights and obligations of the Parties accrued prior to termination. All provisions in this Agreement which, by their nature, extend beyond termination of the Agreement, together with the provisions of Clauses 4(F), 5, 6, 7, 9, 10, 11,and 12 shall survive any termination of this Agreement for any reason.

14. MISCELLANEOUS

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

B. **Independent Contractors.** The Parties acknowledge that the relationship between the Sponsor, CRO, Institution and Principal Investigator created by this Agreement is that of independent contractors and that neither the Principal Investigator nor Institution or CRO may create or assume any obligation on behalf of the Sponsor.

C. **Limitation of Liability.** In no event shall the Parties be liable to each other for any special, incidental, or consequential damages arising out of or relating to this Agreement, or the subject matter hereof, however caused and whether such claim is based in contract, tort (including negligence), or otherwise, even if an authorized representative of the Sponsor is advised of the possibility of such damages.

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

Any notice to the Sponsor shall be addressed as follows:

Address: **Morningside Healthcare Ltd**
Morningside House
Unit C, Harcourt Way
Meridian Business Park
Leicester, LE19 1WP
UK, Tel# +44116045950

Any notice to Institution shall be addressed as follows:

Address : Father Muller Charitable Institutions
Attn. : Rev .Fr. Richard Aloysius Coelho
Director

Any notice to Principal Investigator shall be addressed as follows:

Address : Deapartment of Dermatology Venereology and Leprosy,
Father Muller Medical College & Hospital,
Father Muller Road , Kankanady ,
Mangalore 575002, Karnataka, India
Attn. : Dr. Ramesh Bhat M.

Any notice to CRO shall be addressed as follows:

Cliantha Research Limited.
Commerce House II, Opp. Pushparaj Towers, Nr. Judges Bungalows,
Bodakdev, Ahmedabad - 380 054, Gujarat, India
Attention : Dr. Dharmesh Domadia,
Associate Vice President - Global Clinical Operations
+91-79-66219 555 (phone)
+91-79-66219 549 (fax)

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

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

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

H. **Severability.** In the event that any provision of this Agreement is determined to be illegal, invalid or unenforceable by a court of competent jurisdiction, the remainder of this Agreement shall remain in full force and effect without said provision. The Parties shall negotiate in good faith a substitute clause for any provision declared illegal,

invalid or unenforceable, which shall most nearly approximate the original intent of the Parties in entering this Agreement.

I. **Execution.** The Institution's IRB shall be the authorized representative of the Institution to approve the Protocol and any amendments thereto. This Agreement may be executed in one or more counterparts, all of which together shall constitute one and the same agreement. This Agreement may be executed by facsimile signature.

J. **Changes to the Protocol.** If at a future date changes in the Protocol appear desirable, such changes may be made through prior written agreement between Sponsor and Institution. If such changes affect the cost of the Study, Institution will submit to Sponsor a written estimate for approval. If in the course of performing this Agreement, however, generally accepted standards of clinical research and medical practice relating to the safety of Subjects require a deviation from the Protocol, such standards will be followed. In such case, the Party aware of the need for a deviation will immediately inform the other of the facts causing such deviation as soon as the facts are known to the Party.

K. **Covenant Not to Hire**. Sponsor shall not, and shall not permit any of its affiliates to, employ or offer to employ any Key Personnel (as defined in this Section) until one year following termination or expiration of this Agreement, unless Institution, or Institution's affiliate, as the case may be, gives its written consent thereto. "Key Personnel" shall mean those individuals employed by Institution, who perform research related services for Institution or any of its affiliates, including, but not limited to, persons serving as research coordinators and grant account managers.

L. **Drug Safety and Reporting.** The recording of adverse events (AEs) is an important aspect of the Study documentation. It is the Principal Investigator's responsibility to document all AEs according to the detailed guidelines of the Protocol. The Principal Investigator agrees to answer any questions of SPONSOR and/or CRO's Medical Monitor concerning any AEs and also any follow-up queries from the regulatory authorities to the Sponsor. According to the Protocol, the Principal Investigator will assess at each visit whether any adverse event (AE) including abnormal laboratory values has occurred. The details of all AEs, whether reported by the Subject or observed by the Principal Investigator / Study personnel during the entire Study, will be recorded onto the appropriate source document. Each adverse event must be recorded in the AE section of the case report form (CRF), regardless of the causal relationship.

The Principal Investigator must immediately report all serious adverse events (as defined in Protocol), which occur during the course of the Study and up to the date of the Subject's last visit, to the addressee given below. The SAE Report form will be used for documentation and reporting.

Initial and follow up SAE reports are to be faxed / Mail the Medical Affairs Department of CRO for onward transmission to SPONSOR:

Name:	Dr. Ankesh Barnwal
SAE Fax number:	+91-79-6621-9541
Telephone numbers:	+91-79-66219500
Cell number:	+91-9909019497
E-mail:	abarnwal@cliantha.in

If the event is unexpected and fatal or life threatening and is considered by the Principal Investigator possibly related to the Study medication, the Drug Safety Department of CRO shall be informed immediately by telephone and followed immediately by fax/ Mail.

CRO undertakes to notify the Principal Investigator and SPONSOR of all serious unexpected adverse events, which occur during the course of the Study in any other location and are reported in an expedited manner to health authorities. The Principal Investigator will inform the local ethics committee of SAEs reportable according to its national requirements and timelines, and of findings that could adversely affect the Subject's safety, could have an impact on the conduct of the Study, or could alter the ECs / IRB's approval to continue the Study.

CRO will be responsible to notify on time the health authorities in India.

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

INSTITUTE

By: _____

(Signature & Date)

REV. FR RICHARD ALOYSIUS COELHO
Director
Father Muller Charitable Institutions
Fr Muller Road, Kankanady
MANGALORE-575002

Rev .Fr. Richard Aloysius Coelho
Director

BY EXECUTING THIS DOCUMENT IN THE SPACE PROVIDED BELOW, THE PRINCIPAL INVESTIGATOR HEREBY ACKNOWLEDGES AND AGREES TO COMPLY WITH THE TERMS OF THIS AGREEMENT AND THE APPLICABLE PROTOCOL, AS AMENDED FROM TIME TO TIME

PRINCIPAL INVESTIGATOR

By: _____

(Signature & Date)

DEPT. OF DERMATOLOGY,
VENEREOLOGY AND LEPROSY
Fr. Muller's Medical College
Kankanady, Mangalore-575 002.

Dr. Ramesh Bhat M.
Principal Investigator

CLIANTHA RESEARCH LIMITED

By: _____ 01 Mar 18

(Signature & Date)

Dr. Dharmesh Domadia,
Associate Vice President - Global Clinical Operations

EXHIBIT A: PROTOCOL

Already shared previously

EXHIBIT B: BUDGET AND PAYMENT SCHEDULE

Principal Investigator: Dr. Ramesh Bhat M.

Site Address : Deapartment of Dermatology Venereology and Leprosy, Father Muller Medical College & Hospital, Father Muller Road , Kankanady , Mangalore 575002, Karnataka, India

BUDGET:

CRL111735: Per Patient Grant					
Investigator Grant (All amounts in INR)					
Patient Visits	**PI Charges**	**Lesion Photographs**	**Study Coordinator**	**Patient travel compensation**	**Total Grant Visit vise per Patient**
Screening, Visit-1	2500	×	2000	500	5000
Baseline, Visit-2	1500	750	1000	500	3750
Week-2, Visit 3	1000	×	500	500	2000
Week 5, Visit 4	1000	×	500	500	2000
Week 8, Visit 5	1000	×	500	500	2000
Week 11, Visit 6	2000	750	500	500	3750
Safety FU, Visit 7(EOS)-Telephonically	1000	×	500	×	1500
Total Grant	**10000**	**1500**	**5500**	**3000**	**20,000**

Total Per Patient (INR)	**20,000**
Institutional Overhead (20%)	**4,000**
Grand Total	**24,000**

Budget notes, payment schedule, conditions of payment and payment directions
Note 1: Patient travel reimbursement with maximum cap of INR 500 per visit based on actual patient travel invoices/bill.
Note 2: AE/SAE compensation and/or medical management as per Regulatory Requirement (During SAE management consultant charges if any, will be provided only for consultant who is not a part of study team. Consultant who is part of study team will not be reimbursed for extra visit/charges)
Note 3: Screenfailure payment will be done on 5:1 basis i.e. maximum one screen failure per Five randomized patient
Grand total is Exclusive Archival charges or any other charges
Study Start-Up cost (Advance Payment) of INR 25,000/- will be provided to the PI which will be adjusted against first two invoices raised by PI as per the PI grant.

PAYMENT SCHEDULE

Payment Schedule for the total study Grant for patients is as follows:

Overall Per Patient Budget

Overall Per Patient Budget: INR 24,000.00/- inclusive of all applicable charges

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

Payment Schedule for the other payments is as follows:

Study start-up cost (Advance payment) INR. 25000/- (Twenty five thousand only)

The advance payment provided to the PI will be adjusted against first two invoices raised by PI as per the PI grant.

Sponsor will pay only **INR. 1000/-** amount for screen failure patients as per Exhibit A of this agreement with the maximum ratio of 5:1 i.e. maximum one screen failure per Five randomized patients. Any Study subject who has been enrolled in the Study but does not meet eligibility requirements (as set forth in the Protocol) may be withdrawn from study without any payments. CRO reserves the right to withhold payment for any Study subject: (i) for whom a signed informed consent form has not been obtained prior to enrollment, (ii) for whom reasonably complete Case Report Forms have not been obtained, or (iii) for whom the Protocol has not been followed, absent reasonable explanation from Institution and/or Principal Investigator for the Protocol deviation(s).

Payment Adjustments

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

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

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

In the event the Protocol is amended, compensation paid to the Payee may be adjusted to give effect to the Protocol amendment.

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

Invoices:

Send invoices to	:	Cliantha Research Ltd.
Contact Person:		Devesh Verma
Address	:	Cliantha Research Ltd., Garden View Corporate House No. 08, Opposite AUDA Garden, Bodakdev, Ahmedabad - 380054, Gujarat

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

Final Payment

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

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

1. All amounts above are in Indian Rupee (INR).
2. The lab investigations at screening and end of study would be performed at central lab (Cliantha Research Ltd., Ahmedabad). The study site payment (Investigator grant, CRC grant, CT Scan charges, Miscellaneous charges etc.) would be made visit wise (upon completion of visits at site by the patient).
3. Serious Adverse event related costs: Costs relating to SAE that arise due to study participation would be borne by the Sponsor on actual.
4. Please note that approx. 20 % of the amount for one randomized patient only will be considered as retention amount and will be paid at the end of study/ study close out; once all the study related procedure and documentation would be over.
5. All payments are subject to withholding tax under all applicable laws including GST
6. GST will be deducted and applicable as per current government rules and regulations (i.e. on date of invoice).
7. GST (as applicable) will be considered on total grant subject to availability of service tax registration number with service provider. Service tax will be paid and applicable to service provider, provided to reflect the service tax registration number on Invoice / Bills."
8. In case recruitment is not initiated within a reasonable time period, unutilized amount (In keeping with the payment head above) would have to be returned to Sponsor.

Memorandum of Understanding

By And Between

FATHER MULLER CHARITABLE INSTITUTIONS, MANGALURU

And

INDIAN CANCER SOCIETY, BENGALURU

This **MOU** is entered into on the 17th Day of December, 18 (hereafter the "Effective Date") by and between:

Indian Cancer Society, Bengaluru, with its registered office at CA Site 1, Mahabodhi Meditation Centre, Siddapur Road, Jayanagar 1st Block, Bengaluru, Karnataka 560011 (hereafter "**ICS**");

And

Father Muller Charitable Institutions at Kankanady, Mangalore 575002 (hereafter **FMCI**)

who are referred to, collectively, as "Parties" or, individually, as "Party".

PREAMBLE:

WHEREAS FMCI and ICS, recognize the benefits to be derived from collaboration, cooperation and mutual interaction for the development and promotion of joint activities to address issues of mutual interest, designed to foster and promote collaboration in the field of cancer education, screening and detection.

NOW THE PARTIES HAVE AGREED AS HEREUNDER:

1) **NATURE AND SCOPE OF JOINT ACTIVITIES:**

The parties have agreed to undertake the following activities jointly:

a) Cancer education and awareness in general public
b) Screening & Detection of Oral, Breast and Cervical Cancer in rural setting.
c) Follow up on Cancer screened individuals.

Activities and responsibilities for undertaken under this MoU are listed in Annexure 1 and 2.

2) **INTELLECTUAL PROPERTY:**

a) All material and information provided by either Party under this MOU towards the activities envisaged shall remain the exclusive property of such Party and the Other Party does not and shall not derive or be deemed to have acquired any right, title or interest in the same.

b) Each Party to this MOU represents that it shall not infringe or cause to be infringed any intellectual property rights of the other Party including any brand name, logo, trade name or those associated with any information or material provided under this MOU and shall keep the same strictly confidential.

3) PUBLICITY & MARKETING:

Both Parties agree to consult each other in case of any requirement for publicity of the said project to the media or any other agency and to act diligently in the best interest of the project.

4) CONFIDENTIALITY:

a) Both Parties shall treat as strictly confidential and prevent disclosure thereof, of all Confidential Information exchanged pertaining to the Activities under this MOU including, but not limited to, information related to any processes, techniques, plans, formulations, products, testing, storage and other methodologies and norms, services, trade secrets and other technical knowledge and the fact and contents of and relating to this MOU between FMCI and ICS ("Confidential Information"). Both parties shall not disclose or use such Confidential Information for any other Party in any manner and shall only use such information for the purposes of this MOU.

b) Confidential Information does not include information which

(i) at the time of such disclosure was, or subsequently became, publicly available (other than as a result of its disclosure by either Party, in breach of this MOU);

(ii) at the time of such disclosure, was or subsequently became available on a non-confidential basis from a third Party source provided that such source was not subject to any duty of confidentiality in respect thereof; or

(iii) has been independently acquired or developed by it without relying on any information or material which is disclosed by or available from the other Party or by breaching any of its obligations under this MOU.

5) TERMS OF MOU:

This MOU shall come into force from the **Effective Date** and shall remain in force for a period of 5 years (60 months), from the Effective Date of the MOU. The Term of the MOU may be mutually extended on terms mutually agreed to by the Parties.

6) TERMINATION:

a) On non-performance of the obligations as specified in this MOU, either Party shall be entitled to terminate this MOU for any such breach of the terms of the MOU remains uncured for a period of 15 working days from the date of

the notice to cure such breach. For the purpose of this clause, any breach of the terms of the MOU shall be deemed to have taken place from the date of the receipt of written intimation that a claim of breach has been raised.

b) Notwithstanding anything contrary stated hereinabove, both parties shall have the right to terminate this MOU without assigning any reasons by giving 30 days written notice to the Other Party.

7) FORCE MAJEURE:

a) Neither Party shall be liable for any failure or delay in performance under this MOU to the extent the said failures or delays are proximately caused by causes beyond that Party's reasonable control and occurring without its fault or negligence, including, without limitation, performance failures of parties outside the control of the contracting Party, Acts of God, War, Floods, Earthquakes, Strike, Lockouts, Epidemics, Riots, Civil Disturbance among others, provided that, force majeure will apply only if the failure to perform could not be avoided by the exercise of due care by the Party invoking this clause and such Party does everything reasonably possible to resume its performance under this MOU.

b) A Party affected by an event of force majeure shall give the other Party written notice, with full details as soon as possible and in any event not later than fourteen calendar days of the occurrence of the cause relied upon. If force majeure applies, dates by which performance obligations are scheduled to be met will be extended for a period of time equal to the time lost due to any delay so caused. However, if the performance of the MOU is delayed beyond eight (8) weeks from the date of this MOU either Party may, at its discretion, terminate this MOU.

8) GENERAL:

a) Severability:
If any provision of this MOU is found by any court of competent jurisdiction to be invalid or unenforceable, the invalidity of such provision shall not affect the other provisions of this MOU, and all provisions not affected by such invalidity shall remain in full force and effect.

b) Waiver:
The waiver by either Party of a breach or default in any of the provisions of this MOU by the other Party shall not be construed as a waiver of any succeeding breach of the same or other provisions; nor shall any delay or omission on the part of either Party to exercise or avail itself of any right, power or privilege, operate as a waiver of any breach or default by the other Party.

c) Relationship:
This MOU is being entered into on a principal-to principal basis.

d) Notices:

Any notice shall be given by way of registered post with Acknowledgment Due at the address given in the description of the Parties. Email communications shall not be accepted as valid legal notices. The address and other details of the Parties for the purpose of communication, unless otherwise notified in writing, to the other Parties shall be as provided in this MOU.

e) Binding Nature and Assignment

i. This MOU shall be binding upon and inure solely to the benefit of the parties hereto and their successors and permitted assigns and nothing in this MOU shall confer upon any other person or entity any legal or equitable right, benefit or remedy of any nature whatsoever under or by reason of this MOU. Neither Party shall have the power to assign or transfer this MOU without the prior, written consent of the other Party.

ii. This MOU constitutes the entire MOU between the parties hereto. There are no prior or contemporaneous, oral or written, representations, understandings or MOUs, which are not fully expressed in this MOU.

f) Amendment

No amendment, change order, waiver or discharge shall be valid unless it is in writing and signed by an authorized representative of the Party against whom such amendment, change order, waiver or discharge is sought to be enforced.

g) Limitation of Liability:

In no event shall either party be liable to the other party or any other entity for any kind of losses including analyst profits, or for any indirect, special, consequential or incidental damages arising out of this MOU, under any cause of action, whether or not such party or its agents have been advised of the possibility of such damage.

h) Dispute Resolution

i. Any dispute or difference arising between the parties under this MOU or the implementation of the obligation arising there from shall be discussed mutually and resolved within a period of 30 days.

ii. In the event that no such mutual settlement is reached, any and all disputes arising out of or in relation to this MOU shall be subject to the exclusive jurisdiction of the courts at Bengaluru, Karnataka, to the exclusion of all other courts.

i) Designated contact persons for parties to the MOU

All notices, communication under this MOU will be sent by Registered AD and shall be addressed to:

For FMCI: Rev. Fr Richard Aloysius Coelho
Administrator
Father Muller Charitable Institution,
Kankanady, Mangaluru 575 002

For ICS: Mr. Vijay Sharma,
Honorary Secretary
Indian Cancer Society

IN WITNESS WHEREOF, the parties to this MOU, intending to be legally bound, have duly executed this MOU to become effective as of the date first written above.

For Father Muller Charitable Institution

Rev. Fr Richard Aloysius Coelho
Administrator
Father Muller Charitable Institution

REV. FR RICHARD ALOYSIUS COELHO
Director
Father Muller Charitable Institutions
Fr Muller Road, Kankanady
MANGALORE-575002

For Indian Cancer Society

INDIAN CANCER SOCIETY
CA Site 1, Mahabodhi Meditation Centre, Siddapur Road, Jayanagar 1st Block
Bangaluru - 11

Mr. Vijay Sharma
Honorary Secretary
Indian Cancer Society

ANNEXURE 1

Name of Project: Cancer screening & Awareness Camps in and around Mangalore.

Project Objective:

1. Early diagnosis of certain types of cancer & follow-up with probable cases to initiate medical treatment.

2. To reduce the incidence of Cancer disease through awareness sessions.

Project Activities and Responsibilities:

Activity	Responsibility
Organize Camps	Both Parties
Assign Medical & Nursing Staff to screen for Cancer	FMCI
Assign Volunteers to manage the camp	Both Parties
Pre Camp Survey	Both Parties
Define Process for Cancer Detection Camps in Mangalore region	ICS
Transport Arrangement	FMCI
Maintain Registration Details and track probable cases	Both Parties
Maintain, report and track the referred probable cases	Both Parties
Counselling Cancer Probable Cases	Both Parties
Follow-up diagnostic and treatment	ICS & FMCI
Pathology and investigation charges	ICS, subject to terms & conditions and limits mentioned further below
Camp materials – Consumables (PAP smear kit, slides, Spatula, fixative agents, staining materials)	ICS

Other than the above, both Parties agree that they will bear their respective costs with respect to the above activities.

Reimbursement will be done by ICS to FMCI at the following rates:

A. Investigations:

Sl No	Investigation	Cost in Rupees
1.	PAP Smear	No reimbursement will be made, as under the agreement the PAP smear Kit will be provided by ICS and the procedure will be carried out by personnel from FMCI.
	Mamogram	
	Single breast	600
	Both breasts	900
3.	Biopsy	210
4.	FNAC	330
5.	Cytology	120

ANNEXURE 2

Treatment for individuals screened in ICS camps and diagnosed with cancer:

a. FMCI will utilize the insurance schemes under which the patient is covered for expenses incurred during treatment.

b. If the patient is not covered by any insurance scheme and is unable to meet the costs of treatment, by any other means, FMCI will send the Application for treatment, along with required supporting document to ICS.

c. ICS would review each application and, provide financial support up to 2 patients in a quarter, to a maximum of Rs 25,000 per patient, to meet the initial cost of treatment, subject to the satisfaction of certain criteria and the discretion of the ICS management.

It is understood by both Parties that it is not mandatory for ICS to provide such financial support.

Qualifying Criteria for Funding of Initial Treatment:

- Only those patients whose current family income does not exceed Rs.2,00,000 per annum would be considered eligible for aid.
- The patient must undergo treatment only at the empanelled hospital from which the application is received.
- The patient must be registered as a general ward patient (not private or semi-private).

- To be eligible for initial treatment funding, young patients (below age of 18 years) need to have a projected five-year survival of 70% or more.
- To be eligible for initial treatment funding, adult patients (18 years or above) need to have a projected five-year survival of 50% or more.

The funds would be disbursed for initial treatment only.

ICS would have the right to audit the records of FMCI to the extent necessary, to ensure proper utilization of the funds disbursed by ICS

GENERAL MEMORANDIUM OF UNDERSTANDING (MoU) FOR

ACADEMIC AND RESEARCH COOPERATION

BETWEEN

FATHER MULLER MEDICAL COLLEGE

AND

ST ALOYSIUS INSITUTE OF MANAGEMENT AND INFORMATION TECHNOLOGY, ST ALOYSIUS COLLEGE (AUTONOMOUS) MANGALORE, INDIA

Father Muller Medical College, Kankanady, Mangalore and St. Aloysius Institute of Management & Information Technology (AIMIT), St Aloysius College, Beeri, 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 material in education and research, publication 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 is 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 subscribed 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 effect, validity or interpretation of this MoU or as to their rights, duties or liabilities shall be resolved by mutual discussion between representatives of St. Aloysius Institute of Management & Information Technology (AIMIT) St Aloysius College, Beeri and Father Muller Medical College.

10. Neither St. Aloysius Institute of Management & Information Technology (AIMIT) St Aloysius College, Beeri 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 Sudhir Prabhu H, Associate Professor in Community Medicine, Father Muller Medical College, Mangalore – 575002. Mobile no - +919902331559, Office Phone no +91-0824-2238000, Fax no +91-0824-2436352, email id: sudhirhaladi@fathermuller.in. For St Aloysius Institute of Management &Information Technology (AIMIT) Karnataka, Mangalore, Beeri, the contact person will be Dr. S. Ruban , Assistant Professor and Coordinator of Software Technology department, St Aloysius Institute of Management &Information Technology (AIMIT), St Aloysius college, Beeri, Mangalore, Pin : 575 022, India. Phone No.: +91 9741965134, Email id: ruban@staloysius.ac.in.

Every collaboration will have its own agreement/ contract which address 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.

Director

REV. FR RICHARD ALOYSIUS COELHO
Director
Father Muller Charitable Institutions
Fr Muller Road, Kankanady
MANGALORE-575002

Father Muller Charitable Institutions

Director

St Aloysius Institute of Management & Information Technology (AIMIT)

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

Witness.
DR. JAYAPRAKASH. ALVA
DEAN.

Place : Mangalore
Date : 17/4/19

For **St Aloysius College (Autonomous) Mangalore:**

ST ALOYSIUS COLLEGE (AUTONOMOUS) AIMIT Beeri Campus Mangalore - 575 022 India MANGALORE

Witness.
Prof Santhosh Rebello
Dean - School of IT.

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.

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.

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

DATED THIS DAY OF 24TH DAY OF MAY 2019

BETWEEN

MAHSA UNIVERSITY
MALAYSIA

AND

FATHER MULLER RESEARCH CENTER
UNIT OF FATHER MULLER
CHARITABLE INSTITUTIONS
MANGALORE,
INDIA

MEMORANDUM OF UNDERSTANDING

THIS MEMORANDUM OF UNDERSTANDING is made this 24th day of May 2019

BETWEEN

MAHSA UNIVERSITY of Jalan SP 2, Bandar Saujana Putra, 42610, Jenjarom, Selangor Darul Ehsan, Malaysia

AND

FATHER MULLER RESEARCH CENTER, UNIT OF FATHER MULLER CHARITABLE INSTITUTIONS, Fr Muller Road, Kankanady, Mangalore – 575002, Karnataka, India

WHEREAS

(A) The Parties hereto, recognising the benefits of establishing international links, wish to strengthen the ties between their respective institutions by entering into this Memorandum of Understanding ("MOU").

NOW IT IS HEREBY AGREED

1. The purpose of this MOU is to develop co-operation and promote mutual understanding and excellence in practice-based education, research and knowledge exchange between the Parties.

2. In furtherance of this purpose the Parties agree to develop the following activities in collaboration in areas of mutual academic interest:

   2.1 Exchanges of academic and administrative staff and mutual visits to pursue research and to lecture;
   2.2 Exchanges of students and/or study abroad programmes and other enhancements to the student experience;
   2.3 Identifying opportunities for conducting collaborative research and development;
   2.4 Identifying opportunities for conducting lectures and seminars and organising symposia and conferences;
   2.5 Exchanges of academic information and materials; and
   2.6 Promoting collaboration in fields of mutual interest.

3. The development and implementation of specific activities developed under this MOU will be the subject of formal written agreements negotiated and entered into separately, which will deal with the financial arrangements, confidentiality, ownership and use of intellectual property, publication of articles or other work and other relevant matters.

4. It is understood that the implementation of any of the types of co-operation stated in Clause 2 shall depend upon the availability of resources and financial support of the Parties concerned.

5. Parties acknowledge the need to promote the programme and activities pursuant to this MOU and hereby agree to use promotional materials that have been approved by the other Party.

6. Both Parties agree that staff and students of either institution engaged in activities under this MOU shall carry out these activities in accordance with the laws and regulations of their respective countries after full consultation and approval.

7. The Parties hereby agree that any documents or materials supplied pursuant to this MOU shall be treated as Confidential Information and both Parties hereby agree to ensure the confidentiality of such Confidential Information is maintained at all times for the duration of this MOU or for the duration stated in any formal agreement which may be entered into by the Parties.

8. This MOU may only be amended by a written agreement signed by a duly authorised representative of each Party.

9. This MOU shall commence of the date of its execution by the last Party to sign and shall remain in force for a period of five years. Each Party shall review the status of the MOU at least six months before the end of the five-year period to determine whether it wishes the MOU to continue and, if so, whether any modifications are required. The period of validity of this MOU may only be extended by the mutual written consent of both Parties.

10. Either Party may terminate this MOU by giving six months' notice in writing to the other. The termination of this MOU shall not affect the implementation of any specific activities established under it prior to such termination.

11. Nothing in this MOU shall be construed as creating any legal relationships between the Parties. This MOU is a statement of intent to foster genuine and mutually beneficial collaboration.

IN WITNESS whereof this Agreement has been executed the day and year first above-written

Signed for and on behalf of **MAHSA UNIVERSITY, MALAYSIA** by

.....

Prof. Dato' Dr. Ishak Bin Abdul Razak
Vice Chancellor

MALAYSIAN ALLIED HEALTH SCIENCES ACADEMY SDN BHD
MAHSA UNIVERSITY

Signed for and on behalf of **FATHER MULLER RESEARCH CENTER, UNIT OF FATHER MULLER CHARITABLE INSTITUTIONS, INDIA** by

.....

Rev Fr Richard Aloysius Coelho
Director

FATHER MULLER CHARITABLE INSTITUTIONS
KANKANADY
MANGALORE
575 002

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Government of Karnataka

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Certificate No.	:	IN-KA21157190104345R
Certificate Issued Date	:	04-Jun-2019 05:14 PM
Account Reference	:	NONACC (FI)/ kacrsfl06/ KARANGALPADY/ KA-DK
Unique Doc. Reference	:	SUBIN-KAKACRSFL08708679941763 98R
Purchased by	:	KMC HOSPITAL A UNIT OF MHEPL
Description of Document	:	Article 12 Bond
Description	:	AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	KMC HOSPITAL A UNIT OF MHEPL
Second Party	:	FATHER MULLER HOSPITAL
Stamp Duty Paid By	:	KMC HOSPITAL A UNIT OF MHEPL
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

This Agreement (herein after referred to as "AGREEMENT") is made and executed on 07 June, 2019 at Mangaluru.

Regional Chief Operating Officer
KMC Hospital

MULLER CHARITABLE INSTITUTIONS
KANKANADY
MANGALORE

BETWEEN

KMC Hospital, Mangaluru a unit of Manipal health Enterprises Private Limited situated , at Dr B R Ambedkar Circle, Mangalore (hereinafter referred to as '**KMCHAC**'), represented by its Regional C O O **Mr. Saghir Siddiqui,** which expression unless repugnant to the context thereof, shall mean and include its successors-in-interest and permitted assigns, of the One Part;

AND

Father Muller Charitable Institution having its office at Kankanady, Mangaluru, represented by **Director: Rev. Fr Richard Aloysius Coelho** which expression unless repugnant to the context shall mean and include its legal representatives, affiliate, subsidiary Company, administrators, executors, nominee and assigns of the Other Part;
"KMCHAC Hospital" and **"Father Muller Charitable Institution"** are individually and collectively referred to **Father Muller Charitable Institution** as "First Party" and "Second Party" respectively.

WHEREAS:

A. Department of Laboratory Medicine, a division of KMC Hospital, Mangalore is having a clinical laboratory delivering specialized testing facilities in the field of Biochemistry, Transfusion Medicine Services, Hematology, Histopathology, Microbiology, Serology and Molecular Biology, Pathology, Cytology.

B. **Father Muller Charitable Institution** is engaged in the business of Clinical Research

C. AND WHERE AS **Father Muller Charitable Institution** based on the representation of KMCHAC has expressed its desires to avail the laboratory services from the KMC Hospital on nonexclusive basis and the KMC Hospital has agreed for the same on a mutually agreed terms and conditions mentioned hereinafter.

NOW THEREFORE THE PARTIES TO THE AGREEMENT WITNESS AS UNDER:

1. Term

The term of this agreement shall be for a period of **Two years**, effective from 04-06-2019. Upon the expiry of the Term of this agreement, it may be renewed at the mutual consent of both the parties for an additional term. **("Renewed Term")** on the same or additional terms.

FR. MULLER CHARITA... KANKANADY MANGALORE 575 002

2. **Objective:**

The objective of this agreement is to establish a written document framing a basic understanding under which both the parties shall be governed for conducting diagnostics, monitoring and prognostic screening tests on the samples received.

3. **Scope of Work:**

3.1 During the term hereof or the extended term as the case may be KMC Hospital shall provide the services to **Father Muller Charitable Institution** for all Diagnostics test requested by **Father Muller Charitable Institution** . The list of the Test Menu along with Price List will be provided to **Father Muller Charitable Institution** .

3.2 **Father Muller Charitable Institution** shall be entitled to use all the KMC Hospital Laboratories services as described in this agreement.

3.3 The discount will be applicable on tests performed at KMC Hospital Laboratory only. The tests which are out sourced for any reason will be charged at the existing rates.

4. **Role and Responsibilities of KMC Hospital.**

4.1 KMC Hospital shall conduct test/investigations, as per the duly filled request form filled by **Father Muller Charitable Institution** .

4.2 KMC Hospital shall provide reports of test/investigation conducted through hard Copy and on request E- Mail of the same shall be provided.

4.3 KMC Hospital shall conduct test/investigation for samples received from **Father Muller Charitable Institution** and report the same as per the Turnaround Time defined and agreed upon.

4.4 In case of any Test Cancellation, **Father Muller Charitable Institution** shall inform KMC Hospital in writing before generating of worksheet at KMC Hospital after generation of worksheet no refund will be entertained.

4.5 For any query related to technical issues will be handled by Mrs Mallika 0824-2444590 Etxn 5067 and for other issues Hari Prasad (Ph. No. 7899884041).

Role and Responsibilities of Father Muller Charitable Institution :

5.1 Samples collection shall be done by **Father Muller Charitable Institution** on written request from.

Dr. B R Ambedkar Circle
BANGALURU – 575 00[illegible]

5.2 **Father Muller Charitable Institution** shall be responsible for proper packing of laboratory/diagnostic samples in defined condition and temperature.

5.3 The sample would be collected and packed by **Father Muller Charitable Institution**. The collection is done in sterile and appropriate containers purchased, maintained by Father Muller Charitable Institution and transported by KMC Hospital.

5.4 **Father Muller Charitable Institution** shall make payments to KMC Hospital for services provided under this agreement within 7 days of receiving the invoices

6. **Force Majeure:**

Any delay in reporting the test/investigation shall be subject to Force Majeure, such as unavailability of test kits, failure of test, incomplete patient / test details, problem sample, sample lost in transit, need for repeat sample/testing, instrument or machinery breakdown, civil unrest, riots, change in or in the interpretation of laws, strikes, lockout or other labor problems, unavailability of supply, fire or explosion, act of terrorism and other natural calamities.

7. ***Consideration***

7.1 The billing shall be done on monthly starting from 1st to 31st of each month and **Father Muller Charitable Institution** undertakes to clear all the outstanding payments within 7 days from the date of receiving the invoices.

7.2 Revision of tariff by KMC Hospital will be intimated to **Father Muller Charitable Institution** in writing, upon which the revised rate tariff shall be applicable.

7.3 Credit facility will be given for a period of one month.

Representations and Warranties of the Parties

Each of the parties makes the following representations and warranties to the other party hereto that the representing party has the full power and unrestricted authority to enter into this agreement. Entering this agreement and performing the obligations hereunder does not conflict with and is not prohibited under the terms of any other agreement, document, law, rule, regulation or court order to which the representing party is subject. Each of the parties has the full power and unrestricted authority to grant the licenses that are granted herein.

KMC Hospital
Dr. B R Ambedkar Circle

9. **Termination and Consequences of Termination**

9.1 This agreement may be terminated on mutual consent or by either party with at least 30 days prior written notice after settling all its dues to party, without assigning any reasons.

9.2 All payments due, becoming due and payable to the Parties as on the date of termination, under the terms of this agreement shall continue to be due and payable to the Parties notwithstanding the termination hereof.

10. ***Confidentiality***

10.1 Each Party shall keep secret all Confidential Information, if any, transmitted to it or made available to it by the other Party and shall not pass such Confirmation Information on, wholly or partly, to third parties without express written consent of the other Party.

10.2 The Parties shall not disclose the terms of this agreement or make any announcement in respect of the subject matter thereof without prior written consent of the other Party unless the disclosure is required by law or other regulatory authorities. In the event disclosure is required by law, rules or regulations, such disclosure shall be made after obtaining written permission of other party.

10.3 The Confidentiality obligations in this do not apply to disclosed information that either Party in writing can prove that:

i. It was known at the time of disclosure to be free of any obligation to keep it confidential, as evidenced by written records;

ii. Became publicly known through authorized disclosure;

iii. The information was independently developed without access to or use of any confidential Information, as evidenced by written records; or

iv. The information was rightfully obtained from a third party who had the right to transfer or disclose it without violation of any confidentiality obligations.

KMC Hospital
Dr. B R Ambedkar Circle

11. **Dispute Resolution and Governing Law**

In case of any difference or dispute arises between the Parties herein, the Parties shall hold mutual discussions to resolve such difference and/or dispute in an amicable manner for the best interests of both Parties. Parties shall try to resolve the difference and / or dispute within 30 days or such extended time as agreed between the Parties. In case, any difference and / or dispute could not be resolved through mutual discussion then such difference and / or dispute between the Parties shall be referred to sole arbitrator in accordance with the Indian Arbitration and Conciliation Act, 1996. The venue of the arbitration shall be Mangalore. The award of the arbitration shall be final and binding between the Parties.

12. **Limitation of Liability**

To the fullest extent permitted by Applicable Law neither Party nor its affiliates shall be liable for any special, indirect, consequential, or incidental damages (including but not limited to damages for loss of business profits, business interruption, loss of business information, and the like) arising out of this agreement even if either Party has been advised of the possibility of such damages.

13 Miscellaneous

13.1 Relationship:

No provision of this agreement shall be deemed to constitute a partnership or joint venture between the Parties.

Further, each Party shall inform its employees that they shall not be treated as employees of the other Party for any purpose whatsoever and that they shall not exercise any rights or seek or be entitled to any benefits accruing to the regular employees of the other Party.

No provision of this agreement shall constitute either Party as the legal representative or agent of the other, nor shall either Party have the right or authority to assume, create or incur any liability or any obligation of any kind, express or implied, against or in the name of or on behalf of the other Party except as provided expressly under this Agreement.

13.2 Notices:

Any notice required or permitted to be given hereunder shall be in writing and shall be effectively served

13.2.1 If delivered personally, upon receipt by the other Party;
13.2.2 If sent by prepaid courier service, airmail or registered mail, within five (5) days of being sent; or
13.2.3 If sent by facsimile or other similar means of electronic communication (with confirmed receipt), upon receipt of transmission notice by the sender.
13.2.4 Any notice required or permitted to be given hereunder shall be addressed to the address as given in the title to this agreement.
13.2.5 Any Party hereto may change any particulars of its address for notice, by notice to the other in the manner aforesaid.

13.3 Violation of Terms:

The Parties agree that each Party shall be entitled to an injunction, restraining order, right for recovery, suit for specific performance, or such other equitable relief as a court of competent jurisdiction may deem necessary or appropriate to restrain the other Party from committing any violation or enforce the performance of the covenants, obligations and representations contained in this agreement. These injunctive remedies are cumulative and are in addition to any other rights and remedies the Parties may have at law or in equity, including without limitation, a right for recovery of the amounts due under this Agreement and related costs and a right for damages.

13.4 Execution:

This agreement may be executed in two (2) counterparts, each in the like form and each party shall be in custody of one original agreement and this agreement represents the entire understanding between the Parties and supersedes all previous understandings or communications that the Parties might had with each other with regard to their respective rights and obligations.

IN WITNESS WHEREOF the Parties have through their respectively duly authorized representatives, executed this agreement the day, month and year first hereinabove written.

For and on behalf of
KMC HOSPITAL
LABORATORY SERVICES

Regional Chief Operating Officer
KMC Hospital

Name: Saghir Siddiqui
Title: Regional C O O

Witness:

For and on behalf of
Father Muller Charitable Institution ,
Mangaluru

Name: Rev. Fr Richard Aloysius Coelho
Title: Director

REV. FR RICHARD ALOYSIUS COELH
Director
Father Muller Charitable Institution
Fr Muller Road, Kankanady
MANGALORE-575002

Witness:

LIDIA PAIS

FINANCE OFFICER

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ONCQUEST

Government of National Capital Territory of Delhi

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Certificate No.	:	IN-DL23022765661291R
Certificate Issued Date	:	19-Jul-2019 12:32 PM
Account Reference	:	IMPACC (IV)/ dl720603/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL72060354860562240067R
Purchased by	:	ONCQUEST LABORATORIES LIMITED
Description of Document	:	Article 5 General Agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	ONCQUEST LABORATORIES LIMITED
Second Party	:	FATHER MULLER MEDICAL COLLEGE HOSPITAL
Stamp Duty Paid By	:	ONCQUEST LABORATORIES LIMITED
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

.....Please write or type below this line.....

PROFESSIONAL SERVICES AGREEMENT

This Agreement is made at on this 20 day of July, 2019 ("Effective date") by and between:-

Oncquest Laboratories Limited, a Company incorporated under the Companies Act, 1956 having its corporate office at 3, Factory Road, Adj. Safdarjung Hospital, New Delhi - 110029, India, represented by its authorized signatory, Dr. Ravi Gaur, Chief Operating Officer, (hereinafter referred to as "Oncquest" which expression shall unless repugnant to the context of meaning hereof include its successors, administrator and executors in business and assigns) of the First Part:

AND

Rev. Fr Rudolph Ravi D'Sa
ADMINISTRATOR
Father Muller Medical College Hospital
Kankanady, Mangaluru-575 002

ONCQUEST

Father Muller Medical College Hospital, located at, Father Muller Road, Kankanady, Mengaluru-575002, India, represented by its authorized signatory Rev. Fr Rudolph Rao, D'Sa, (hereafter referred to as **"Father Muller Medical College Hospital"** which expression shall unless repugnant to the context or meaning hereof include its successors, administrator and executors in business and assigns) of the Second Part;

Oncquest and **Father Muller Medical College Hospital** shall also be referred to individually as "Party" or collectively as "Parties" and hereby agree on following key details across operations and commercials aspects of the partnership-

Operations-

1. **Range of investigations**

Our specialized tests menu covers technologies such as Molecular Biology, Flowcytometery, Cytogenetics, IHC & Histopathology, FISH based, Real time PCRs and other advanced technologies. We also provide an extensive test menu across Hematology, Biochemistry, Immunoassay, Hormonal assay as part of our routine test offerings.

2. **Specimen Packaging**

Oncquest shall replenish the necessary specimen packaging material for the transport of these specimens such as specimen vials, Styrofoam containers and corrugated boxes at its own expenses.

3. ***Logistics***

Oncquest shall provide requisition forms to your centre, which have to be dully authorized by any of your predestinated personnel, for the specimen to be collected.

The specimens shall be dispatched by reputed courier services or collected by our representative as per below terms-

.....**At time and dates as required by Father Muller Medical College Hospital**.....

While the courier service provider shall make every effort to deliver all specimens to us intact and within the specified time, Oncquest is not responsible for any loss or damage arising in transit. No legal claim would be entertained against Oncquest for any such loss or damage arising in transit. All samples shall be collected at the risk of the client and Oncquest will in no way be responsible for any loss or damage to the samples. Our local sales team shall keep you informed with more details on this as and when required.

4. ***Reporting***

We shall provide timely report delivery through our courier network. You may also avail of our customer care facilities and get results over phone when the situation so requires. We shall provide such a service at our cost. Below are details of our customer care for your reference-

Contact no: 011-26101240/ 30611432/ 30611467
Timings: Mon to Sat - 8 am to 8 pm
Email Id: teamcustomercare@oncquest.net

ONCQUEST LABORATORIES LIMITED NEW DELHI

Rev. Fr [illegible]
ADMINISTRAT
Father Muller Medical Coll
Kankenady, Mangalur

Alternatively, we have started providing access to online test reports and facility to archive all previous specimens directly through our website through a secure server transaction at some of the locations. We shall endeavor to extend the same to you in near future.

5. **Governing Law, Arbitration and Jurisdiction**

Father Muller Medical College Hospital agrees that Diagnostic Material will not be used by it, its employees, officers, directors, employees of affiliated company/s of **Father Muller Medical College Hospital** group and other representatives (collectively representatives') in any way detrimental to Oncquest. The diagnostic material will be treated as Oncquest belonging, and shall not, without prior written consent, be disclosed in any manner, in whole or in part, to anyone who is not its representatives.

If **Father Muller Medical College Hospital** is required disclosing any confidential information pursuant to a legal obligation, **Father Muller Medical College Hospital** will disclose the confidential information to such statutory authority, under notification to Oncquest.

All disputes and controversies of every kind and nature between the parties to this agreement arising out of or in connection with this Agreement, as to the existence, construction, validity, interpretation or meaning, performance, non-performance, enforcement, operation, breach, continuance, or termination of the agreement shall be submitted to arbitration pursuant to the procedure set forth in this agreement and shall be referred to arbitration as provided under the Indian Arbitration and Conciliation Act, 1996 and any amendment made thereto. The venue of the Arbitration will be Delhi/ New Delhi, India and the language of the arbitral proceedings will be English.

6. **Validity**

The agreement shall commence from 20 July, 2019, and will be valid up to 36 months from the date of signing of agreement, unless terminated by either party giving three months' written notice to the other. Oncquest management has the right to make necessary amendments, any time during the contract period and shall appraise the client 15 days in advance.

Commercials-

1. **Pricing Terms**

The attached test menu contains test-wise list price, which are the rates chargeable to your patients. As our client, however, you will be eligible for a discount on these list prices. Oncquest shall offer **15%** discount on its specialized menu and **15%** discount on its routine price list for all samples sourced from your centre unless the test is a part of the maximum discount list wherein the discount shall vary. Oncquest management has the right to make necessary revision in the Price List, any time during the contract period and appraise the client 15 days in advance and shall specify the applicability in billing cycle.

-Other Enclosures (if applicable)-

1. **DOS (Directory of Services)**
2. **Maximum discount list**

egistered Office:
ncquest Laboratories Limited, 3- Factory Road, Adjoining Safdarjung Hospital, New Delhi – 29
l: +91 11 30611300 Website: www. oncquest.net

Rev. Fr Rudolph Ravi D'S

2. **Payment Terms**

For Credit Clients-

- As client and partner of Oncquest, you will be responsible for collecting the charges for the investigations as listed in our Price List. On a **Monthly** billing basis, Oncquest shall raise the bill against these charges. The Invoices are payable within **30** days of presentation by Cheque/Demand Draft. Payment to be deposited in either:
  HDFC Bank A/c No: 05032320002468 or
  ICICI Bank A/C No: 032205001306 drawn in favor of Oncquest Laboratories Ltd.

- In the event of any delay in payments beyond credit period, Oncquest shall charge an interest at the rate of 1% for every 30 days delay. Any such interest surcharge or rebate, as the case may be, shall appear in the next invoice.

We look forward to your endorsement of the terms proposed above, and an early, successful start to this partnership

This Agreement is made in two original copies and each signed will be with one party respectively.

Signed for and on behalf of

Father Muller Medical College Hospital

Name: Rev. Fr [illegible] Ravi D'Sa

Title: ADMINISTRATOR
Father Muller Medical College Hospital
Kankanady, Mangaluru-575002

Place:

Dated:

Signed for and on behalf of

Oncquest Laboratories Limited

Name: **Dr. Ravi Gaur**

Title: **Chief Operating Officer**

Place: **New Delhi**

Dated:

List of Documents Required:

- Copy of PAN Card
- Copy of Address Proof

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Certificate No.	:	IN-KA27174810280113R
Certificate Issued Date	:	13-Jun-2019 04:17 PM
Account Reference	:	NONACC (FI)/ kaksfcl08/ MANGALORE/ KA-DK
Unique Doc. Reference	:	SUBIN-KAKAKSFCL08825143671376 26R
Purchased by	:	METROPOLIS HEALTHCARE LTD
Description of Document	:	Article 12 Bond
Description	:	AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	METROPOLIS HEALTHCARE LTD
Second Party	:	FATHER MULLAR MEDICAL COLLEGE AND HOSPITAL
Stamp Duty Paid By	:	METROPOLIS HEALTHCARE LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

For Shri Saraswathi Credit Co-operative Society Ltd., Mangalore Branch

Authorised Signatory/ies

Please write or type below this line

CLIENT AGREEMENT

This Indenture of Agreement has been made and executed at Mangalore on 13 June 2019

BETWEEN

M/S METROPOLIS HEALTHCARE LIMITED, having its registered office at 250 D, Udyog Bhavan Behind Glaxo Worli, Mumbai 400030

AND

FATHER MULLAR MEDICAL COLLEGE & HOSPITAL, KANKANADY, MANGALORE-575002

Rev. Fr Rudolph Ravi D'S
ADMINISTRATOR
Father Muller Medical College Hospi

Statutory Alert:

Metropolis Healthcare Limited takes pleasure in contracting with you as a Client with the following terms and conditions on 13 JUNE 2019

1 **Investigations:** All the investigations and services will be provided as described in the directory of services effective from Nov 2018. However, changes if any will be intimated through circular. However, selected tests may be discontinued without prior intimation in unavoidable circumstances.

2 **Logistics:**

a. Metropolis shall give sample pickup services during working hours. However, in case of genuine emergency (Sunday pick up), the services shall be rendered at odd hours depending on availability of the courier boy at additional cost.

b. The client shall web-download the reports so that Turnaround time is substantially reduced.

c. The logistics assistant may deliver the report during his regular round.

d. While all care will be taken to ensure sample integrity is maintained during transit, Metropolis will not be responsible for any sample loss due to leakage or loss in transit.

e. It will be our endeavor to send you the reports of the specimens sent to us as per the schedule defined in our DOS. However, Metropolis will not be responsible for delays due to circumstances beyond our control. No claim for refunds or any other action can be made against Metropolis for delays in dispatch of test reports.

f. Serum vials and all vacuum containers except gel tubes will be provided by Metropolis at no cost, on replacement basis only.

3 **Pricing:** Refer to Metropolis' latest directory of services for the test charges. The client is expected to adhere to the same prices and is requested not to charge lesser than the charges mentioned in the directory of services.

4 **Discounts:** Please refer to Metropolis' latest directory of services for all the test details. Metropolis shall provide the discount **L1, L2, L3,L4, category of test 30% and L5 10% and Metro 50 special transfer** price for given category of test.

5 **Billing:** A Fortnightly bill statement describing patient's name, date of receipt of sample, SID number, total charges, collection charges, and net charges payable will be issued of every 15 days. Any discrepancy

Client Signature :

Rev. Fr Rudolph Ravi D'S
ADMINISTRATOR
Father Muller Medical College Hosp

in the bill has to be reported within 5 days of the receipt of the bill in writing at our email address on receivables.lm@metropolisindia.com Delayed request will not be addressed

6 **Payments:**

a. Payments should reach us within 15 days from date of receiving the bill.
b. Delayed payments beyond 15 days will attract interest at the rate of 18% per annum.
c. Prolonged payment delays may lead to code inactivation at the discretion of Metropolis.
d. Payments to be made by Cheque or DD favoring 'Metropolis **Healthcare Limited'.**
e. For TDS purpose, our **PAN no. ALTPP7238B**. Certificate is to be issued to us timely, maximum by 30th April of every financial year.
f. We recommend avoiding cash payments. Cash transaction should be done with prior information to the management, solely at your responsibility. Metropolis will not be responsible for loss of cash in transit and such complaints will not be entertained.
g. Please take an acknowledgement and signature of the Metropolis representative receiving cash, which needs to be produced in case of dispute.
h. Though we shall be sending the receipts of the payments, you are requested to pursue the matter in case the receipt is not obtained.
i. In case of default of payment client code will be deactivated with immediate effect without notice or cheque bounce Rs 500/- will charge as Bank charges. Under the circumstances integrity of samples will be responsibility of lab concerned

7 **Accounts:** For account/audit purpose, if required by us, you are requested to share your statement of account with us.

8 **Services Support -**

a. A "Service Support Head" will take care of any questions/suggestions with regards to reports, samples, urgent pickups, billing and operations.

b. To provide you with the latest technical updates and expertise through CME's and business management education through workshops which will aid you in your growth plans

Client Signature

Rev. Fr Rudolph Ravi
ADMINISTRATOR

9 **Confidentiality:** You shall not share any confidential information with third party/parties.

10 **Loyalty:** The collection center agrees to send all the possible referral tests to Metropolis.

This non-exclusive agreement will be valid till the launch of new DOS and can be extended by mutual consent of both the parties. However, either party will be at liberty to terminate this agreement by giving 30 day notice in writing after settling all its dues to the other party.

For Metropolis Healthcare Ltd.

Mr. Ajit Vetha
(SBU-HEAD-SOUTH)

Accepted by

Name: **Date:**

Rev. Fr Rudolph Ravi D'Sa
ADMINISTRATOR
Father Muller Medical College Hospital
Kankanady, Mangaluru-575 002

Signature of the Client & Stamp

Client Signature : _____

Rev. Fr Rudolph Ravi D'Sa
ADMINISTRATOR
Father Muller Medical College Hospital
Kankanady, Mangaluru-575

1. **Introduction:** This Client Services Agreement (the "**Agreement**" or "**CSA**"), by and between CORE Diagnostics Pvt. Ltd. ("CORE") and Father Muller Medical College and Hospital ("**Partner**"), is effective as of this 2019-09-04 (the "**Effective Date**"). CORE and Partner may be referred to individually as a Party and collectively as the Parties.

2. **Background:** Partner is engaging CORE, to provide laboratory services to Partner's network of patients and physicians. Partner hereby appoints CORE as its exclusive outsource partners for tests that it doesn't conduct in its own facilities.

3. **Laboratory Services and Pricing:** A list of tests performed by CORE along with prices is appended in Attachment A to this Agreement, which is incorporated herein by reference (the "**Laboratory Services**"), at the pricing ("**Pricing**") set forth in Attachment A. All amounts payable by Partner shall be paid within 30 days of generation of an invoice for services rendered by CORE. Following 30 days, if unpaid, a late payment charge at a rate of 1% per month of outstanding payments shall be applied until paid, calculated from the original invoice date.

4. **Billing Responsibility:** CORE shall offer Flat 20% discount to Partner on the gross testing charges, except on tests outsourced outside India and on tests as mentioned in the Attachment B. Partner shall pay CORE a fee for each individual patient for whom the results of the Laboratory Services are reported. Taxes arising out of the sale or use of products or services, or transportation of materials under this Agreement are the Partner's responsibility and are not part of the Laboratory Services.

5. **Licensure and Accreditation:** CORE represents that it is duly licensed to perform testing services hereunder in accordance with regulation and guidelines prescribed by NABL and other competent regulatory authorities.

6. **Term and Termination:** The initial term of this Agreement shall be for a 3 years period commencing on the Effective Date ("**Initial Term**") and thereafter shall renew for successive 365 days periods (each a "**Renewal Term**" and collectively "**Term**"), unless earlier terminated by mutual written agreement as provided in this Agreement. Either Party may terminate this Agreement without cause upon ninety (90) days prior written notice to the other Party. In the event of a material breach of this Agreement, either Party may terminate this Agreement upon thirty (30) days prior written notice to the other Party of such other Party's material breach of this Agreement; provided that such notice offers a detailed description of the alleged breach and the other Party is afforded an opportunity to cure but fails to do so during such thirty (30)-day period.

7. **Partner Support Responsibilities:** Partner shall provide the following support to CORE: (a) assist in the collection and shipping of patient specimens to CORE; (b) ensure that initial specimen processing and handling standards and requirements (as specified by CORE) are met; and (c) provide CORE such information as reasonably requested by CORE to assist CORE in performing the Laboratory Services, providing reasonable assistance with data collection for research or product improvement (collectively, the "CORE Services"). In the event that a specimen (or associated data) does not meet the standards for quality laboratory testing, CORE may cancel the order/request for Laboratory Services with respect to such specimen by written (including email) notice to Partner, at no additional cost to Partner and (d) Partner shall obtain requisite consent of the patient to disclose his/ her information to CORE including

CORE DIAGNOSTICS PVT. LTD. GURGAON

Rev. Fr Rudolph Ravi D'Sa
ADMINISTRATOR
Father Muller Medical College Hospital

but not limited to condition/disease information, diagnosis date, first symptom information, and family history, biographical information, including bio, gender, age, location (city), general notes and details of test sought from CORE. Further, Partner shall ensure to take written consent from Patients that upon completion of the tests, the remaining sample and test data may be "de-identified" and CORE may use this sample and test data for further quality improvement, and/or research studies. Upon signing of this agreement, it shall be deemed that Partner has already obtained the written consent from Patients and CORE is authorized to use it for quality improvement, and/or research studies.

8. **Notices:** All notices given under this Agreement shall be in writing, addressed to the receiving Party's address set forth below or to such other address as the receiving Party may designate by notice hereunder, and shall be delivered by hand or by traceable courier service or sent by registered or certified mail, return receipt requested.

To CORE:
CORE Diagnostics Pvt. Ltd.
Attn: Ashish Singhal
406 Udyog Vihar Phase III
Gurugram-122016, Haryana, India
Phone: +91 124 4615615

To Partner:
Father Muller Medical College and Hospital
Attn: FR RUDOLPH RAVI D'SA
Address: Fr Muller Road, Mangaluru, Karnataka 575002
Phone: 8242238000

All notices shall be deemed to have been given, if by hand, are traceable courier service, at the time of the delivery to the receiving Party at the address so specified hereunder, or if sent by certified or registered mail, on the 7th business day after such mailing.

9. **Insurance:** Each Party shall maintain general and professional liability coverage in amounts required by applicable law, consistent with applicable standards in the industry and sufficient to cover any liability or indemnification obligations that may arise in connection with this Agreement. Each Party shall, upon written request of the other Party, promptly provide satisfactory evidence of such coverage.

0. **Shipping:** Unless otherwise requested by CORE, Partner shall at no cost to CORE transport patient specimens from Partner to CORE for testing. Partner shall not transmit, handover or allow to be handed over any shipment consisting of banned, restricted or dangerous goods without the supporting documents. The Parties shall use reasonable efforts to ship specimens in bulk to reduce shipping costs. Further, Partner shall arrange to send the Test Requisition Form, duly filled in along with each sample sent to CORE for testing. CORE shall not be responsible for any loss, damage, mutilation, delay of the sample or report in transit or if it falls in unauthorized hands. However, in the event the report is lost, duplicate report shall be nade available to Partner at no extra cost.

'ORE Support: CORE services can be contacted by calling [1800 103 2673] or as otherwise

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Rev. Fr Rudolph Ravi D'Sa
ADMINISTRATOR

406, Udyog Vihar, Phase III, Gurgaon - 122 016

directed by CORE, for consultation on matters related to specimen procurement and handling, technical questions concerning individual assays and test interpretation. CORE shall provide training to Partner via web-seminar or face-to-face-meetings as requested for the purposes of ensuring adequate familiarity with the CORE's service offering to maximize future success. CORE will provide Partner with collateral materials at CORE's expense.

12. **Privacy:** The Parties agree to protect the privacy and provide for the security of any information that relates to a patient's past, present or future physical or mental health condition in accordance with the requirements of The Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011 and any other applicable laws and regulations.

13. **Compliance:** CORE shall provide all Laboratory Services to Partner in accordance with industry standards and applicable laws and regulations upon Partner's submission of a signed or authorized physician order and necessary patient authorizations. CORE and Partner shall comply with applicable statutes, rules, and regulations as promulgated regulatory agencies or legislative authorities of Government of India.

14. **Indemnification; Limitation of Liability:** Each Party shall defend, indemnify and hold harmless the other Party, its officers, directors, employees and physicians from any third-party claims or damages arising from (a) any negligent act or omission, willful misconduct or violation of applicable law by the indemnifying Party in connection with the performance of its duties and services under this Agreement, or (b) any breach of this Agreement by the indemnifying Party. Notwithstanding the foregoing or any other provision of this Agreement to the contrary, under no circumstances shall (i) either Party be liable for any special, indirect, consequential or punitive damages (other than such Party's indemnification obligations for such damages recoverable by a third party pursuant to a third party claim), including (without limitation) damages for lost profits, (ii) either Party be liable for any claims or damages that may result out of a failure or delay that is due to any act beyond its reasonable control. COREs and its Affiliates' aggregate and collective liability arising out of or in connection with this Agreement (whether in contract, tort, negligence, under an indemnity or by statute or otherwise) entered into subject to its terms, will, to the extent permissible by law, be limited to the amount of loss directly resulting from the relevant cause of action and will, in any case whatsoever, not exceed the amount of the test fees actually paid for the services that directly cause the loss in connection with claims arising out of this agreement or otherwise relating to services. No warranties, expressed or implied, are given in respect of the tests, and any implied warranty, including that of merchantability or fitness for any purpose, is hereby expressly disclaimed.

15. **Confidentiality:** The Pricing and Billing terms of this Agreement shall be deemed Confidential Information, along with such other non-public information designated as such by a disclosing Party as "Confidential Information" (including, without limitation, information of an affiliate, collaborator or other third party disclosed by or through the disclosing Party to the receiving Party). Confidential Information of a disclosing Party shall only be provided to employees, contractors or agents of the receiving Party on a need-to-know basis and shall be utilized only in fulfillment of the research or work that is the subject of the applicable task order hereunder. Neither Party shall disclose the other Party's Confidential Information to any third party, except as required to perform its obligations with respect to an applicable higher-tier contract

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Rev. Fr Rudolph Ravi D'Sa
ADMINISTRATOR

105, Udyog Vihar, Phase III, Gurgaon - 122 016
T: +91 124 4615 615 | 1800 103 2673 (Toll Free)
E:info@corediagnostics.in | www.corediagnostics.in | CIN: U85100HR2012PTC046376

or grant award. Each Party shall not disclose Confidential Information to any third party that is not bound by confidentiality obligations equivalent to or more stringent than those in this Agreement. A disclosure or use by such Party's representatives that would not be permitted by such Party under this Agreement shall be deemed to be a breach of this Agreement by such Party.

16. **Intellectual Property:** CORE and Partner retain all right, title and interest in and to their respective inventions (whether patentable or not), patents, know-how, trademarks, methods, copyrights, information, data, writings, trade secrets and other intellectual property which was in existence prior to signing this Agreement. CORE and Partner shall own all right, title and interest in and to all inventions, improvements, modifications and discoveries that they each respectively make to their respective intellectual property. CORE hereby grants Partner a limited right to use the information contained in any report provided as part of the Laboratory Services only for (i) the associated evaluation of a patient in respect of whom such Laboratory Services have been provided, and (ii) the marketing and use of patient biomarker results for clinical trial work.

17. **Public Statements:** Partner shall not, without the prior written approval of CORE, make public statements regarding the existence of this Agreement, its terms and conditions and an accurate description of the product or services being supplied. Any press release or broad public communication including CORE shall require written approval from CORE prior to release.

18. **Assignment:** Neither Party may assign or otherwise transfer this Agreement or any of its rights or obligations hereunder, without the other Party's prior written consent, except that either Party may assign its rights and/or obligations hereunder to an affiliate or in the event of a change of control or sale of all or substantially all of its assets related to this Agreement, whether by merger, reorganization, operation of law, conversion to a for-profit, or otherwise, provided that the assignee in question concurrently agrees to assume all of the assigning Party's obligations hereunder. Notwithstanding the foregoing no such assignment by a Party or assumption by any such assignee shall relieve the assigning Party of its obligations hereunder with respect to confidentiality, intellectual property, non-competition or indemnification. Partner may subcontract with third parties to deliver some or all of the Laboratory Services, provided that in instances of subcontracting by Partner, except as otherwise agreed, Partner shall remain solely responsible for the fulfillment of all of Partner's obligations under this Agreement.

19. **Relationship of the Parties:** The Parties are independent contractors, and neither Party shall be deemed an employee or agent of the other, nor shall either Party be entitled to employee benefits from the other Party.

20. **Force Majeure:** Neither Party shall be liable for any failure to perform its obligations under this Agreement to the extent prevented from doing so due to acts of God, regulations or laws of any government, acts of terrorism, war, or any other condition or cause beyond its reasonable control.

21. ***Injunctive Relief:*** Each Party acknowledges and agree that (i) the provisions of this Agreement are reasonable and necessary to protect the legitimate business interests of the Parties, (ii) any violation by either Party of any such provision would result in irreparable

CORE DIAGNOSTICS PVT. LTD. GURGAON

Rev. Fr Rudolph Ravi D'Sa
ADMINISTRATOR

injury to the other Party, the exact amount of which would be difficult, if not impossible, to ascertain or estimate, and (iii) the remedies at law for any such violation would not be reasonable or adequate compensation to the affected Party for such a violation. Accordingly, each Party agrees that if such Party violates any of its covenants or obligations under this Agreement, then, in addition to any other remedy which may be available to the other Party, at law or in equity, such other Party shall be entitled to injunctive relief against the violating Party, and such other Party may seek such relief through any court of competent jurisdiction.

22. **Choice of Law:** This Agreement shall be governed and construed in accordance with the laws of India, without regard to its conflict of law principles. Each Party irrevocably submits to the jurisdiction of the courts of Gurugram, Haryana in relation to all matters arising out of or in connection with this Agreement.

23. **Non-Discrimination:** All services provided to Partner hereunder shall be in compliance with all applicable laws in India prohibiting discrimination on the basis of race, color, religion, sex, national origin, handicap, or veteran status.

24. **Waiver:** The rights and remedies of the Parties hereunder are cumulative and not alternative. The failure of any Party to insist on anyone or more instances upon performance of any terms or conditions of this Agreement shall not be construed as a waiver of future performance of any such term or condition. No waiver shall be valid unless in writing and signed by the Party waiving the applicable right or obligation. No waiver that may be given by a Party shall be applicable except in the specific instance for which it is given.

25. **Severability:** The provisions of this Agreement are severable. The invalidity or unenforceability of any term or provision hereto in any jurisdiction shall in no way affect the validity or enforceability of any other terms or provisions in that jurisdiction or of this entire Agreement.

26. **Headings:** The headings appearing in this Agreement are for convenience of reference only and are not intended to and shall not define or limit the scope of the provisions to which they relate.

27. **Dates and Times:** Dates and times set forth in this Agreement for the performance of the Parties' respective obligations hereunder or for the exercise of their rights hereunder shall be strictly construed, time being of the essence of this Agreement. All provisions in this Agreement which specify or provide a method to compute a number of days for the performance, delivery, completion or observance by either Party of any action, covenant, agreement, obligation or notice hereunder shall mean and refer to calendar days, unless otherwise expressly provided.

28. **Entire Agreement:** This Agreement, including the Attachments attached hereto, constitutes the entire agreement between the Parties with respect to the subject matter hereof and supersedes any and all prior or contemporaneous agreements, representations, communications and understandings, either oral or written, between the Parties (including without limitation, any prior agreement between CORE and Partner or any of its subsidiaries or affiliates) with respect to the subject matter hereof.

9. **Joint Preparation:** Each Party to this Agreement (a) has participated in the preparation of this Agreement; (b) has read and understands this Agreement; and (c) has been represented

CORE DIAGNOSTICS PVT. LTD. GURGAON

Rev. Fr Rudolph Ravi D'Sa
ADMINISTRATOR

by counsel of its choice in the negotiation and preparation of this Agreement. Each Party represents that this Agreement is executed voluntarily and should not be construed against a Party solely because it drafted all or a portion of the Agreement.

30. **Counterparts:** This Agreement may be executed in any number of counterparts which, when taken together, shall constitute one original, and photocopy, facsimile, electronic or other copies shall have the same effect for all purposes as an ink-signed original.

Rev. Fr Rudolph Ravi D'Sa
ADMINISTRATOR
Father Muller Medical College Hospital
Kankanady, Mangaluru-575 002

CORE DIAGNOSTICS PVT. LTD.
GURGAON

CORE DIAGNOSTICS

Attachment A: Labora

AGREED AND ACCEPTED:

CORE Diagnostics Pvt. Ltd.

By: _____

Name: DINESH CHAUHAN.

Title: GLOBAL - VICE PRESIDENT

Date: 3rd Oct 2019

CORE DIAGNOSTICS PVT. LTD. GURGAON

Father Muller Medical College and Hospital

By: _____

Name: Rev. Fr Rudolph Ravi D'Sa

Title: ADMINISTRATOR
Father Muller Medical College Hospital
Kankanady, Mangaluru-575 002

Date: _____

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA33450546880775R
Certificate Issued Date	:	23-Jan-2019 10:04 AM
Account Reference	:	NONACC (FI)/ kacrsfl08/ DERALAKATTE/ KA-DK
Unique Doc. Reference	:	SUBIN-KAKACRSFL08010362150529l7R
Purchased by	:	JUSTICE K S HEGDE CHARITABLE HOSPITAL DERALAKATTE
Description of Document	:	Article 12 Bond
Description	:	M O U
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	JUSTICE K S HEGDE CHARITABLE HOSPITAL DERALAKATTE
Second Party	:	FATHER MULLER MEDICAL HOSPITAL
Stamp Duty Paid By	:	JUSTICE K S HEGDE CHARITABLE HOSPITAL DERALAKATTE
Stamp Duty Amount(Rs.)	:	20 (Twenty only)

VIJAYA CREDIT CO-OP. SOCIETY LTD.,
Branch : Deralakatte

Authorised Signatory

Please write or type below this line

MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (herein after referred to as "MOU") is made and executed on this date **January 28, 2019** at Mangalore

BY AND BETWEEN

Father Muller Medical College Hospital, Mangalore (a unit of Father Muller Charitab Institutions) situated at Father Muller Road, Kankanady, Mangalore – 575002 represented Rev Fr. Rudolph Ravi D'sa, Administrator (hereinafter referred to as "FMMCH") which term

Rev. Fr Rudolph Ravi D'Sa
ADMINISTRATOR
Father Muller Medical College Hospital

Major (Dr.) Shivakumar Hiren
Medical Superintendent
Justice K.S. Hegde Charitable Hos
Medical Science Complex, University
Deralakatte, Mangalore - 575 01

unless repugnant to the context thereof, shall mean and include its successors-in-interest and permitted assigns, of the FIRST PART

AND

Justice K.S.Hegde Charitable Hospital having its office at Deralakatte, Mangalore, D.K- 575018 duly represented by Major (Dr.) Shivakumar Hiremath, Medical Superintendent, (hereinafter referred to as "JKSHCH")which term unless repugnant to the context shall mean and include its successors and permitted assigns, of the SECOND PART

"FMMCH" and "JKSHCH" are individually and collectively referred to as "Party" and "Parties" respectively.

WHEREAS

1. Father Muller Medical College Hospital Laboratory, a division of Father Muller Medical College Hospital is a clinical laboratory delivering specialized testing facilities in the field of Biochemistry, Hematology, Histopathology and Microbiology.

2. FMMCH offers Inter Laboratory Quality Control specialized pathological diagnostic services on a per-request basis from similar health care facilities.

3. JKSHCH, a teaching hospital of K.S.Hegde Medical Academy, a constituent college of Nitte (Deemed to be University)owns and operates Justice K.S.Hegde Charitable Hospital Laboratory Services.

4. Justice K.S.Hegde Charitable Hospital Laboratory Services is a clinical laboratory offering specialized testing facilities in the field of Biochemistry, Hematology, Histopathology and Microbiology.

5. JKSHCH desires to obtain services from FMMCH of the type offered by them and FMMCH is willing to provide such services to JKSHCH, in accordance with the terms and conditions set forth within.

Wherefore, it is agreed between the Parties as under:

6. Term

6.1 This agreement shall be a valid for a period of one year from the date of execution of this agreement. This agreement shall come into effect from January 28, 2019. However either party will renew this agreement for further period of one year with mutual consent.

7. Objective

7.1 The objective of this MOU is to establish a written document framing a basic understanding under which both the parties shall be governed for conducting and monitoring diagnostic tests on the samples received by JKSHCH.

Rev. Fr Rudolph Ravi D'Sa
ADMINISTRATOR

8. Scope of Work

8.1 During the term hereof or the extended term as the case may be FMMCH shall provide the services to KSHEMA for all the tests requested by JKSHCH. The list of tests annexed to this agreement as **Annexure 1**.

9. Role and Responsibilities of Father Muller Medical College Hospital

9.1 FMMCH shall conduct tests/investigations as per duly filled test requisition form requested by JKSHCH. The testing and reporting shall be carried out conforming to prevalent high standards of quality.

9.2 FMMCH shall conduct tests/investigations on the basis of samples received from JKSHCH. The sample received from JKSHCH shall be tested and reported within two or three working days under normal circumstances. Reporting timeliness will be in accordance with prevalent quality standards.

9.3 FMMCH shall provide reports of tests/ investigations through hard copy by courier.

10. Roles and Responsibilities of KSHEMA

10.1 JKSHCH shall be responsible for proper packing of samples and transportation in defined condition and temperature. FMMCH will not be responsible for packing and transportation.

10.2 JKSHCH shall be responsible for sending duly filled test requisition form, patient history, samples packing and labeling at required temperature in good condition to FMMCH for test/ investigations.

10.3 JKSHCH shall make payments to FMMCH for services provided under this MOU within 15 days of receiving the invoices.

10.4 It is the responsibility of JKSHCH to provide additional details requested by FMMCH to conduct the test/ investigation.

11. Force Majeure

11.1 Any delay in reporting the test/ investigation shall be subject to Force Majeure, such as unavailability of test kits, failure of test, incomplete patient / test details, problem sample, need for repeat sample/ testing, instrument or machinery breakdown, civil unrest, riots, change in or in the interpretation of laws, strikes, lockout or other labour problems, unavailability of supply, fire or explosion, act of terrorism and other natural calamities. FMMCH would make efforts to mitigate the impact of such Force Majeure conditions and ensure timely testing as feasible and inform JKSHCH accordingly.

12. Consideration:

12.1 The billing shall be done on monthly basis starting from 1st to 31st of each month and JKSHCH undertakes to clear all the outstanding payments within 15 days from the date of receiving the invoices.

7.2 Revision of tariff by FMMCH will be intimated to JKSHCH in writing, upon which the revised rate tariff shall be applicable from the date revision.

13. Termination and Consequences of Termination

13.1 Each of the parties makes the following representations and warranties to the other party hereto that the representing party has the full power and unrestricted authority to enter into this MOU. Entering this MOU and performing the obligations hereunder does not conflict with and is not prohibited under the terms of any other agreement, document,

Rev. Fr Rudolph Ravi D'Sa
ADMINISTRATOR
Father Muller Medical College Hospital

law, rule, regulation or court order to which the representing party is subject. Each of the parties has the full power and unrestricted authority to grant the licenses that are granted herein.

14. Termination and Consequences of Termination

14.1 This MOU may be terminated on mutual consent or by either party with at least 30 days' prior written notice without assigning any reasons.

14.2 All payments due, becoming due and payable to the Parties as on the date of termination, under the terms of this MOU shall continue to be due and payable to the Parties notwithstanding the termination hereof.

15. Confidentiality:

15.1 Each Party shall keep secret all Confidential Information, if any, transmitted to it or made available to it by the other Party and shall not pass such Confidential Information wholly or partly, to third parties without express written consent of the other Party.

15.2 The Parties shall not disclose the terms of this MOU or make any announcement in respect of the subject matter thereof without prior written consent of the other Party unless the disclosure is required by law or other regulatory authorities. In the event disclosure is required by law, rules or regulations, such disclosure shall be made after obtaining written permission of other party.

15.3 The Confidentiality obligations in this do not apply to disclose information that either Party in writing can prove that:

i. It was known at the time of disclosure to be free of any obligation to keep it confidential, as evidenced by written records.

ii. Became generally publicly known through authorized disclosure.

iii. The information was independently developed without access to or use of any confidential Information, as evidenced by written records, or

iv. The information was rightfully obtained from a third party who had the right to transfer or disclose it without violation of any confidentially obligations.

16. Dispute Resolution and Governing Law

16.1 In case if any difference or dispute arises between the Parties herein, the Parties shall hold mutual discussions to resolve such difference and / or dispute in an amicable manner for the best interests of both Parties. Parties shall try to resolve the difference and / or dispute within 30 days or such extended time as agreed between the Parties. In case, any difference and / or dispute could not be resolved through mutual discussion then such difference and / or dispute between the Parties shall be referred to sole arbitrator appointed by both the parties in accordance with the Arbitration and Conciliation Act, 1996. The venue of the arbitration shall be Mangalore. The award of the arbitration shall be final and binding between the Parties.

17. Limitation of Liability

17.1 To the fullest extent permitted by Applicable Law neither Party nor its affiliates shall be liable for any special, indirect, consequential, or incidental damages (including but not limited to damages for loss of business profits, business interruption, loss of business information, and the like) arising out of this MOU even if either Party has been

Rev. Fr Rudolph Ravi D'Sa
ADMINISTRATOR
Father Muller Medical College Hospital

advised of the possibility of such damages.

18. Miscellaneous:

Relationship: No provision of this MOU shall be deemed to constitute a partnership or joint venture between the Parties.

Further, each Party shall inform its employees that they shall not be treated as employees of the other Party for any purpose whatsoever and that they shall not exercise any rights or seek or be entitled to any benefits accruing to the regular employees of the other Party.

No provision of this MOU shall constitute either Party as the legal representative or agent of the other, nor shall either Party have the right or authority to assume, create or incur any liability or any obligation of any kind, express or implied, against or in the name of or on behalf of the other Party except as provided expressly under this Agreement.

Notices:

Any notice required or permitted to be given hereunder shall be in writing and shall be effectively served.

18.1.1 If delivered personally, upon receipt by the other party;

18.1.2 If sent by prepaid courier service, airmail or registered mail, within seven (7) days of being sent; or

18.1.3 If sent by facsimile or other similar means of electronic communication (with confirmed receipt), upon receipt of transmission notice by the sender.

18.1.4 Any notice required or permitted to be given hereunder shall be addressed as given in the title to this MOU.

18.1.5 Any party hereto may change any particulars of its address for notice, by notice to the other in the manner aforesaid.

Violation of terms:

The Parties agree that each party shall be entitled to an injunction, restraining order, right for recovery, suit for specific performance, or such other equitable relief as a court of competent jurisdiction may deem necessary or appropriate to restrain the other party from permitting any violation or enforce the performance of the covenants, obligations and representations contained in this MOU. These injunctive remedies are cumulative and are in addition to any other rights and remedies the Parties may have at law or in equity, including without limitation, a right for recovery of the amounts due under this Agreement and related costs and a right for damages.

Rev. Fr Rudolph Ravi D'Sa
ADMINISTRATOR
Father Muller Medical College Hospital
Kankanady, Mangaluru 575 002

IN WITNESS THEREOF the Parties have through their respectively duly authorized representatives, executed this MOU the day, month and year fist hereinabove written.

Signed and delivered by FMMCH	Signed and delivered by JKSHCH
Father Muller Medical College Hospital	Justice K.S.Hegde Charitable Hospital
(Sign) Rev. Fr Rudolph Ravi D'Sa ADMINISTRATOR Father Muller Medical College Hospital Kankanady, Mangaluru-575 002	(Sign) Major (Dr.) Shivakumar Hiremath Medical Superintendent Justice K.S. Hegde Charitable Hospital Deralakatte, Mangalore - 575 018
By: Rev Fr. Rudolph Ravi D'sa Title: Administrator	By:Major (Dr.) Shivakumar Hiremath. Title:Medical Superintendent
Witness1: (Sign)	Witness1: MEDICAL RECORD OFFICER (Sign) Justice K.S. Hegde Charitable Hospital
Name: LIDIA PAIS FINANCE OFFICER	Name: Medical Science Complex University Road, Deralakatte MANGALORE - 575 018
Witness 2: (Sign)	Witness2: (Sign)
Name: Dr. SUMANTH DEVARAJU.	Name: Dr. P. Kathyayani

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Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA18803613955563R
Certificate Issued Date	:	01-Jan-2019 11:20 AM
Account Reference	:	NONACC (FI)/ kaksfcl08/ KANKANADY/ KA-DK
Unique Doc. Reference	:	SUBIN-KAKAKSFCL08725719062540 21R
Purchased by	:	FATHER MULLER MEDICAL COLLEGE HOSPITAL MANGALORE
Description of Document	:	Article 12 Bond
Description	:	MOU
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	FATHER MULLER MEDICAL COLLEGE HOSPITAL MANGALORE
Second Party	:	SPARSHA DIAGNOSTICS
Stamp Duty Paid By	:	FATHER MULLER MEDICAL COLLEGE HOSPITAL MANGALORE
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

SUGOI ... MANGALURU - 575 002

Please write or type below this line

MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (herein after referred to as "MOU") is made and executed on this date **January 7, 2019** at Mangalore

Rudolph Ravi D'Sa
DMINISTRATOR
ler Medical College Hospital
dy, Mangaluru-575 002

Dr. MURALI KESHAVA S.
MEDICAL DIRECTOR
SPARSHA DIAGNOSTICS
Ground Floor, "Vishwas Springfield"
Opp. Hotel Maya International
Upper Bendoor, Mangalore - 575 002

Statutory Alert:

1. The authenticity of this Stamp Certificate should be verified at "www.shcilestamp.com". Any discrepancy in the details on this Certificate and as available on the website renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority

BY AND BETWEEN

Father Muller Medical College Hospital, Mangalore (a unit of Father Muller Charitable Institutions) situated at Father Muller Road, Kankanady, Mangaluru – 575002 represented by Rev. Fr Rudolph Ravi D'Sa, Administrator (hereinafter referred to as "FMMCH") which term unless repugnant to the context thereof, shall mean and include its successors-in-interest and permitted assigns, of the FIRST PART

AND

Sparsha Diagnostics, its office at Ground Floor, Vishwas Springfield, Opposite Maya International Hotel, Upper Bendoor, Mangaluru, duly represented by Medical director (hereinafter referred to as "Sparsha") which term unless repugnant to the context shall mean and include its successors and permitted assigns) of the SECOND PART

"FMMCH" and "Sparsha" are individually and collectively referred to as "Party" and "Parties" respectively.

WHEREAS

1. Father Muller Medical College Hospital Laboratory, a division of Father Muller Medical College Hospital is a clinical laboratory delivering specialized testing facilities in the field of Biochemistry, Hematology, Histopathology and Microbiology.
2. FMMCH offers Inter Laboratory Quality Control specialized pathological diagnostic services on a per-request basis from similar health care facilities.
3. Sparsha owns and operates a hospital, requires services of the type offered by FMMCH.
4. Sparsha desires to obtain services from FMMCH and FMMCH is willing to provide such services to Sparsha, in accordance with the terms and conditions set forth within.

Wherefore, it is agreed between the Parties as under:

1. Term

1.1 This agreement shall be a valid for a period of one year from the date of execution of this agreement. This agreement shall come into effect from January 7, 2019. However either party will renew this agreement for further period of one year with mutual consent.

2. Objective

2.1 The objective of this MOU is to establish a written document framing a basic understanding under which both the parties shall be governed for conducting diagnostics and monitoring tests on the samples received by Sparsha.

3. Scope of Work

3.1 During the term hereof or the extended term as the case may be FMMCH shall provide the services to Sparsha for all the tests requested by Sparsh. The list of tests annexed to this agreement as **Annexure 1**.

4. Role and Responsibilities of Father Muller Medical College Hospital

4.1 FMMCH shall conduct tests/investigations as per duly filled request form filled by Sparsha. The testing and reporting shall be carried out conforming to prevalent high standards of quality.

Fr Rudolph Ravi D'Sa
ADMINISTRATOR
Muller Medical College Hospital

Dr. MURALI KESHAVA S.
MEDICAL DIRECTOR
SPARSHA DIAGNOSTICS
Ground Floor, "Vishwas Springfield"
Opp. Hotel Maya International
Mangalore - 575 002

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4.2 FMMCH shall provide reports of tests/ investigations through hard copy by courier.

4.3 FMMCH shall conduct tests/investigations on the basis of samples received from Sparsha. The sample received from Sparsha shall be tested and reported within two or three working days under normal circumstances. Reporting timeliness will be in accordance with prevalent quality standards

5. **Roles and Responsibilities of Sparsha**

5.1 Sparsha shall be responsible for proper packing of samples and transportation in defined condition and temperature. Hospital will not be responsible for packing and transportation.

5.2 Sparsha shall be responsible for sending duly filled test requisition form, patient history, samples packing and labeling at required temperature in good condition to FMMCH for test/ investigations.

5.3 Sparsha shall make payments to FMMCH for services provided under this MOU within 15 days of receiving the invoices.

5.4 It is the responsibility of Sparsha to provide additional details requested by FMMCH to conduct the test/ investigation.

6. **Force Majeure**

6.1 Any delay in reporting the test/ investigation shall be subject to Force Majeure, such as unavailability of test kits, failure of test, incomplete patient / test details, problem sample, need for repeat sample/ testing, instrument or machinery breakdown, civil unrest, riots, change in or in the interpretation of laws, strikes, lockout or other labour problems, unavailability of supply, fire or explosion, act of terrorism and other natural calamities. FMMCH would make efforts to mitigate the impact of such Force Majeure conditions and ensure timely testing as feasible and inform Sparsha accordingly.

7. ***Consideration:***

7.1 The billing shall be done on monthly basis starting from 1st to 31st of each month and Sparsha undertakes to clear all the outstanding payments within 15 days from the date of receiving the invoices.

7.2 Revision of tariff by FMMCH will be intimated to Sparsha in writing, upon which the revised rate tariff shall be applicable from the date revision.

8. ***Termination and Consequences of Termination***

8.1 Each of the parties makes the following representations and warranties to the other party hereto that the representing party has the full power and unrestricted authority to enter into this MOU. Entering this MOU and performing the obligations hereunder does not conflict with and is not prohibited under the terms of any other agreement, document, law, rule, regulation or court order to which the representing party is subject. Each of the parties has the full power and unrestricted authority to grant the licenses that are granted herein.

9. ***Termination and Consequences of Termination***

9.1 This MOU may be terminated on mutual consent or by either party with at least 30 days prior written notice without assigning any reasons.

9.2 All payments due, becoming due and payable to the Parties as on the date of termination, under the terms of this MOU shall continue to be due and payable to the Parties notwithstanding the termination hereof.

10. ***Confidentiality:***

10.1 Each Party shall keep secret all Confidential Information, if any, transmitted to it or made available to it by the other Party and shall not pass such Confidential Information on, wholly or party, to third parties without express written consent of the other Party.

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Mr. Ravi D'Sa

Dr. MURALI KESHAVA S.
MEDICAL DIRECTOR
SPARSHA DIAGNOSTICS
"Vishwas Springfield"

10.2 The Parties shall not disclose the terms of this MOU or make any announcement in respect of the subject matter thereof without prior written consent of the other Party unless the disclosure is required by law or other regulatory authorities. In the event disclosure is required by law, rules or regulations, such disclosure shall be made after obtaining written permission of other party.

10.3 The Confidentiality obligations in this do not apply to disclose information that either Party in writing can prove that:

i. It was known at the time of disclosure to be free of any obligation to keep it confidential, as evidenced by written records.

ii. Became generally publicly known through authorized disclosure.

iii. The information was independently developed without access to or use of any confidential Information, as evidenced by written records, or

iv. The information was rightfully obtained from a third party who had the right to transfer or disclose it without violation of any confidentially obligations.

11. Dispute Resolution and Governing Law

11.1 In case if any difference or dispute arises between the Parties herein, the Parties shall hold mutual discussions to resolve such difference and / or dispute in an amicable manner for the best interests of both Parties. Parties shall try to resolve the difference and / or dispute within 30 days or such extended time as agreed between the Parties. In case, any difference and / or dispute could not be resolved through mutual discussion then such difference and / or dispute between the Parties shall be referred to sole arbitrator appointed by both the parties in accordance with the Arbitration and Conciliation Act, 1996. The venue of the arbitration shall be Mangalore. The award of the arbitration shall be final and binding between the Parties.

12. Limitation of Liability

12.1 To the fullest extent permitted by Applicable Law neither Party nor its affiliates shall be liable for any special, indirect, consequential, or incidental damages (including but not limited to damages for loss of business profits, business interruption, loss of business information, and the like) arising out of this MOU even if either Party has been advised of the possibility of such damages.

13. Miscellaneous:

Relationship: No provision of this MOU shall be deemed to constitute a partnership or joint venture between the Parties.

Further, each Party shall inform its employees that they shall not be treated as employees of the other Party for any purpose whatsoever and that they shall not exercise any rights or seek or be entitled to any benefits accruing to the regular employees of the other Party.

No provision of this MOU shall constitute either Party as the legal representative or agent of the other, nor shall either Party have the right or authority to assume, create or incur any liability or any obligation of any kind, express or implied, against or in the name of or on behalf of the other Party except as provided expressly under this Agreement.

Notices:

Any notice required or permitted to be given hereunder shall be in writing and shall be effectively served.

13.1.1 If delivered personally, upon receipt by the other party;

13.1.2 If sent by prepaid courier service, airmail or registered mail, within seven(7) days of being sent; or

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udolph Ravi D'Sa
INISTRATOR
Medical College Hospital

Dr. MURALI KESHAVA S.
MEDICAL DIRECTOR
SPARSHA DIAGNOSTICS
Ground Floor, "Vishwas Springfield"
Opp. Hotel Maya International
Bondoor, Mangalore - 575 002

13.1.3 If sent by facsimile or other similar means of electronic communication (with confirmed receipt), upon receipt of transmission notice by the sender.
13.1.4 Any notice required or permitted to be given hereunder shall be addressed as given in the title to this MOU.
13.1.5 Any party hereto may change any particulars of its address for notice, by notice to the other in the manner aforesaid.

Violation of terms:
The Parties agree that each party shall be entitled to an injunction, restraining order, right for recovery, suit for specific performance, or such other equitable relief as a court of competent jurisdiction may deem necessary or appropriate to restrain the other party from permitting any violation or enforce the performance of the covenants, obligations and representations contained in this MOU. These injunctive remedies are cumulative and are in addition to any other rights and remedies the Parties may have at law or in equity, including without limitation, a right for recovery of the amounts due under this Agreement and related costs and a right for damages.

IN WITNESS THEREOF the Parties have through their respectively duly authorized representatives, executed this MOU the day, month and year fist hereinabove written.

Signed and delivered by FMMCH	Signed and delivered by Sparsha
Father Muller Medical College Hospital	SPARSHA DIAGNOSTICS
(Sign) By: Rev. Fr Rudolph Ravi D'Sa Title: Administrator	(Sign) By: Dr Murali Keshava S Title: Medical Director
Witness1: (Sign) Name: LIDIA PAIS, FINANCE	Witness1: (Sign) (PEETHAMBAR) Name:
Witness 2: (Sign) Name: JYOTHI PINTO	Witness2: (Sign) Name: (DR. KIRANA PAILOOR).

Dr. MURALI KESHAVA S.
MEDICAL DIRECTOR
SPARSHA DIAGNOSTICS
Ground Floor, "Vishwas Springfield"
Opp. Hotel Maya International
Upper Bendoor, Mangalore - 575 002

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R.PREMNATH
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L.No.8053/B3/07
HIGH COURT CAMPUS
CHENNAI - 600 104

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11/6/2018 Anderson Diagnostic Services pvt Ltd.

LABORATORY SERVICE AGREEMENT

This Laboratory Service Agreement is entered in to at Chennai on this the day of 20th July 2019.

BETWEEN

ANDERSON DIAGNOSTIC SERVICES PVT LTD, also known as **ANDERSON DIAGNOSTICS & LABS**,No 150, Poonamallee High Road, (Opp:Dasaprakash Hotel), CHENNAI- 600084, an **NABL** accredited lab (Reg No: N-0535) represented by **Dr.G.SRINIVASARAMAN** (Director), hereinafter referred to as Party of the **First Part**.

AND

FATHER MULLER MEDICAL COLLEGE, MANGALORE, KARNATAKA Father Muller Road, Kankanady, Mangaluru, Karnataka 575002 herein after called the Party of the **Second Part.**

ANDERSON DIAGNOSTIC SERVICES PVT. LTD.

Director

Rev. Fr Rudolph Ravi D'Sa
ADMINISTRATOR
Father Muller Medical College Hospital
Kankanady, Mangaluru-575 002

The terms Party of the First Part and Party of the Second Part shall mean and include unless repugnant to the context their respective officers, Administrators and Assigns.

WHEREAS the Party of the First Part is engaged in providing clinical diagnostic services for the last ten years.

WHEREAS the Party of the Second Part is engaged in providing medical care to its patients in the medical field and operating clinical laboratories at its place.

WHEREAS the Party of the Second Part wishes to engage the Party of the First Part to provide clinical diagnostic services upon the terms and conditions set forth in this agreement and the Party of the First Part has also agreed for the same.

In consideration of the mutual covenants hereinafter set forth, the parties agree as follows:

1. Terms of Agreement

The terms of this agreement shall commence on the Effective Date and shall continue for a period of one year, subject to early termination if any. The terms of this agreement may be extended for further periods as per the mutual agreement of both the parties.

2. Services

Upon the request of the Party of the Second Part, the Party of the First Part shall provide to the Party of the Second Part clinical diagnostic services as per Annexure - A

3. Pre -processing Requirements:

3.1 During the period of this agreement, the Party of the Second Part shall under strict hygienic conditions, collect samples at their medical centers, store and label the same for testing to the Party of the First Part strictly in accordance with the Standard Samples Collection Guidelines provided to the Party of the Second Part.

3.2 The Party of the Second Part shall also collect Patients relevant demographic details and clinical details and furnish the same to the Party of the First Part at the time of handing over of the samples.

3.3 The Party of the Second Part shall inform the Party of the First Part about the drawl of samples within 2 hours and the Party of the First Part shall take delivery of the samples from the Party of the Second Part within 2 hours thereafter. The samples shall be kept intact by the Party of the Second Part with the quality materials so that there shall not be any damages to the samples.

3.4 The Party of the Second Part shall provide pre-test and/or post-test counselling strictly in accordance with the Standard Samples Collection Guidelines provided to the Party of the Second Part.

3.5 Both parties shall follow all local and Indian Laws, rules and regulations for collection, disposal of Biohazardous waste materials.

ERSONAGE SERVICES PVT. LTD.
Director

Rev. Fr Rudolph Ray
ADMINISTRATO
Father Muller Medical College

4. Processing Requirements:

4.1 The Party of the First Part shall provide the services of collecting the sample and transporting the same from the Party of the Second Part. The Party of the First Part shall facilitate the pick-up of specimen and delivery of reports from the Party of the Second Part and may contract with multiple courier services to perform this assignment.

4.2 The Party of the First Part shall conduct diagnostic test and study of the samples provided by the Party of the Second Part and prepare report regarding the same in the name of the patient and hand over the reports to the Party of the Second Part.

4.3 Critical Reports: The Party of the First Part shall communicate all **'CRITICAL REPORTS'** by phone to the Party of the Second Part, by contacting the designated representative of the Party of the Second Part. However, the Party of the Second Part shall Endeavour to keep abreast of the critical tests out of its own accord. This will further be confirmed by the party of the first part by sending the soft copy of the report.

4.4 Samples which are rejected because of various reasons, including but not limited to, packing, collection methods etc shall be intimated to the Party of the Second Part and the Party of the Second Part shall Endeavour to provide fresh samples at its own costs.

4.5 The Party of the First Part shall maintain required licenses, permits and approvals as mandated under law and shall adhere to Good Laboratory Practice norms.

5. Submission of Reports and Test Results

The Party of the First Part shall use its best efforts to ensure its turnaround time for delivering laboratory test results to Party of the Second Part as mentioned in the Annexure-B. The entire results and records shall be sent by the Party of the First Part in digital format only.

6. Processing Charges

6.1 The Party of the First part shall provide the diagnostic services to the Party of the second Part in accordance with the Pricing Schedule attached as Annexure A

6.2 The Party of the First Part shall raise an invoice on the Party of the Second Part for the test processing charges at the end of every month for all the tests performed during that month in respect of samples sent by the Party of the Second Part. The Party of the Second Part shall pay the invoice in full after appropriate tax deductions at source (if applicable) through cheque only,

ANDERSON DIAGNOSTIC SERVICES PVT. LTD.

Director

Rev. Fr Rudolph Ravi D'Sa
ADMINISTRATOR

within a period of 30 days from the date of the bill. No tests or service will be priced or offered below the fair market price.

6.3 Under no circumstances the Party of the First Part shall accept the payment in CASH and payments shall be made through banking channels only i.e. Cheque/Demand Draft/RTGS/NEFT. In case of cheques which are returned unpaid (bounced cheque), payment shall have to be made by demand draft only within 3 working days from the date of intimation to the Party of the Second Part.

6.4 The Party of the Second Part shall raise bill on the Party of the First Part and receive the amount for diagnostic charges as mentioned in annexure A. The Party of the First Part shall not be liable or responsible for any charges that may be billed by the Party of the Second Part on its patients/third parties.

6.5 Both parties agree to mutually indemnify, defend and hold each other from any claim, liability, loss, suit, damages, cost or expense to the extent arising out of or attributable to the negligence, breach of this agreement or willful misconduct by either Party relating to this agreement including but not limited to any third party claim , billing claims brought and any claim brought against either, arising out of or attributable to either for collecting the samples, preprocessing and other matters relating to the same.

7. Promotional Materials

Neither party shall use the name, symbol, logo or any trademark or service mark of the other party in any promotional or advertising materials, nor for any other purpose unless advance written consent has been received from the other party.

8. Patient Confidentiality and intellectual property rights

8.1 Sharing of the intellectual property of the Party of the First Part or price list or any other components as referred to in this agreement is strictly prohibited. Any violation of the same shall attract measures, including termination.

8.2 Both Parties agree that confidentiality regarding the patient's identity and the diagnosis shall be strictly maintained and not divulged to any third party.

9. Regulatory Compliance

Each party represents and warrants that in the performance of its obligations under this agreement, it will comply with all applicable law, rules or regulations. Failure by either party to comply with any applicable law as

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Director

Rev. Fr Rudolph Ravi D'Sa

required shall be considered as a material breach of this agreement. In the event of a determination that this agreement is not in compliance with any applicable law, then the parties shall negotiate in good faith to bring this agreement into compliance.

10. **Termination of the MOU: -**

10.1 Either Party may terminate this agreement by giving one month notice in writing. However, both parties shall continue to honor the agreement during the notice period.

10.2 If any of the parties violates any of the terms and conditions of this agreement, the other party shall first intimate the defaulting party to rectify the same within two weeks from the date of intimation. But even thereafter if the same is not rectified, the other party can terminate the agreement with immediate effect by writing a letter to other party.

10.3 This MOU shall be terminated in case of insolvency or bankruptcy of either party.

11. **Miscellaneous**

11.1 The Party of the Second Part shall not assign any of its rights or obligation under this agreement to any other person/ s without the written consent of the Party of the First Part.

11.2 That this Agreement relates only to the activities submitted hereunder and shall not restrict either of the party from carrying on its normal activities or such other activities undertaken by the parties, independently. Subject to the terms of this Agreement, nothing contained herein shall preclude either party from its normal effort in connection with its activities.

11.3 That neither party shall have any right, power, or authority to create any obligation, express or implied, on behalf of the other except to the extent provided herein.

11.4 The Party of the First Part will communicate all relevant details directly to the Party of the Second Part upon introduction of new diagnostic tests. The Sales and scientific team of the Party of the First Part would also help the Party of the Second Part with the relevant specimen requirement, charges, turnaround times, etc.

11.5 Nothing contained in this agreement shall be construed as creating a joint venture, partnership or employment relationship between the parties. Neither party is an agent of the other, and neither party has any authority whatsoever to bind the other party, by contract or otherwise.In witness

For ANDERSON DIAGNOSTIC SERVICES PVT. LTD.

Director

Rev. Fr Rudolph Ravi D'S
ADMINISTRATOR
Esther Miller Medical College Hos

whereof, the parties on the first part and the second part have affixed their signatures herein the presence of the following witnesses.

IN THE PRESENCE OF

(WITNESSES):

For ANDERSON DIAGNOSTIC SERVICES PVT. LTD.

Director

PARTY OF THE FIRST PART

PARTY OF THE SECOND PART

Rev. Fr Rudolph Ravi D'Sa
ADMINISTRATOR
Father Muller Medical College Hospital
Kankanady, Mangaluru-575 002

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INDIA NON JUDICIAL

Government of Karnataka

Rs. 100

e-Stamp

Certificate No.	:	IN-KA26094431855876R
Certificate Issued Date	:	11-Jan-2019 11:05 AM
Account Reference	:	NONACC (FI)/ kacrsfl08/ HAMPANKATTA/ KA-DK
Unique Doc. Reference	:	SUBIN-KAKACRSFL08868109038165 21R
Purchased by	:	SRL DIAGNOSTIC PVT LTD
Description of Document	:	Article 12 Bond
Description	:	AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	FATHER MULLER MEDICAL COLLEGE HOSPITAL
Second Party	:	SRL DIAGNOSTIC PVT LTD
Stamp Duty Paid By	:	SRL DIAGNOSTIC PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

सत्यमेव जयते

THANNIRBHAVI MULTIPURPOSE CO-OP SOCIETY LTD. Authorised Signatory HAMPANKATTA BRANCH * D.K. *

SRL DIAGNOSTIC PVT LTD IN-KA26094431855876R RS. 100 11-JAN-2019 11:05 AM

Please write or type below this line

MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (herein after referred to as "MOU") is made and executed on this date **January 7, 2019** at Mangalore

BY AND BETWEEN

Father Muller Medical College Hospital, Mangalore (a unit of Father Muller Charitable Institutions) situated at Father Muller Road, Kankanady, Mangalore – 575002 represented by Rev Fr. Rudolph Ravi D'sa, Administrator (hereinafter

Rev Fr Rudolph Ravi D'Sa

SRL Diagnostics MANGALORE

referred to as "FMMCH") which term unless repugnant to the context thereof, shall mean and include its successors-in-interest and permitted assigns, of the FIRST PART

AND

SRL Diagnostics Pvt Ltd its office at Falnir Road,Mangalore duly represented by G S Balasubramanyam Center Head (hereinafter referred to as "SRL") which term unless repugnant to the context shall mean and include its successors and permitted assigns) of the SECOND PART

"FMMCH" and "SRL" are individually and collectively referred to as "Party" and "Parties" respectively.

WHEREAS

1. Father Muller Medical College Hospital Laboratory, a division of Father Muller Medical College Hospital is a clinical laboratory delivering specialized testing facilities in the field of Biochemistry, Hematology, Histopathology and Microbiology.
2. FMMCH offers Inter Laboratory Quality Control specialized pathological diagnostic services on a per-request basis from similar health care facilities.
3. SRL requires services of the type offered by FMMCH.
4. SRL desires to obtain services from FMMCH and FMMCH is willing to provide such services to SRL, in accordance with the terms and conditions set forth within.

Wherefore, it is agreed between the Parties as under:

1. Term

1.1 This agreement shall be a valid for a period of one year from the date of execution of this agreement. This agreement shall come into effect from January 7, 2019. However either party will renew this agreement for further period of one year with mutual consent.

2. Objective

2.1 The objective of this MOU is to establish a written document framing a basic understanding under which both the parties shall be governed for conducting diagnostics and monitoring tests on the samples received by FMMCH.

3. Scope of Work

3.1 During the term hereof or the extended term as the case may be FMMCH shall provide the services to SRL for all the tests requested by SRL. The list of tests annexed to this agreement as **Annexure 1**.

4.1 FMMCH shall conduct tests/investigations as per duly filled request form filled by SRL. The testing and reporting shall be carried out conforming to prevalent high standards of quality.

4.2 FMMCH shall provide reports of tests/ investigations through hard copy by courier.

4.3 FMMCH shall conduct tests/investigations on the basis of samples received from SRL. The sample received from SRL shall be tested and reported within two or three working days under normal circumstances. Reporting timeliness will be in accordance with prevalent quality standards.

5. **Roles and Responsibilities of SRL**

5.1 SRL shall be responsible for proper packing of samples and transportation in defined condition and temperature. Hospital will not be responsible for packing and transportation.

5.2 SRL shall be responsible for sending duly filled test requisition form, patient history, samples packing and labeling at required temperature in good condition to FMMCH for test/ investigations.

5.3 SRL shall make payments to FMMCH for services provided under this MOU within 15 days of receiving the invoices.

5.4 It is the responsibility of SRL to provide additional details requested by FMMCH to conduct the test/ investigation.

6. **Force Majeure**

6.1 Any delay in reporting the test/ investigation shall be subject to Force Majeure, such as unavailability of test kits, failure of test, incomplete patient / test details, problem sample, need for repeat sample/ testing, instrument or machinery breakdown, civil unrest, riots, change in or in the interpretation of laws, strikes, lockout or other labour problems, unavailability of supply, fire or explosion, act of terrorism and other natural calamities. FMMCH would make efforts to mitigate the impact of such Force Majeure conditions and ensure timely testing as feasible and inform SRL accordingly.

7. ***Consideration:***

7.1 The billing shall be done on monthly basis starting from 1st to 31st of each month and SRL undertakes to clear all the outstanding payments within 15 days from the date of receiving the invoices.

7.2 Revision of tariff by FMMCH will be intimated to SRL in writing, upon which the revised rate tariff shall be applicable from the date revision.

8. **Termination and Consequences of Termination**

8.1 Each of the parties makes the following representations and warranties to the other party hereto that the representing party has the full power and unrestricted authority to enter into this MOU. Entering this MOU and performing the obligations hereunder does not conflict with and is not prohibited under the terms of any other agreement, document, law, rule, regulation or court order to which the representing party is subject. Each of the parties has the full power and unrestricted authority to grant the licenses that are granted herein.

9. Termination and Consequences of Termination

9.1 This MOU may be terminated on mutual consent or by either party with at least 30 days prior written notice without assigning any reasons.

9.2 All payments due, becoming due and payable to the Parties as on the date of termination, under the terms of this MOU shall continue to be due and payable to the Parties notwithstanding the termination hereof.

10. Confidentiality:

10.1 Each Party shall keep secret all Confidential Information, if any, transmitted to it or made available to it by the other Party and shall not pass such Confidential Information on, wholly or party, to third parties without express written consent of the other Party.

10.2 The Parties shall not disclose the terms of this MOU or make any announcement in respect of the subject matter thereof without prior written consent of the other Party unless the disclosure is required by law or other regulatory authorities. In the event disclosure is required by law, rules or regulations, such disclosure shall be made after obtaining written permission of other party.

10.3 The Confidentiality obligations in this do not apply to disclose information that either Party in writing can prove that:

i. It was known at the time of disclosure to be free of any obligation to keep it confidential, as evidenced by written records.

ii. Became generally publicly known through authorized disclosure.

iii. The information was independently developed without access to or use of any confidential Information, as evidenced by written records, or

iv. The information was rightfully obtained from a third party who had the right to transfer or disclose it without violation of any confidentially obligations.

11. Dispute Resolution and Governing Law

11.1 In case if any difference or dispute arises between the Parties herein, the Parties shall hold mutual discussions to resolve such difference and / or dispute in an amicable manner for the best interests of both Parties. Parties shall try to resolve the difference and / or dispute within 30 days or such extended time as agreed between the Parties. In case, any difference and / or dispute could not be resolved through mutual discussion then such difference and / or dispute between the Parties shall be referred to sole arbitrator appointed by both the parties in accordance with the .Arbitration and Conciliation Act, 1996. The venue of the arbitration shall be Mangalore. The award of the arbitration shall be final and binding between the Parties.

12. Limitation of Liability

12.1 To the fullest extent permitted by Applicable Law neither Party nor its affiliates shall be liable for any special, indirect, consequential, or incidental damages (including but not limited to damages for loss of business profits,

Mr. Ravi D'Sa

Dr. Ajjagnostics MANGALORE

business interruption, loss of business information, and the like) arising out of this MOU even if either Party has been advised of the possibility of such damages.

13. Miscellaneous:

Relationship: No provision of this MOU shall be deemed to constitute a partnership or joint venture between the Parties.

Further, each Party shall inform its employees that they shall not be treated as employees of the other Party for any purpose whatsoever and that they shall not exercise any rights or seek or be entitled to any benefits accruing to the regular employees of the other Party.

No provision of this MOU shall constitute either Party as the legal representative or agent of the other, nor shall either Party have the right or authority to assume, create or incur any liability or any obligation of any kind, express or implied, against or in the name of or on behalf of the other Party except as provided expressly under this Agreement.

Notices:

Any notice required or permitted to be given hereunder shall be in writing and shall be effectively served.

13.1.1 If delivered personally, upon receipt by the other party;

13.1.2 If sent by prepaid courier service, airmail or registered mail, within seven(7) days of being sent; or

13.1.3 If sent by facsimile or other similar means of electronic communication (with confirmed receipt), upon receipt of transmission notice by the sender.

13.1.4 Any notice required or permitted to be given hereunder shall be addressed as given in the title to this MOU.

13.1.5 Any party hereto may change any particulars of its address for notice, by notice to the other in the manner aforesaid.

Violation of terms:

The Parties agree that each party shall be entitled to an injunction, restraining order, right for recovery, suit for specific performance, or such other equitable relief as a court of competent jurisdiction may deem necessary or appropriate to restrain the other party from permitting any violation or enforce the performance of the covenants, obligations and representations contained in this MOU. These injunctive remedies are cumulative and are in addition to any other rights and remedies the Parties may have at law or in equity, including without limitation, a right for recovery of the amounts due under this Agreement and related costs and a right for damages.

Rev. Fr Rudolph Ravi D'Sa
ADMINISTRATOR.
Fatima Health Medical College Hospital

IN WITNESS THEREOF the Parties have through their respectively duly authorized representatives, executed this MOU the day, month and year fist hereinabove written.

Signed and delivered by FMMCH	Signed and delivered by SRL
Father Muller Medical College Hospital	For SRL Diagnostics Private Limited Mangaloro
(Sign)	(Sign) Authorised Signatory
By: Rev Fr. Rudolph Ravi D'sa Title: Administrator	By: G. S. Balasubramanyam Title: CENTER HEAD
Witness1: (Sign)	Witness1: (Sign)
Name: MS. LIDIA PAIS, FINANCE	Name: Dr. Chandrayya Achary.
Witness 2: (Sign)	Witness2: (Sign)
Name: JYOTHI PINTO - HRM	Name:

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA80068006007734R
Certificate Issued Date	:	22-Mar-2019 03:04 PM
Account Reference	:	NONACC (FI)/ kaksfcl08/ KANKANADY/ KA-DK
Unique Doc. Reference	:	SUBIN-KAKAKSFCL0891074350343047R
Purchased by	:	FATHER MULLER CHARITABLE INSTITUTIONS
Description of Document	:	Article 12 Bond
Description	:	AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	FATHER MULLER CHARITABLE INSTITUTIONS
Second Party	:	DISTRICT PROGRAMME MANAGER
Stamp Duty Paid By	:	FATHER MULLER CHARITABLE INSTITUTIONS
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

MEMORANDUM OF UNDERSTANDING (MOU) BETWEEN DISTRICT HEALTH AND FAMILY WELFARE SOCIETY (R) (BLINDNESS CONTROL DIVISION) AND FATHER MULLER CHARITABLE INSTITUTIONS

1. Preamble :

1.1. WHEREAS the Union Cabinet has approved continuation of National Program for Control of Blindness, hereafter referred to as NPCB, for implementation in all the States of the Country during the 11th Plan (2007-2012).

..... 2

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

Statutory Alert:

1. The authenticity of this Stamp Certificate should be verified at "www.shcilestamp.com". Any discrepancy in the details on this Certificate and as available on the website renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

1.2. WHEREAS the Cabinet has also agreed to follow the strategies of "Vision 2020 : The Right to Sight" in NPCB as per Plan of Action developed for the country.

1.3. WHEREAS NPCB aims to reduce prevalence of blindness by implementing various activities through State and District Blindness Control Societies established in all the districts of the country;

1.4. Whereas the NPCB seeks to involve eye care facilities in Government, Non-Government and Private sectors having capacity to perform various activities under National Programme for Control of Blindness;

1.5. AND WHEREAS schemes for Non-Government Organizations (hereafter referred as NGO) providing eye care services are implemented as per pattern of assistance approved by the Cabinet;

1.6. NOW THEREFORE the signatories of Memorandum of Understanding (MOU) have agreed as set out herein below :

2. Parties of MOU :
This MOU is an agreement between District Health and Family Welfare Society (R.) (Blindness Control Division) of Dakshina Kannada of the State of Karnataka; hereafter called District Health and Family Welfare Society (R.) (Blindness Control Division) and Father Muller Charitable Institutions.

3. Duration of MOU :
This MOU will be operative from the date of its signing by the parties and remain in force till **31st March 2020**. MOU can be renewed through mutual agreement by the parties.

4. Commitments of NGO :
Through this MOU the NGO agrees to provide following services under National Programme for Control of Blindness :

Sl.No.	Activities	Yes / No
a)	Screening of population in all the villages / townships in the area allotted to the NGO and preparation of village wise blind registers.	Yes
b)	Identification of cases fit for cataract surgery, motivation thereof and transportation to the base hospital	Yes
c)	Pre-operative examination and investigation as required	Yes
d)	Performance of cataract surgery preferably IOL implantation through ECCE / IOL, Small Incision Cataract Surgery (SICS) or Phaco-emulsification of patients identified in allotted areas, self motivated walk-in cases and those referred by DH &FWS (BCD)	Yes
e)	Post-operative care including management of complications, if any and post-operative counselling regarding use of glasses;	Yes

DIRECTOR

f)	Follow-up services including refraction and provision of glasses, if required providing best possible correction.	Yes
g)	Submission of cataract surgery records of operated cases.	Yes
h)	Eye operation for poor and deserving patients other than cataract surgery	Yes

5. Commitments of District Health and Family Welfare Society (Blindness Control Division) :
Through this MOU, the DH & FWS (BCD) agrees to provide following support to participating NGO to facilitate service delivery :

Clause	Clause of Agreement	Yes / No
5.1	Issue Certificate of Recognition about participation in NPCB	Yes
5.2	Undertake random verification of operated cases not exceeding 5% before discharge of patients;	Yes
5.3	Sanction cost of free cataract operations performed by the NGO as per GOI guidelines indicated in para 6 below within one month of submission of claim along with Cataract Surgery Records;	Yes
5.4	Make payment of the sanctioned amount to the NGO on monthly/quarterly basis;	Yes
5.5	Regularly disseminate literature, guidelines or any other relevant information to participating NGO)	Yes

6. Grant-in-aid to NGO for the Scheme other than Cataract Surgery :

1.	Cataract Surgery	Rs. 2,000.00
2.	Diabetic Retinopathy	Rs. 2,000.00
3.	Childhood Blindness	Rs. 2,000.00
4.	Glaucoma	Rs. 2,000.00
5.	Keratoplasty	Rs. 7,500.00
6.	Vitreoretinal Surgery	Rs.10,000.00

7. Termination of MOU :
Commitments agreed to by the Parties are meant for prevention and control of blindness and therefore MOU should generally not be suspended or terminated. However, both parties can decide to suspend or terminate the MOU.

Signed this day, the 2nd of April 2019

Dist. Programme Manager,
Dist. Blindness Control Programme
Dakshina Kannada District
Mangalore.
For and on behalf of,
District Health and Family Welfare Society (BCD)

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

THE AJARA URBAN CO-OP. BANK LTD
Authorised Signatory

भारत 59557 महाराष्ट्र
157928 FEB 07 2019
Rs.0000200/- PB650E
INDIA STAMP DUTY MAHARASHTRA

200

CLINICAL STUDY AGREEMENT

This Clinical Agreement ("Agreement") is entered into as of 7th *Feb 2019* ("Effective Date") between Novartis Healthcare Private Limited, a company registered under the Companies Act, 1956 and having its registered office at 6th & 7th floor, Inspire BKC, G Block, 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 Instituions) 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 *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 *Ligelizumab (QGE031)* (hereafter the "Study Drug") in accordance with a protocol entitled *PEARL- 2 (CQGE031C2303)* 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 Code of Conduct, 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 ***10 Sep 2018***, 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 ***21 Oct 2021*** 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 ***5 Feb 2019*** ('Effective Date') and shall expire upon ***4 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 ***Father Muller Medical College Hospital:*** (hereinafter the "**Study Site**").

6.3 **Use of Study Drug:**

Novartis shall provide *Ligelizumab* (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- Payment schedule

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 *4 Feb 2022.*

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:

Ms. Jayshree Bagul

Novartis Healthcare Private Limited

GDO Trial Monitoring, India

Novartis Healthcare Private Limited

Inspire BKC, 'G' Block,

6 & 7 Floor, BKC Main Road,

Bandra Kurla Complex,

Bandra (E) Mumbai 400051, 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 ***Institution/Principal Investigator*** 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. K. Murugananthan

GDO Trial Monitoring,

Novartis Healthcare Private Limited

Inspire BKC, 'G' Block,

6 & 7 Floor, BKC Main Road,

Bandra Kurla Complex,

Bandra (E) Mumbai 400051, India

Email: murugananthan.k@novartis.com

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.

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: Sealini Sujit

Title: Head - CTO

Date: 7th Feb 2019

FATHER MULLER MEDICAL COLLEGE HOSPITAL

By: _____

Name: Rev. Fr. Richard Aloysius Coelho

Title: Director of Father Muller Charitable Institutions

Date: 12-02-2019

FATHER MULLER CHARITABLE INSTITUTIONS
KANKANADY
MANGALORE
575 002

DR. RAMESH BHAT M.

By: _____

Name: Dr. Ramesh Bhat M

Title: Professor of dermatology department

Date: _____

DEPT. OF DERMATOLOGY,
VENEREOLOGY AND LEPROSY
Fr. Muller's Medical College
Kankanady, Mangalore-575 002.

ANNEX 1: PAYMENT SCHEDULE

STUDY NUMBER: CQGE031C2303

STUDY NAME: PEAR- 2

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: 05

List of Equipments provided to Institution / Principal Investigator:

- AV recording camera used for study AIN457F2366 can be used, to be retrieved during study close out
- ERT log pads- to be retrieved during study close out
- Hard disk
- DVD for AV consenting storage
- ERT machine- to be retrieved during study close out

Payment Schedule:

	Screening		Double blind treatment												
Visit	1	20	110	120	130	140	150	160	170	180	190	200	210	220	230
Week	-4	-1	R	4	8	12	16	20	24	28	32	36	40	44	48
Protocol Procedures	9300	2800	6000	5000	5000	5000	3500	3500	5000	3500	3500	3500	3500	3500	3500
Investigator Fees	4000	3000	5000	3000	3000	3000	3000	3000	3000	3000	3000	3000	3000	3000	3000
Coordinator Fees	1000	1000	1500	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000
Unblinded Pharmacist fee			1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000
Institutional Overhead @ 30%	5434	2584	5130	3800	3800	3800	3230	3230	3800	3230	3230	3230	3230	3230	3230
TOTAL (INR)	19734	9384	18630	13800	13800	13800	11730	11730	13800	11730	11730	11730	11730	11730	11730

post treatment follow up			
240/EoT/TD	310	320	1999/EOS/PSD
52	56	60	64
6200	5000	5000	5700
4000	3000	3000	4000
1000	1000	1000	1000
1000	1000	1000	1000
4636	3800	3800	4446
16836	13800	13800	16146
TOTAL COST 1 PT			257370

Payment Terms:

- A start -up cost of Rs. 30,000/- will be paid after the EC submission and EC approval is obtained. Invoice needs to be submitted for processing the start- up cost.
- 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 screening cost will be paid only for randomized subjects. No separate screen failure cost will be provided
- Any other third parties designated by the Institution/Investigator that would receive remuneration, will be managed by & paid by the Institution/Investigator.
- The work performed by the hospital laboratory in addition to budget schedule shall be paid based on actuals. It is the Investigators responsibility to liaise with the hospital laboratory.
- 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.
- The Ethics committee charge will also be paid via Novartis, and this cost is not included in the budget schedule.
- Unscheduled visits covers subject visits that are not expressly set forth in the Study Schematic of the Protocol, but are otherwise required for the study. Medically necessary procedure, test performed during unscheduled visits would be paid as per actual bills. Payment for unscheduled visits will be payable to the institution within 60 days of receipt of original, itemized invoice by Novartis.
- 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.

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: _____

Name: Dr. Ramesh M. 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

We, the undersigned Institution and Principal Investigator for study number CQGE031C2303 declare I have received a copy of;

(a) Novartis global Antibribery Policy

(b) Professional Practices Policy

We, have read the policy (ies) understood its meaning and shall comply with the same.

Father Muller Medical College Hospital By: _____ Name: Rev. Fr. Richard Aloysius Coelho Title: Director of Father Muller Charitable Institutions Date: 15/02/19	Dr. Ramesh Bhat M By: _____ Name: Director of Father Muller Charitable Institutions Title: Principal Investigator Date: 15/02/2019

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

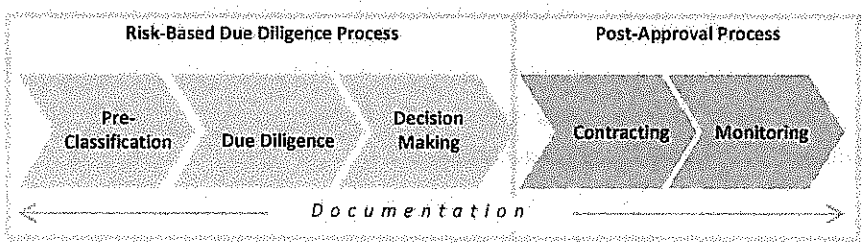
Further guidance to support the identification of Third Parties that fall within the scope of this Guideline can be found in Annex 6.

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.

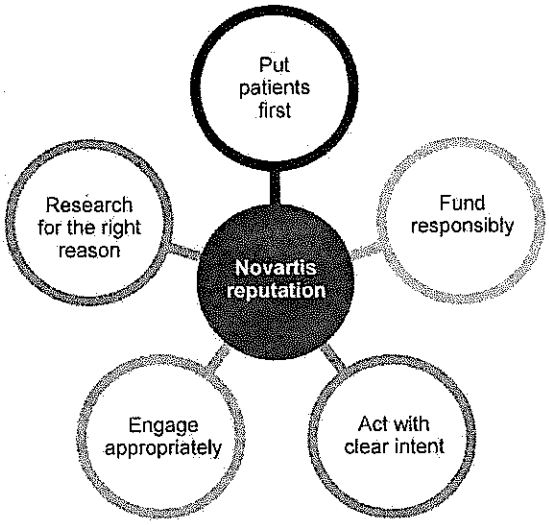
Allowable items of value, when provided to customers, must be modest, reasonable, infrequent, free from actual and perceived conflicts of interest, and disclosed where required.

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.

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Navanidhi Vividhoddesha Sahakara Sangha Ltd.

Authorised Signatory

Please write or type below this line

Memorandum of Understanding

This agreement is signed on 30th of January 2019 at Mangalore

Between

Indiana Hospital & Heart Institute Ltd., having a registered office at Mahaveer Circle, Pumpwell, Mangalore - 2, represented by its authorized representative Mr. Sameer PT, Chief Operating Officer hereafter referred as First Party.

INDIANA HOSPITAL AND HEART INSTITUTE LIMITED MANGALORE

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And

Father Muller Medical College Hospital, having its registered office at Kankanady, Mangalore - 2 represented by its authorised representative Fr. Rudolph Ravi D'sa, Administrator hereafter referred as second Party

Both parties to this agreement agrees the following terms and conditions

A) Scope of Services:

First party is a leading corporate hospital treating all kind of tertiary care services excluding Radiation Oncology services. Where as second party is leading medical college, offering all kind of treatments including radiation oncology services. First party contacted second party for availing radiation oncology services for the referred patients

B) Services

Radiation oncologist from the second party will be contact person on behalf of second party and he/she will be part of Tumour board of first party and will participate in the clinical decisions of patients referred for radiation services.

Second party will do all required investigations and therapies as per the discussion with consultants of first party. Referred patients will be shifted to second party's hospital by first party and First party will make arrangements to shift the patients back to first party hospital after the procedures / investigations.

C) Rates and Payments

First party will refer following different types of patients according to the financial support.

1.Cash Patients
2.Scheme Patients

Second party will not collect any amounts from patients directly for any services. Credit bills generated by second party will be settled by the first party on monthly basis. Second party agrees for a credit period of 30 days for settlement of bills

Cash patients will be billed according to the normal rates and second party agrees to give 20% discount to first party for the investigations / procedures.

MANGALORE

Scheme patients will be charged as per the special rates fixed by the government or the board and second party agrees for giving 10% discount on the special rate or the rate agreed for the cash patients which ever is lesser.

C) Validity and Termination

This agreement will be for a period of three years and can be extended to further years as per the mutual agreement of parties. Both parties to this agreement can be terminated this agreement by giving a notice of 30 days to either party.

This agreement is signed on 30th January 2019

For First Party

SAMEER P.T.
Chief Operating Officer
Indiana Hospital & Heart Institute Ltd.

SAMEER P.T.
CHIEF OPERATING OFFICER
INDIANA HOSPITAL & HEART INSTITUTE LTD...
Mahaveer Circle, Pandeswell
Kankanady P.O., Mangalore - 575 002

For Second Party

Fr. RUDOLPH RAVI D'SA
Administrator
Father Muller Medical College Hospital

Rev. Fr Rudolph Ravi D'Sa
ADMINISTRATOR
Father Muller Medical College Hospital
Kankanady, Mangaluru-575 002

Memorandum of Understanding

between

Father Muller Charitable Institution, Kankanady, Mangalore 575 002 (henceforth referred to as First Party)

and

St Aloysius College (Autonomous), Light House Hill Road Mangalore 575 003 (henceforth referred as Second Party)

The First Party is in the profession of imparting medical education. The Second Party is looking for someone to impart basic medical education to its students and hence, willing to tie up with the First Party for the same under the following terms.

Terms:

1. The First Party will provide the following services to the Second Party:
   a. Health Education;
   b. First Aid Training; and
   c. Conduct other medical and health related activities
2. The resource personnel will be arranged by the First Party while the activities will be carried out on the premises of the Second Party.
3. The topics, timing and participants for the above-mentioned activities will be discussed and mutually decided by both Parties in consultation with each other.
4. The Second Party will intimate the First Party with a minimum of 7 working days prior to the training to be conducted.
5. If the First Party is unable to conduct a health related activity, the Second Party is free to make alternate arrangements with any other entity it deems fit.

This MOU is signed by the authorized officials from the First Party and Second Party and will remain in effect until modified or terminated by any one of the Parties by mutual consent.

The validity of this MOU shall be for one year from the date of signing. However it shall be extended automatically for further periods of one year unless notified thereto by either Party to the other, within three months of expiry of the active period.

First Party

Rev. Fr Richard Aloysius Coelho
Director

Date : 29-01-2019

REV. FR RICHARD ALOYSIUS COELHO
Director
Father Muller Charitable Institutions
Fr Muller Road, Kankanady
MANGALORE-575002

Seal

Father Muller Charitable Institution,
Kankanady,
Mangalore 575 002

Second Party

Principal
ST.ALOYSIUS COLLEGE (AUTONOMOUS)
MANGALORE-575003

Fr Dr Praveen Martis SJ
Principal

Date : 31/01/2019

Seal

St Aloysius College (Autonomous)
P.O.Box 720,
Mangalore 575 003

ST. ALOYSIUS COLLEGE
MANGALURU
575 003
AUTONOMOUS

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Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Sri Sri Poornananda Vividhoddesha
Souharda Sahakari Ni

Authorised Signatory

----------Please write or type below this line----------

Administrator
Father Muller Medical College Hospital
Fr. Muller Road, Kankanady
MANGALORE-575002
Karnataka State

Centre For Development Studies & Education (R),
MANGALA NAGARA, KUDUPU P.O.
VIA VAMANJOOR, MANGALORE - 575 028

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MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding, hereinafter referred to as the "**MOU**", is executed in Mangalore on this 1st day of May 2016 between

CENTRE FOR DEVELOPMENT STUDIES AND EDUCATION (CEDSE) (R), MANGALA NAGARA, KUDUPU P O, MANGALORE – 575 028

Represented by the Managing Trustee, CEDSE

AND

FATHER MULLER CHARITABLE HOSPITAL (FMCH), KANKANADY, MANGALORE – 575 002

Represented by the Administrator, FMCH

CEDSE has established **Childhood Cancer Foundation** (CCF) dedicated to the curable cause of cancer in children primarily from the economically and socially marginalized groups. The aim is to provide resources to the deserving **pediatric patients** and families of Father Muller Charitable Hospital for treatment, drugs and supplies and family support. In order to achieve this objective CEDSE and Father Muller Charitable Hospital are entering into a memorandum of understanding that outlines the terms and conditions of this collaboration.

SCOPE

The purpose of this MOU is to collaborate in providing support to the deserving pediatric patients undergoing treatment at the **Pediatric Oncology Center** (POC) of Father Muller Charitable Hospital.

The support provided by CEDSE-CCF will include medications, medical supplies as well as financial resources for patient and/or patient's family.

CEDSE-CCF staff will work with the POC doctors of FMCH in gathering and maintaining the information listed below at the start of the program as well as at a periodic frequency.

Administrator
Father Muller Medical College Hospital
Fr. Muller Road, Kankanady
MANGALORE-575002
Karnataka State

Centre For Development Studies & Education (R)
MANGALA NAGARA, KUDUPU P.O.
VIA VAMANJOOR, MANGALORE - 575 028

- **Identification data** of children affected and their families
- **Details of the disease** - History of the disease and nature of treatment already undergone, hospital and duration of treatment.....
- **Disease investigation** - Investigation done and required. Assistance needed in investigations that are not covered by the government/other agencies.
- **Drugs and supplies**: Details of drugs and supplies needed along with the duration of the treatment cycles.
- **Family situation** - Socio-economic/financial details inclusive of loans, health/substance abuse issues among parents/other family members
- **Government and NGO covered plans** for children and families: **Support provided to children under Vajpayee Arogya Scheme, Rashtriya Balaswasthya Karyakrama or other programmes of the government or NGOs**

  Details of access to government provisions for the affected families – i.e. BPL ration card, Yashaswini registration for farmers, Pradhanmanthri Swasthya Bhima Yojana, MGNREGA employment card.

Terms and Conditions

- This MOU is for voluntary support of the pediatric cancer patients being treated at POC of FMCH
- This program will cover pediatric patients of less age than 14 years belonging to BPL and deserving APL families.
- FMCH – POC will provide patient/family details of pediatric patients for identifying deserving patients
- CEDSE-CCF is solely responsible for determining the pediatric patient(s) that will be covered under the support program and the extent of support that would be available in each case with due consultation with the doctor concerned.
- CEDSE-CCF may also seek to sponsor a single patient for the entire duration of the treatment (6 to 18 months or more) aimed at achieving complete cure.

Administrator
Father Muller Medical College Hospital
Fr. Muller Road, Kankanady
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- Direct monetary contributions to the deserving families will be restricted to Rs.100/- per day during the period of hospitalization (Up to 15 day's only)
- Laboratory and other bills in patients name will be reimbursed subject to the claims based on actual receipts.
- For any other urgent requirements, decisions to support will be made on a case to case basis by both the parties/ representatives engaged in the contract.
- The initial tenure of this MOU will be for a period of two years, renewable for a further longer period with mutual consent.
- CEDSE-CCF and FMCH – POC will begin the operations and follow the action points as defined by and agreed to between them from time to time.

Doctor responsible for coordination: **Dr. Nishitha Shetty,** Department of Medical Oncology, Father Muller Charitable Hospital, Kankanady, Mangalore.

Signatures:

Fr. Richard Coelho,
Administrator, FMCH

Administrator
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Dr. Rita Noronha
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