World Association of Laparoscopic Surgeons

Hereby certify that

DR. JOHN JOSEPH S. MARTIS

2282/D.MAS/09/2014

Has fulfilled the requirements of the satisfactory training, experience, examinations and project submission as required by the Constitution, Bylaws and Board of Examiners of World Association of Laparoscopic Surgeons and here by has been awarded on September 2014.

DIPLOMA IN MINIMAL ACCESS SURGERY

Recognized as being dedicated to the advancement of the highest standards of academic and clinical achievement in Minimal Access Surgery.

President
World Association of Laparoscopic Surgeons

Course Director
Minimal Access Surgery

Course Director and Chairman
World Laparoscopy Hospital
Gurgaon, India

Dr. Muralidhar K.
Director (Academic)
Chief Consultant Anaesthesia and Intensive Care
Prof. University of Minnesota, USA
Prof. Rajiv Gandhi University of
Health Sciences, Karnataka

Unit of Narayana Health

December 3, 2015

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Dr. Vishak S was registered with the Rajiv Gandhi University of Health Sciences (RGUHS) for a 18-month fellowship in the speciality of Head and Neck Surgical Oncology at Narayana Health city, Bangalore. He joined the course on 3rd March 2014 and completed mandatory training on 2nd September 2015. He appeared for the fellowship exit examination in July 2015 and is awaiting the results.

It is also certified that the candidate has worked during the above stated period as a resident-fellow in Head and Neck Surgical Oncology in accordance with guidelines of RGUHS.

Dr. MURALIDHAR K.
DIRECTOR (ACADEMIC)

Narayana Hrudayalaya Pvt. Ltd.
Nh Health City, 258/A, Bommasandra Industrial Area, Hosur Road, Bangalore 560 099.
Tel : +91 80 2783 6956, Fax : +91 80 2783 5322
Email : muralidhar.kanchi.dr@nhhospitals.org www.narayanahealth.org

TRUE COPY

DEAN
MULLER'S MEDICAL COLLEGE
Muller's Road, Kankanady

[redacted]nation with

smith&nephew
Medical Education

CERTIFICATE OF VISITING SURGEON PROGRAM

This Certificate is presented to

Prashant upendra acharya

for successfully completed the Knee & Shoulder Arthroscopy Surgery Visiting Surgeon Program On 29th Feb - 4th March 2016

A/Prof Dr Bancha Chernchujit
Senior Consultant Orthopaedic Surgery
Thammasat University Hospital
Thailand

Dr Nadthaporn Saengpetch
Consultant of Orthopaedic Surgery
Faculty of medicine Ramathibodi Hospital ,Thailand

Dr Nattha Kulkhamtorn
Consultant of Orthopaedic Surgery
Phramongkutklao Hospital & College of Medicine
Thailand

Dr Mason Porramatitkul
Sports Medicine Department of Orthopaedic Surgery
Faculty of medicine Vajira Hospital,Thailand

Dr Thanathep Tanpowpong
Consultant of Orthopaedic Surgery
Faculty of medicine Chulalongkorn University, Thailand

smith&nephew

BMH COMMITTED TO CARE

Baby Memorial Hospital
(NABH Accredited, ISO 9001:2008 & ISO 14001:2004 Certified Hospital)

CENTRE FOR ARTHROSCOPY & SPORTS INJURIES

THIS IS TO CERTIFY THAT

DR. ASHWIN KAMATH

HAS SUCCESSFULLY COMPLETED
FELLOWSHIP IN ARTHROSCOPY & SPORTS INJURY
AT BABY MEMORIAL HOSPITAL FROM 1st JUNE 2017 TO 31st AUGUST 2017
AND HAD DISCHARGED HIS DUTIES OF THE POSITION WITH ABILITY AND FAITHFUL CONFORMITY
TO THE RULES OF THE CENTRE

Prof. N.J. Mani
Head - Dept. of Orthopaedics

Dr. Schiller Jos
Dept. of Arthroscopy & Sports Injury

KKR ENT HOSPITAL AND RESEARCH INSTITUTE (P) LTD.*

No. 274 (827), Poonamallee High Road, Chennai - 600 010. Tel.: 26411444 / 26411987 / 26411612
Fax : 91-44-26412727 E-mail : kkrenthospital@gmail.com
website : http//www.kkrenthospital.org

Prof. K. K. RAMALINGAM M.B.B.S., F.R.C.S., D.L.O

Prof. RAVI RAMALINGAM M.B., M.S., Dip NB (ENT)., F.R.C.S,

30th March 2018

Letter of recommendation

TO WHOMSOEVER IT MAY CONCERN

It gives me immense pleasure to write this letter of recommendation for Dr Vinay V Rao whom I've known from past couple of years. After finishing his residency in ENT from Father Muller Medical College, Mangalore in 2009 he was trained in Tata Memorial Hospital, Mumbai in head and neck surgery and has been to various institutes to garner surgical experience which has turned him into a competent surgeon.

He was instrumental in organising surgical workshops in the field of otology and endoscopic sinus surgery in his institute which I was a part of, he did a splendid job which highlights his organisational skills. He spent some time in my institute observing cochlear implant surgery, during this time I got to know him better, he expressed his keen interest in the field of paediatric ENT and his desire to learn and practice it was very evident.

He's hardworking and sincere, personally a pleasant person and a team player. He'd be an asset to whichever organisation he chooses to work with.

I give my strongest possible letter of recommendation for Dr Vinay for the fellowship he wants to pursue in your institute and wish him all the best for his future endeavours.

Dr. Ravi Ramalingam

Prof. RAVI RAMALINGAM,
M.B.,M.S.,Dip NB(ENT).,FRCS
Reg.No. 49980
KKR ENT HOSPITAL &
RESEARCH INSTITUTE (P) LTD.
274, (Old # 827), Poonamallee High Road,
KILPAUK, CHENNAI-600 010.

FAIMER®

Foundation for Advancement of International Medical Education and Research

Dr. **NAGESH KARPUR RAMEGOWDA**

Father Muller Medical College,

Mangalore, Karnataka, India.

was awarded and has completed

with Distinction

the two-year Education & Leadership Fellowship

The PSG FAIMER Regional Institute

at

Coimbatore, India

April 2015 through June 2017

Thomas V Chacko
Director, PSG-FAIMER Regional Institute

Ralf Rundgren Graves
Director, FAIMER Regional Institutes

ISCCM™

Indian College of Critical Care Medicine

Indian Society of Critical Care Medicine

This is to certify that

Dr. Glenn Austin Fernandes

has completed the training requirements and passed the written and practical examination for the award of

Indian Diploma in Critical Care Medicine (IDCCM)

in April, 2017

Dr. Kapil Zirpe
ISCCM, President
Chancellor, ICCM

Dr. Deepak Govil
Vice Chancellor, ICCM

Dr. Rajesh Kumar Pande
Secretary, ICCM

63rd

AMASI SKILL COURSE & FMAS EXAMINATION

The Association of Minimal Access Surgeons of India

Certifies that

Dr. Caren Dsouza

has participated as a DELEGATE in the

63rd AMASI SKILL COURSE & FMAS EXAMINATION held at

MLT, College Building , Seth GS Medical College & KEM Hospital

31st May - 2nd June 2019

Dr. C. Palanivelu	Dr. Bhupinder Singh Pathania	Dr. Kalpesh Jani	Dr. Dilip Gode	Dr Sameer Rege
Founder President	President	Secretary	National Course Convener	Course Convener
AMASI	AMASI	AMASI	AMASI	63rd Skill Course

INDIAN COUNCIL OF MEDICAL RESEARCH
ANSARI NAGAR, NEW DELHI-110 029

Dated. 15.6.2011

No. 5/8/3(9)/2010-ECD-I(B)
ID No. 2011-03980

To

The Dean.
Father Muller Medical College (**FMMC**),
Mangalore-575002

Subject: - Sanction and budget allotment for the New Scheme entitled.
"Occurrence of drug resistance among relapse cases. poor responders and new cases of leprosy"

Sir,

1. The Director General of the Council sanctions the above mentioned research scheme initially for a period of One year from 1.7.2011 to 30.6.2012 subject to extension upto the total duration specified in para 3(3) below.

2. The Director General of the Council also sanctions the budget allotment of Rs.4,89,456/- (Rupees four lakh eighty nine thousand four hundered fifty six only) as detailed in the attached statement for the year 2011-12.

3. The grant-in-aid will be given subject to the following conditions:

1. The payment of the grant will be made in lump-sum to the Head of the Institution. The first installment of the grant will be paid generally as soon as a report regarding the commencement of the project and appointment of the staff is received by the Council. The demand for payment of the subsequent installment of the grant should be placed with the Council in the prescribed proforma attached.

2. The staff appointed on the project should be paid as indicated in the budget statement attached.

3. The approved duration of the scheme 3 years. The annual extension will be given after review of the work done on the scheme during the previous year.

4. A report on the progress made will be submitted to the Council as and when called for.

Contd.....2..

5. The institute will maintain a separate account of the receipts and the expenditure incurred on the scheme and will furnish a utilization certificate and an audited statement of account pertaining to the grant.

6. The other terms and conditions are indicated in Annexure I. The receipt of this letter may please be acknowledged.

Yours faithfully,

Admn. Officer
for Director General.

No. 5/8/3(9)/2010-ECD-I(B)

1. Copy together with a copy of the budget statement forwarded for information to: - Dr. Nand Kishore B. Professor and Unit Head. Deptt. Of Dermatology, Venerology and leprosy. Father Muller Medical College (**FMMC), Mangalore-575002**
2. Copy together with two copies of the budget statement forwarded to the Accounts Section, ICMR for information and necessary action. RFC No. ECD/NTF/8/2011-12 dated 7.6.2011
3. Copy together with two copies of the budget forwarded to the Finance Section. ICMR for compilation of the Council's budget.
4. IRIS Cell (Division of P & I). ICMR.
5. D.E.O. (Div. of ECD-I), ICMR.
6. Main file

for Director General.

Names and Designations of Co-Principal Investigator(s)

At Mumbai center

1) Dr. Nerges F Mistry, Director, fmr@fmrindia.org

2)Dr. Vivek V Pai,Director; Bombay leprosy project (BLP) Mumbai.blpproject@vsnl.net

3) Dr. R Ganapati , Ex Director (BLP); Mumbai

4) Mr. Uday Thakar, Secretary, (KNS). Dist- Raigadh,Maharastra

At Father Muller Medical college, Kankanadi Mangalore

1) Dr. Srinath M K, Assistant Professor srinath76@yahoo.co.in

At LEPRA India-BPHRC

1) Dr. V, Vijaya Lakshmi vijayavalluri@leprahealthinaction.in
2) Dr. Subbanna subbanna@leprahealthinaction.in
3) Dr. Ranganadha Rao ranganadh@leprahealthinaction.in
4) Dr. Porichcha
5) Dr. Suman Jain drsumanjain@hotmail.com
6) Dr. Rama Prasad

At NIE centre

1) Dr. P Krishna Murthy, DFIT, damienin@airtelbroadband.in
2) Dr. P. Vijaya Kumaran, DFIT, damienin@airtelbroadband.in
3) Dr. Rajendra Prasad, District Leprosy Officer, admhovsp@yahoo.com
4) Dr. R.Ramakrishnan, Scientist E, NIE, contact_murthybn@yahoo.co.in
5) Dr. Joseph.K.David, Scientist C, NIE, drjosephkdavid@gmail.com

Duration of Research Project: 3 years

i) Period which may be needed for collecting the data: **32months**

ii) Period that may be required for analyzing the data: **4months**

3. **Amount of grant-in-aid asked for (IN INR – IN LAKHS)**

	1st year	2nd year	3rd year	Total
A. FMR				
1. Staff	14.48	14.48	15.16	44.12
2. Contingencies				
Recurring	6.25	9.25	7.00	22.50
Non recurring	5.20			5.20
3. Overheads	2.07	2.37	2.22	6.66
Total	**28.00**	**26.10**	**24.38**	**78.48**
B. FMMC				
1. Staff	2.76	2.94	3.13	8.83
2. Contingencies	2.23	2.52	1.15	5.9
Recurring				
3. Overheads	0.25	0.27	0.21	0.73
Total	**5.24**	**5.73**	**4.49**	**15.46**
C. BPRCH				
1. Staff	2.88	3.18	3.55	9.61
2. Contingencies				
Recurring	4.10	4.28	3.82	12.20
Non recurring	1.15			1.15
3. Overheads	0.50	0.50	0.50	1.50
Total	**8.63**	**7.96**	**7.87**	**24.46**
D. NIE				
2. Contingencies				
Recurring	11.06	12.14	12.14	35.34
3. Overheads	0.55	0.60	0.60	1.75
Total	**11.61**	**12.74**	**12.74**	**37.09**
GRAND TOTAL				
(A+B+C+D)	**53.48**	**52.53**	**49.48**	**155.49**

Note – Budget for the participating Institutes are projected as per their request. **NIE** has projected budget for a total of 8 years, only 1st 3 years budget has been projected here.

Names and Designations of Co-Principal Investigator(s)

At Mumbai center

1) Dr. Nerges F Mistry, Director, fmr@fmrindia.org

2)Dr. Vivek V Pai,Director; Bombay leprosy project (BLP) Mumbai.blpproject@vsnl.net

3) Dr. R Ganapati , Ex Director (BLP); Mumbai

4) Mr. Uday Thakar, Secretary, (KNS). Dist- Raigadh,Maharastra

At Father Muller Medical college, Kankanadi Mangalore

1) Dr. Srinath M K, Assistant Professor srinath76@yahoo.co.in

At LEPRA India-BPHRC

1) Dr. V, Vijaya Lakshmi vijayavalluri@leprahealthinaction.in
2) Dr. Subbanna subbanna@leprahealthinaction.in
3) Dr. Ranganadha Rao ranganadh@leprahealthinaction.in
4) Dr. Porichcha
5) Dr. Suman Jain drsumanjain@hotmail.com
6) Dr. Rama Prasad

At NIE centre

1) Dr. P Krishna Murthy, DFIT, damienin@airtelbroadband.in
2) Dr. P. Vijaya Kumaran, DFIT, damienin@airtelbroadband.in
3) Dr. Rajendra Prasad, District Leprosy Officer, admhovsp@yahoo.com
4) Dr. R.Ramakrishnan, Scientist E, NIE, contact_murthybn@yahoo.co.in
5) Dr. Joseph.K.David, Scientist C, NIE, drjosephkdavid@gmail.com

Duration of Research Project: 3 years

i) Period which may be needed for collecting the data: **32months**

ii) Period that may be required for analyzing the data: **4months**

E-mail: kirankatoch@rediffmail.com

Fax No: 91 05622331755

5. Institutional ethical clearance and Project approval: **Will be obtained shortly**
6. Is radio tagged material proposed to be used in the project either for clinical trials or experimental purposes -**No**
7. Involvement of Recombinant DNA/ Genetic Engineering work- **No**
8. IEC approval – **Will follow.**
9. Conflict of interest- **Nil**

DECLARATION AND ATTESTATION

i. I/We have read the terms and conditions for ICMR Research Grant. All necessary Institutional facilities will be provided if the research project is approved for financial assistance.

ii. I/We agree to submit within one month from the date of termination of the project the final report and a list of articles, both expendable and non-expendable, left on the closure of the project.

iii. I/ We agree to submit audited statement of accounts duly audited by the auditors as stipulated by the ICMR.

iv. It is certified that the equipment(s) is/are not available in the Institute/Department or these are available but cannot be spared for the project

v. It is further certified that the equipment(s) required for the project have not been purchased from the funds provided by ICMR for another project(s) in the Institute.

If any equipment already exists with the Department/Institute, the investigator should justify purchase of the another equipment.

Signature of the:

a) Principal Investigator ____ _____

(Dr. Vanaja P. Shetty)

b) Co-Investigator(s) _____

c) Head of the Department _____

Signature of the Head of the Institution with seal

(Dr. Nerges Mistry, Director)

Date: 15 September 2010

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/IEC/895/2012 *Date :* 09.08.2012

To,

Dr. Ramesh Bhat M

Prof & HOD

Dept. of Dermatology, Venereology & Leprosy

Father Muller Medical College

Mangalore.

Dear Dr. Ramesh Bhat M,

Subject : IEC approval for the Study **"Safety and Efficacy of a 60% Formic Acid formulation combined with a hydrocolloid patch for the treatment of Corns/ Calluses"**

Your study entitled "Safety and Efficacy of a 60% Formic Acid formulation combined with a hydrocolloid patch for the treatment of Corns/ Calluses" was discussed during the meeting and it was approved.

Yours Sincerely,

Dr. B. Sanjeev Rai
Secretary
Institutional Ethics Committee

Secretary
Institutional Ethical Committee
Father Muller Medical College
Mangalore-575002

unigroup

From Unigroup Denmark

Study Title: (ISD study)
Role of scalp cleansers in the management of Infantile seborrheic dermatitis (ISD).

A comparative study of Spray cleanser containing Squalane, GLA and Viatmin E(Unigroup) with a Shampoo cleanser containing Cocamidopropyl Betaine, PEG-80 Sorbitan Laurate, Sodium Trideceth Sulfate (Johnson's baby shampoo)

Amount sent 3,200$s

Towards Initial Payment(Includes Hospital charges, PI , Coordinator's charges, Trial expenses)

Unigroup ApS
Diplomvej 373
DK-2800 Lyngby

Tel. +45 70 22 28 18
Fax +45 70 22 28 19

E-mail
info@unigroup.dk

CVR No. [illegible]
VAT No. [illegible]

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/1025/2012 *Date :* 07.12.2012

To,

Dr. Ramesh Bhat

Prof & HOD

Dept. of Dermatology, Venereology & Leprosy,

Father Muller Medical College,

Mangalore.

Dear Dr. Ramesh Bhat,

Subject : FMIEC approval for the Study **"A study of epidemiology, clinical, histopathological characterstics and immunohistochemical findings in patients with Lichen planus pigmentosus"**

Your study entitled "A study of epidemiology, clinical, histopathological characterstics and immunohistochemical findings in patients with Lichen planus pigmentosus" was discussed during the meeting and it was approved.

Yours Sincerely,

Dr. B. Sanjeev Rai

Secretary

Father Muller Institutional Ethics Committee

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

A clinico-epidemiological, dermoscopic and histopathological study of Dermatosis Papulosa Nigra in a tertiary care hospital of South India

Chief investigator- Dr. Nelee Bisen

Co-investigators- Dr. Ramesh Bhat, Dr. Sukumar D,

Dr. Rachel Pavey, Dr. Deepti D'Souza

The study would be conducted in Father Muller Medical College and Hospital, Mangalore

INTRODUCTION

Dermatosis papulosa nigra (DPN) is a benign cutaneous condition which occurs commonly in dark skinned people especially Asians and African Americans. It is considered as one of the variants of seborrheic keratosis. Females are affected more frequently than males.[1] It usually begins in adolescence and its incidence as well as the number and size of individual lesions, increases with age. Clinically DPN presents as multiple, small, hyperpigmented, asymptomatic papules mostly on the face and also on neck, upper back, and chest. Dermatosis papulosa nigra is likely to be genetically determined, with 40-54% of patients having a family history of involvement. It is believed to be caused by a nevoid developmental defect of the pilosebaceous follicle. Hairston et al have suggested that it should be classified within the group of epithelial nevi.[2]

Histologically, dermatosis papulosa nigra resembles seborrheic keratosis showing hyperkeratosis, irregular acanthosis, keratin-filled invaginations of the epidermis (horn cysts), and marked hyperpigmentation of the basal layer. However depending upon the morphology, seborrheic keratosis has various histopathological variants like classic acanthotic type, adenoid/ reticulate type, hyperkeratotic type, clonal type etc. Dermoscopic findings of seborrheic keratosis include Comedo-like (CL) openings, milia-like (ML) cysts, fissures and ridges (FR), fingerprint (FP)-like structures, moth-eaten (ME) border, hairpin (HP) blood vessels, network-like (NL) structures, and sharp demarcation (SD).[3] But specific dermoscopic findings for DPN have not been described. Treatment is usually sought for cosmetic reasons. Abrasive curettage, superficial liquid nitrogen cryotherapy, electrodesiccation followed by curettage and laser therapy have been shown to be effective.[4,5]

NEED FOR STUDY

DPN is one of the very commonly encountered skin lesions in Indian population. However, there is lack of data relating to its clinical, dermoscopic and histopathological correlation. This study may provide useful information regarding the etiology and pathology of DPN.

AIMS

1. To study the clinical characteristics of patients with Dermatosis papulosa nigra (DPN).

2. To correlate the clinical findings with dermoscopic and histopathological findings in DPN.

MATERIALS AND METHODS

Source of data collection

Patients attending Dermatology OPD, Father Muller Medical College and Hospital, Mangalore with clinical diagnosis of DPN

Inclusion criteria-

- Age more than 18 years
- Patients willing to participate in the study

Exclusion criteria-

- Patients not willing for biopsy
- Uncooperative patients

Method of data collection

A written informed consent will be taken from all patients.

Detailed history taking and thorough clinical examination will be done. The following parameters will be recorded: age, sex, age of onset, duration, family history, site, number and size of lesions and their morphology. Dermoscopy will be performed in all cases in randomly chosen pigmented lesions. 3 mm punch biopsies will be taken from the lesions and evaluated for histopathological findings. For the descriptive statistics, the SPSS software package will be used.

Sample size - 100

Study period

January 2012 to December 2013

REFERENCES

1. Grimes PE, Arora S, Minus HR, Kenney JA Jr. Dermatosis papulosa nigra. Cutis. Oct 1983;32(4):385-6.
2. Hairston MA Jr, Reed RJ, Derbes VJ. Dermatosis papulosa nigra. Arch Dermatol. May 1964;89:655-8.
3. Malvehy J, Puig S, Braun RP, Marghoob AA, Kopf AW, editors. Handbook of dermoscopy. 1 st ed. London: Taylor and Francis; 2006. p. 10-20.
4. Polder KD, Landau JM, Vergilis-Kalner IJ, Goldberg LH, Friedman PM, Bruce S. Laser eradication of pigmented lesions: a review. Dermatol Surg. 2011 May;37(5):572-95.
5. Garcia MS, Azari R, Eisen DB. Treatment of dermatosis papulosa nigra in 10 patients: a comparison trial of electrodesiccation, pulsed dye laser, and curettage. Dermatol Surg. 2010 Dec;36(12):1968-72.

PROFORMA

Name- Age- Sex-

Hospital number- Date-

Address- Mobile no.-

History-

Age of onset-

Duration of onset-

H/O progression of lesions-

H/O any associated symptom-

H/O exposure to sunlight-

Occupation-

Family H/O similar lesions-

Any systemic disease-

Any other relevant history-

Examination-

Morphology and site of lesions-

Dermoscopy findings –

Histopathology findings –

INFORMED CONSENT FORM

Title: **A clinico-epidemiological, dermoscopic and histopathological study of Dermatosis Papulosa Nigra in a tertiary care hospital of South India.**

Name of the Research Subject:

Age of the Research Subject

I have been explained in detail about this study, the potential benefits and side effects of the biopsy procedure and dermoscopy.

I understand that my participation in the study is voluntary and that I have the right to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

I understand that my taking part in this study will be kept confidential and my identity will not be revealed in any circumstances.

I agree to take part in the above study.

_____ _____

Signature of the research subject Date

_____ _____

Signature of the investigator Date

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

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/1804/2014 *Date :* 12.08.2014

To,

Dr. Jacintha Martis
Principal Investigator
Dept. of Dermatology,
Father Muller Medical College Hospital,
Kankanady, Mangalore.

Dear Dr. Jacintha Martis,

Subject : IEC approval for the Study **"A Phase 3, Multicenter, Three Arm, Randomised, double blind, active controlled, parallel study to evaluate the efficacy and safety of Tretinoin (Microsphere) 0.4% and Clindamycin 1% combination Gel in Comparison to Tretinoin 0.025% Gel and Clindamycin 1% gel in the treatment of Acne Vulgaris"**

Your study entitled "A Phase 3, Multicenter, Three Arm, Randomised, double blind, active controlled, parallel study to evaluate the efficacy and safety of Tretinoin (Microsphere) 0.4% and Clindamycin 1% combination Gel in Comparison to Tretinoin 0.025% Gel and Clindamycin 1% gel in the treatment of Acne Vulgaris" was discussed during the IEC meeting held on 9th August 2014 and it was approved.

You are not to start your study till you get a registration done by Clinical trial Registry. You are requested to submit the CTRI registration number to the office of the undersigned.

Yours Sincerely,

Dr. B. Sanjeev Rai
Secretary
Father Muller Institutional Ethics Committee

Secretary
Father Muller Institutional Ethics Committee
Father Muller Medical C...

FATHER MULLER MEDICAL COLLEGE

(A unit of Father Muller Charitable Institutions)
Father Muller Road, Kankanady, Mangalore-575002

FMMC/GEN/184/2014

27.05.2014

The Director,
F.M.C.I

Dear Rev. Father,

Enclosed herewith the letter received from the Department of Atomic Energy (DAE) and Board of Research in Nuclear Sciences (BRNS) related to the approval and sanction to the research project titled "Identification of specific variability parameters and pulse patterns for disease characterization using peripheral pulse analyzer" under my guidance an amount of Rs. 14,23,100/- of which Rs. 8,33,400/- for I Year and Rs. 5,00,150/- for II Year.

This is for your kind information.

Thanking you,

Yours faithfully,

Dr. Jayaprakash Alva
D E A N

C.C: The Administrator, FMMC/ CMS/ File

jp/jp

सत्यमेव जयते

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

Shri D. K. Dalal
Programme Officer (ATC)

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

No. 34/14/18/2014-BRNS/ 0310-11 Date: 16 MAY 2014

OFFICE MEMORANDUM

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

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

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

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

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

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

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

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

3. The expenditure involved is debitable to:

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

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

Sd/-
(D. K. Dalal)

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

FATHER MULLER MEDICAL COLLEGE HOSPITAL

ADM/FMMCH/085 /2013 *26.02.2013*

To,

Dr.Rochelle C Monteiro
Senior Resident
Department of Dermatology
FMMCH

Dear Dr.Rochelle,

Ref: Your letter no FMMC/DERM/GEN/310/2013 dated 29.01.2013
Sub: A randomized comparative study of the efficacy of intralesional 5-FU VS combined intralesional 5-FU and traiamcinolone acetonide in the treatment of keloids - reg

In response to your above letter, it has been decided to grant concession to 50 patients under the "Randomized Comparative Study for treatment of Keloids". These patients will be given 100% concession on the procedural charges but the cost of the medicines will have to be borne by the patients.

Bills for these patients must mention "DERMATOLOGY KL". These bills are to be accounted for under the "Research Cell".

With regards,

Rev.Fr Richard Coelho
ADMINISTRATOR

cc:
Director – for information
Dr Ramesh Bhat- HOD Dermatology
I/C- Billing – with a request to raise the bill
I/C – Accounts – with a request to credit 100% amount of the bill from Father Muller Research Centre
File

rc/ld

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/2514/2015 *Date* : 14.10.2015

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: CIGE025EIN01

Protocol Title: "A prospective, Post Marketing Surveillance study to study the safety and effectiveness of omalizumab in Indian patients with Chronic Spontaneous Urticaria refractory to standard of care"

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 CIGE025EIN01

entitled "A prospective, Post Marketing Surveillance study to study the safety and effectiveness of omalizumab in Indian patients with Chronic Spontaneous Urticaria refractory to standard of care" on 10th October 2015.

FATHER MULLER INSTITUTIONAL ETHICS COMMITTEE

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

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

FMMC/FMIEC/2389/2015 14.08.2015

Ref. No : ..... *Date :* .....

Protocol title: "Antifungal drug sensitivity in treatment of dermatophytic infections"
Principal Investigator: : Dr. Jyothi Jayaraman
Name & Address of Institution : Dr. Jyothi Jayaraman Dept. of Dermatology, Father Muller Medical College, Kankanady, mangalore – 575002.
New review ✓ **Revised review** **Expedited review**
Date of review: 08/08/2015 **Date of previous review, if revised application:** Nil
Decision of the Ethics Committee: > Recommended ✓ > Recommended with suggestions > Revision/ Resubmission > Rejected
Suggestions /Reasons/Remarks: Nil
Recommended for a period of : 1 Year

Please note:

> Inform Ethics Committee immediately in case of any adverse events and serious adverse events.
> Inform Ethics Committee in case of any change of study procedure, site and investigator.
> This permission is only for a period mentioned above. Annual report to be submitted to Ethics Committee.
> Members of Ethics committee have right to monitor the trail with prior intimation.

You are not to start your study till you get a registration done by Clinical trial Registry. You are requested to submit the CTRI registration number to the office of the undersigned.

Dr. B. Sanjeev Rai
Member Secretary
Father Muller Institutional Ethics Committee

FATHER MULLER INSTITUTIONAL ETHICS COMMITTEE

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

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

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Dr. Ashok Shenoy
Professor of Pharmacology
KMC, Mangalore-575001
Phone : +919880530703
E-mail: ashok.shenoy@manipal.edu

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

FMMC/FMIEC/4276/2017... *Date :* ....23.05.2017.....

Protocol title: "A multicentric study to evaluate the host and pathogen factors in recurrent dermatophytoses"
Protocol No: 5174/17
Principal Investigator: Dr. Ramesh Bhat
Name & Address of Institution : Dr. Ramesh Bhat Dept. of Dermatology Father Muller Medical College, Kankanady, Mangalore – 575002
New review: Exempt review **Expedited review** **Full review** ✓
Review of Revised Submission: Nil
Date of review: 19/05/2017 **Date of previous review, if revised application:**
Decision of the Ethics Committee: > Approved > Approved with suggestions ✓ > Revision/ Resubmission > Rejected
Suggestions /Reasons/Remarks: Do CTRI registration of the study and submit the registration No. Have the patient information sheet and informed consent form in Kannada.
Recommended for a period of : 1 Year

Please note:

> Inform Ethics Committee immediately in case of any adverse events and serious adverse events.
> Inform Ethics Committee in case of any change of study procedure, site and investigator.
> This permission is only for a period mentioned above. Annual report to be submitted to Ethics Committee.
> Members of Ethics committee have right to monitor the trial with prior intimation.

Following Members of the Committee Ratified the Expedited Review and Approved the Research Proposal.

Dr.Ashok Shenoy	Professor of Pharmacology	Chairperson
Mr.Eric Sequeira	Lawyer	Member –legal expert
Dr.Shivashankara A.R.	Biochemistry faculty	Member Secretary
Dr.Sudhir Prabhu	Community Medicine Faculty	Joint Secretary
Dr.Safeek AT	Professor of Psychiatry	Member-Clinician
Dr .Kurian PJ	Homeopathy faculty	Member –Homeopathy Expert
Mr.Sudeep Pais	Physiotherapy Faculty	Member –Physiotherapy Expert
Fr.Dr.Leo D'Souza	Director of Applied Biology Laboratory	Member-Ethicist /Philosopher
Ms. Anuradha Shetty	Faculty of School of Social Work	Member-Social Scientist

Dr. Shivashankara A R
Member Secretary
Father Muller Institutional Ethics Committee

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

FATHER MULLER INSTITUTIONAL ETHICS COMMITTEE

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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/2388/2015 *Date* : .....14.08.2015.....

Protocol title: "A multicentric, prospective and retrospective study of Stevens Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) & SJS-TEN overlap in Indian scenario"
Principal Investigator: Dr. Ramesh Bhat M
Name & Address of Institution : Dr. Ramesh Bhat M Prof. & HOD, Dept. of Dermatology, Father Muller Medical College, Kankanady, Mangalore – 575002.
New review ✓ **Revised review** **Expedited review**
Date of review: 08/08/2015 **Date of previous review, if revised application:** Nil
Decision of the Ethics Committee: > Recommended ✓ > Recommended with suggestions > Revision > Rejected
Suggestions /Reasons/Remarks: Nil
Recommended for a period of : 1 Year

Please note:

> Inform Ethics Committee immediately in case of any adverse events and serious adverse events.
> Inform Ethics Committee in case of any change of study procedure, site and investigator.
> This permission is only for a period mentioned above. Annual report to be submitted to Ethics Committee.
> Members of Ethics committee have right to monitor the trail with prior intimation.

You are not to start your study till you get a registration done by Clinical trial Registry. You are requested to submit the CTRI registration number to the office of the undersigned.

Dr. B. Sanjeev Rai
Member Secretary
Father Muller Institutional Ethics Committee

FATHER MULLER INSTITUTIONAL ETHICS COMMITTEE

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

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

Ref. No. FMMC/FMIEC/4332/2017 *Date :* 16.08.2017

Protocol title: "Comparative study of nail whitening solution with 5% w/ vamorolfine nail lacquer in treatment of onychomycosis "
Protocol No: 5228/17
Principal Investigator: Dr. Ramesh Bhat & Dr. Jyothi Jayaraman
Name & Address of Institution : Dr. Ramesh Bhat & Dr. Jyothi Jayaraman Dept. of Dermatology Father Muller Medical College, Kankanady, Mangalore – 575002
New review: Exempt review **Expedited review** **Full review ✓**
Review of Revised Submission: Nil
Date of review: 12/08/2017 **Date of previous review, if revised application:**
Decision of the Ethics Committee: > Approved > Approved with suggestions ✓ > Revision/ Resubmission > Rejected
Suggestions /Reasons/Remarks: Have the patient information sheet and informed consent form in Kannada.
Recommended for a period of : One Year

Please note:

> Inform Ethics Committee immediately in case of any adverse events and serious adverse events.
> Inform Ethics Committee in case of any change of study procedure, site and investigator.
> This permission is only for a period mentioned above. Annual report to be submitted to Ethics Committee.
> Members of Ethics committee have right to monitor the trial with prior intimation.

Following Members of the Committee Ratified the Full Review and Approved the Research Proposal.

Mr.Eric Sequeira	Lawyer	Member –legal expert
Dr.Shivashankara A.R.	Biochemistry faculty	Member Secretary
Dr.Sudhir Prabhu	Community Medicine Faculty	Joint Secretary
Dr.Varadraj Shenoy	Professor of Pediatrics	Member-Clinician
Dr.Safeek AT	Professor of Psychiatry	Member-Clinician
Dr .Kurian PJ	Homeopathy faculty	Member –Homeopathy Expert
Mr.Sudeep Pais	Physiotherapy Faculty	Member –Physiotherapy Expert
Fr.Dr.Leo D'Souza	Director of Applied Biology Laboratory	Member-Ethicist /Philosopher
Mrs.Veena Manoj	MA, BEd. Qualified	Member – Lay Person
Ms. Anuradha Shetty	Faculty of School of Social Work	Member-Social Scientist
Dr. Anup Kumar Shetty	Associate Professor of Microbiology	Member - Clinician

Dr. Shivashankara A R
Member Secretary
Father Muller Institutional Ethics Committee

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

FATHER MULLER INSTITUTIONAL ETHICS COMMITTEE

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Prof. of Obstetrics & Gynaecology
Kasturba Medical College
Mangalore - 575 001
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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/2602/2015 *Date :* 20.11.2015

Protocol title: "A STUDY OF THE ANEROBIC BACTERIA IN ACNE AND IN VITRO ANTIBIOTIC SUSCEPTIBILITY PATTERNS OF ORAL AND TOPICAL ANTIBIOTICS IN THE TREATMENT OF ACNE"
Principal Investigator : Dr. Rochelle C Monteiro
Name & Address of Institution : Dr. Rochelle C Monteiro Dept. of Dermatology, Father Muller Medical College, Kankanady, Mangalore – 575002.
New review **Revised review ✓** **Expedited review**
Date of review: 13/11/2015 **Date of previous review, if revised application:** 10/10/2015
Decision of the Ethics Committee: > Recommended ✓ > Recommended with suggestions > Revision/ Resubmission > Rejected
Suggestions /Reasons/Remarks: Nil
Recommended for a period of : 1 Year

Please note:

> Inform Ethics Committee immediately in case of any adverse events and serious adverse events.
> Inform Ethics Committee in case of any change of study procedure, site and investigator.
> This permission is only for a period mentioned above. Annual report to be submitted to Ethics Committee.
> Members of Ethics committee have right to monitor the trail with prior intimation.

You are not to start your study till you get a registration done by Clinical trial Registry. You are requested to submit the CTRI registration number to the office of the undersigned.

Dr. B. Sanjeev Rai
Member Secretary
Father Muller Institutional Ethics Committee

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

Clinical Trial Details (PDF Generation Date :- Wed, 09 Mar 2016 07:15:19 GMT)

CTRI Number	CTRI/2016/03/006724 [Registered on: 09/03/2016] - **Trial Registered Prospectively**
Last Modified On	02/03/2016
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group, Placebo Controlled Trial
Public Title of Study	A study for Evaluation of effectiveness and Safety of Minoxidil (5%) plus Finasteride (0.1%) Solution in Adult Male Patients with Androgenetic Alopecia
Scientific Title of Study	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%) plus Finasteride (0.1%) Lipid Solution in Comparison with Minoxidil (5%) Lipid Solution and Finasteride (0.1%) Lipid solution in Adult Male Patients with Androgenetic Alopecia

Secondary IDs if Any

Secondary ID	Identifier
605-12, Version: 2.0, Date: 31/07/2015	Protocol Number

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

Details of Principal Investigator	
Name	Rajesh C N
Designation	Assistant General Manager
Affiliation	Lambda Therapeutic Research Ltd
Address	Plot No. 38, Near Silver Oak Club S. G. Highway, Gota Ahmadabad GUJARAT 380061 India
Phone	07940202051
Fax	07940202021
Email	rajeshcn@lambda-cro.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr Ankit Ranpura
Designation	Manager
Affiliation	Lambda Therapeutic Research Ltd
Address	Plot No. 38, Near Silver Oak Club S. G. Highway, Gota Ahmadabad GUJARAT 380061 India
Phone	07940202074
Fax	07940202021
Email	ankitranpura@lambda-cro.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr Manjunath K
Designation	General Manager
Affiliation	Lambda Therapeutic Research Ltd
Address	Plot No. 38, Near Silver Oak Club S. G. Highway, Gota Ahmadabad GUJARAT 380061 India
Phone	07940202290

Fax	07940202021
Email	manjunathk@lambda-cro.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> Intas Pharmaceuticals Ltd., 2nd Floor, Chinubhai Center, Ashram Road, Ahmedabad 380-009, Gujarat, India, Tel. No.: 07926576655, Fax: 07926578862

Primary Sponsor

Primary Sponsor Details	
Name	Intas Pharmaceuticals Ltd
Address	2nd Floor, Chinubhai Center, Ashram Road, Ahmedabad 380-009, Gujarat, India, Tel. No.: 07926576655, Fax: 07926578862
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
NA	NA

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr AM Jayaraaman	Chennai Meenakshi Multispeciality Hospital	Dept. of Clinical Research, Dept. of Dermatology, Room no. 12, New#72, Old#172, Luz Church Road, Mylapore-600004 Chennai TAMIL NADU	9444119274 clinsolve@gmail.com
Dr Ramesh Bhatt	Father Muller Medical College Hospital	Room No. 65, Dept. of Dermatology, Father Muller Road, Kankanady, Mangalore-575002 Dakshina Kannada KARNATAKA	9845084224 rameshderma@gmail.com
Dr Jayesh Mukhi	Government Medical College & Hospital	Department of skin, VD & leprology, Room No. 1, Government Medical College & Hospital, Medical college square road, - 440003, Nagpur MAHARASHTRA	9822467967 jayesh.mukhi@gmail.com
Dr Rachita S Dhurat	Lokmanya Tilak Municipal Medical College & General hospital	Room No. 16, 2nd Floor, Dept. of Dermatology, Dr. Babasaheb Ambedkar Road, Sion-400022 Mumbai MAHARASHTRA	9870390057 rachitadhurat@yahoo.co.in
Dr T K Sumathy	M.S. Ramaiah Medical College & Hospital	Room No. 104, Dept. of Dermatology, MSR Nagar, MSRIT Post-560054 Bangalore KARNATAKA	9845163009 tksumathy@gmail.com
Dr O R Jayanthi	Meenakshi Mission Hospital & Research Centre	Dept. of Dermatology, Room no. 8, Melur Road, Lake Area-	9489378314 drjayanthi@gmail.com

		625107, Madurai TAMIL NADU	
Dr Hemant Talnikar	Padmashree Dr. D Y Patil Medical College, Hospital and Research Centre	Dept. of Dermatology, Room no. 18, Sant Tukaram Nagar, Pimpri-411018 Pune MAHARASHTRA	9422087726 hemant.vasant16@gmail.com
Dr V V V Satyanarayana	Rajiv Gandhi Institute of Medical Sciences & RIMS Government General Hospital	Room No. 16, Department of Dermatology, Research Wing, 2nd Floor, Beside Female Medical Ward-532001 Srikakulam ANDHRA PRADESH	9963744345 vellasatyanarayana@gmail.com
Dr Bhavik Bhavsar	Ratandeep Multispeciality Hospital	2nd floor, Dept. of Dermatology, Room no. 15, Nakshatra complex, Above HDFC Bank, Maninagar cross roads, Maninagar- 380008 Ahmadabad GUJARAT	9825953263 bhavikbhavsar78@gmail.com
Dr S C Bharija	Sir Ganga Ram Hospital	Dept. of Dermatology, Room no. 14, Old Rajinder Nagar-110060 New Delhi DELHI	9891667044 drscbharija@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Ethics Committee, Chennai Meenakshi Multispeciality Hospital, Dr. A.M. Jayaraaman	Submittted/Under Review	No Date Specified	No
Ethics Committee, Lokmanya Tilak Municipal Medical College & Lokmanya Tilak Municipal General Hospital, Dr. Rachita S Dhurat	Submittted/Under Review	No Date Specified	No
Ethics Committee, M.S. Ramaiah Medical College & Hospitals, Dr. T. K. Sumathy	Approved	05/02/2016	No
Ethics committee, Ratan Deep Multispecialty Hospital, Dr. Bhavik Bhavsar	Submittted/Under Review	No Date Specified	No
Ethics Committee-Dr. D. Y. PatilVidyapeeth, Dr Hemant Talnikar	Submittted/Under Review	No Date Specified	No
Father Muller Institutional Ethics Committee, Dr. Ramesh Bhatt	Submittted/Under Review	No Date Specified	No

Institutional Ethics Committee, Government Medical College & Hospital, Dr Jayesh Mukhi	Submittted/Under Review	No Date Specified	No
Institutional Ethics Committee, Meenakshi Mission Hospital & Research Centre, Dr. O. R. Jayanthi	Submittted/Under Review	No Date Specified	No
Institutional Ethics Committee, Rajiv Gandhi Institute of Medical Sciences & RIMS Government General Hospital, Dr. V. V. V. Satyanarayana	Submittted/Under Review	No Date Specified	No
Sir Ganga Ram Hospital Ethics Committee, Dr. S. C. Bharija	Submittted/Under Review	No Date Specified	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	17/12/2015

Health Condition / Problems Studied

Health Type	Condition
Patients	Adult Male Patients with Androgenetic Alopecia

Intervention / Comparator Agent

Type	Name	Details
Intervention	Arm A: Fixed dose combination of Minoxidil (5%) plus Finasteride (0.1%) as lipid solution.	Dose: 01 ml; Frequency: twice daily; Mode of Administration: Topically Duration of treatment: 24 weeks
Comparator Agent	Arm B: Minoxidil (5%) lipid solution. Arm C: Finasteride (0.1%) lipid solution. Arm D: Matching lipid solution placebo.	Dose: 01 ml; Frequency: twice daily; Mode of Administration: Topically Duration of treatment: 24 weeks

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	45.00 Year(s)
Gender	Male
Details	1. Male patients in good general physical and mental health, with Androgenetic alopecia. 2. Subjects willing to provide written informed consent, indicating that they thoroughly understand the purpose of and procedures required for the study and are willing to participate in the study.

Exclusion Criteria

Exclusion Criteria	
Details	1. Concomitant dermatological disorders on the scalp other than Androgenetic alopecia. 2. Serious cardiovascular diseases (uncontrolled hypertension, angina pectoris, myocardial infarction, etc.), renal diseases or hepatic diseases. 3. History of drug hypersensitivity (including contact dermatitis to cosmetics), breast disorders (including gynecomastia, breast enderness) or testicular disorders (testicular growth, testicular pain). 4. History of treatment with a systemic or locally acting medication which may interfere with the study objectives, such as Minoxidil

	treatment in the 06 months prior to dosing, Finasteride treatment in the 12 months prior to dosing, or treatment with other investigational hair growth products in the 06 months prior to dosing 5. Ongoing use of prohibited medications (as specified in the protocol) 6. Use of any investigational product within 03 months prior dosing of study drug 7. Judged by the investigator as otherwise being unsuitable for participation in this trial.

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Not Applicable
Blinding/Masking	Participant, Investigator, Outcome Assessor and Date-entry Operator Blinded

Primary Outcome

Outcome	Timepoints
1) Change from baseline in Target Area Hair Count (TAHC) 2) Change in the Subject Self Assessment (SSA) Score	Baseline to week 24

Secondary Outcome

Outcome	Timepoints
1) Change in the Investigator assessment score 2) Evaluation of pharmacokinetic profile	At the end of study

Target Sample Size	**Total Sample Size=**160 **Sample Size from India=**160
Phase of Trial	Phase 4
Date of First Enrollment (India)	01/04/2016
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**7 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	NA
Brief Summary	Many factors cause clinical hair loss, or alopecia, including endocrine abnormalities, genetic predisposition, systemic illness, drugs, psychological abnormalities, diet, trauma, infections, autoimmunity, and structural hair defects. Because of the multiplicity of disorders that can result in hair loss, a thorough history and physical examination are important, and ancillary laboratory workup could be necessary. Androgenetic Alopecia (AGA) produces patterned hair loss, beginning with bitemporal recession of the frontal hair line, followed by diffuse thinning over the vertex. Over time there is complete hair loss centrally on the vertex, producing a bald patch. Currently there are two treatments available for the treatment of AGA in men: topical Minoxidil and oral Finasteride. The efficacy study with the combination of topical Minoxidil and oral Finasteride indicates that the best results recorded with a combination of Finasteride and Minoxidil compared with either of the treatment alone. Subjects receiving Finasteride in combination with Minoxidil showed statistically significant improvement ($p<0.05$) over Minoxidil only

recipients. No significant side-effects related to the drugs were observed. The study with topical application of Minoxidil and Finasteride indicated that the combination treatment leads to better hair growth. Combination therapy was thrice as effective as any one of them. Further, the quality of the newly grown hair was also better in the combination group.

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")

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Kankanady,
Mangalore-575002

(Hereinafter referred to as the "Investigator")

AND:

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

(Hereinafter referred to as the "Institute")

WHEREAS:

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

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

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

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

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

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

1 Definitions

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

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

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

2 Investigator/Institution responsibilities

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

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

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

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

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

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

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

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

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

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

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

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

f) Inform the Ethics Committee of study closure.

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

h) Handling and storage of compound according to protocol.

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

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

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

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

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

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

3 CRO responsibilities

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 Payment terms

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

6 Period of validity of the Agreement

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

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

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

7 Data ownership / Intellectual property rights

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

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

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

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

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

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

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

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

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

8 Publication

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

9 Indemnity / Liability

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

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

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

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

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

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

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

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

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

10 Compensation / Insurance

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

11 Confidentiality

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

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

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

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

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

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

11.7 Confidential information shall not include any information which:

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

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

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

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

e) Has been permitted to be disclosed by Sponsor.

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

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

12 Privacy

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

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

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

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

13 Independent Contractor

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

14 Termination

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

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

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

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

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

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

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

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

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

15 Record retention

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

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

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

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

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

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

16 Representation and Warranty

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

17 Laws and Jurisdiction

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

18 Notice

18.1 All notices shall be delivered to the following addresses:

CRO

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

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

Institution

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

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

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

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

19 Miscellaneous

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

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

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

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

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

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

LAMBDA:

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

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

Witness:

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

Witness Name : **Dr. Dharmesh Domadia**

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

Institute:

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

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

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

Witness:

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

Witness Name: **Mrs. PreethaLinet Pereira**

Designation: Secretary

Department/Work Unit: Department Of Dermatology

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

Investigator: Dr. Ramesh Bhat M.

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

Principal Investigator:

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

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

Witness:

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

Witness Name: Laveena Rodrigues

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

Schedule A

Study Protocol

Protocol No: 175-14

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

Schedule B
Budget and Payment Agreement:

(I) Budget

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

Note:

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

The above budget also includes the

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

(II) Payment Schedule

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

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

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

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

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

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

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

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

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

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

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

Method of payment

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

Payee: Father Muller Research Centre

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

PAN / TAN Number: AAATF0345D0

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

(III) Per Patient Fee, Payment Schedule and Terms

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

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

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

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

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

- EC submission fee

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

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

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

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

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

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

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

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

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

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

FATHER MULLER INSTITUTIONAL ETHICS COMMITTEE

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

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

CHAIRPERSON
Dr. Ashok Shenoy
Professor of Pharmacology
KMC, Mangalore-575001
Phone : +919880530703
E-mail: ashok.shenoy@manipal.edu

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

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

To,

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

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

Dear Dr.Sukumar D,

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

We have rechecked for following documents:

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

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

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

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

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

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

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

We approve the trial to be conducted in its presented form

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

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

Yours Sincerely,

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

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

Rajiv Gandhi University of Health Sciences, Karnataka
4th T Block, Jayanagar, Bangalore – 560 041

PROCEEDINGS OF THE RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES, BANGALORE

Sub: Financial assistance for Research under RGUHS sanction of grant-in-aid for various teaching faculties of affiliated institutions of RGUHS – reg.

Ref: 1. University notification No: RGUHS/Adv.Research: 2015-16 dated:29-04-2015
2. Approval of the Syndicate in its 116th meeting held on 16th December 2015.

- - -

READ:

One of the main objectives of the University is to promote research activities in the University and also affiliated colleges. In this regard University had invited applications for financial assistance for conducting of advanced research projects for the year 2015-16. University had received 366 research proposals. The University had earmarked Rs.5.00 crores in its budget estimate for the year 2015-16 for this purpose. In order to meet this expenditure the concerned Subject Experts as suggested by the concerned BOS PG chairpersons and the Expert Committee comprising of all the BOS PG chairpersons have scrutinized the proposals and shortlisted them based on the criteria set out by the University. Such of the proposals which have fulfilled the norms have been recommended by the Expert Committee for sanction of grants.

The Syndicate in its 116th meeting held on 16th December 2015 has approved to sanction the grant-in-aid as per the recommendations of Expert Committee for 159 selected proposals in medical, dental, pharmacy, ayurveda, nursing, physiotherapy, allied health sciences and BNYS faculties for the year 2015-16.

As per the decision of the Syndicate the following orders are made.

ORDER NO. RGU: Adv. Res.:Proposal-M-97: 2015-16 DATE:05-01-2016

Pursuant to the approval of the Syndicate, sanction is hereby accorded for release of grant-in-aid amounting to Rs. 4,85,000-00 (Rupees Four lakhs eighty five thousand only) towards research proposal "A Comparative and Correlative Study of

Professor and Head
Department of Biochemistry
Father Muller Medical College
Kankanady, Mangalore-575002

Glycoproteins, Enzymes and Oxidative Stress Markers in Blood and Saliva of Alcohol-Dependent Males" furnished by Dr Shivashankara A.R., Associate Professor of Biochemistry, Father Muller Medical College, Mangalore-575002. for the year 2015-16. The Grant-in-aid will be released in the name of Director/Principal of Father Muller Medical College, Mangalore subject to following terms and conditions mentioned hereunder.

1. The Principal / Head of Institution shall open a separate joint account for the financial grant released by RGUHS in the name of Principal / Head of the Institution and the Principal Investigator.
2. Principal / Head of the Institution and the Principal Investigator shall be responsible for the accounts and the proper utilization of the funds. The grants released shall be used only for research purpose.
3. 50% of the grant-in-aid approved by RGUHS shall be released as 1st installment. 25% of the grant-in-aid shall be released after the Utilization Certificate for the money released in the 1st installment is given. Balance of 15% shall be released after the Utilization Certificate for the money released in the 2nd installment is given. Remaining 10% will be released after the submission of Project Report to the University. Audit report shall be submitted along with every Utilization Certificate.

   The bifurcation of grant-in-aid as per the above criteria applicable to you is as follows:

1	Total grant-in-aid sanctioned	Rs. 4,85,000-00
2.	First Installment (50%)	Rs. 2,42,000-00
3.	Second Installment (25%)	Rs. 1,21,000-00
4.	Third Installment (15%)	Rs. 74,000-00
5.	Fourth Installment (10%)	Rs. 48,000-00

4. The project shall be completed within 2 years from the time of release of 1st installment of grant-in-aid. However, the University in deserving cases may extend this time frame.
5. Principal Investigator shall furnish project status report once in six months till the completion of the project.
6. During the research work, officials of the Expert Committee along with Subject Experts shall reserve the right of inspection.

Professor and Head
Department of Biochemistry
Father Muller Medical College
Kankanady, Mangalore-575002

7. All the details about the conduct of research activity along with documents should be properly maintained by the Principal Investigator. He/She should submit such details of research to monitoring committee or to the University whenever it is called for.
8. ICMR and MCI guidelines especially with regard to ethical issues shall be followed strictly in the research activity.
9. Regarding ethical issues in various faculties, the guidelines prescribed in the apex bodies or any other related authorities regarding the conduct of study should strictly be adhered to.
10. Research project shall be published in national/international indexed journals after the completion of the project. During such publication it is the duty of the Principal Investigator to acknowledge the assistance given by the University as a source of funding for the research activity.
11. In case the Principal Investigator discontinues the research work under unforeseen circumstances, the co-investigator shall continue the research work and complete the project with the approval of the University. It is the responsibility of the Principal/Head of the Institution to ensure, in such circumstances, that the research is completed with the co-investigator of the research project.
12. It is the responsibility of the Principal/Head of the Institution and Principal Investigator to ensure that research work is completed within the stipulated time.
13. The grants released by the University shall not be utilized for the purpose of purchase of equipments.
14. The honorarium for the supportive staff, purchase of consumables, tests carried outside the institution because of lack of infrastructural facilities in the institution, travel grants for attending conference for presenting the research work and for publication of papers in national / indexed journals shall be met out of the grant-in-aid.
15. After the completion of the project the entire project report shall be submitted to the University and will become property of the University.
16. If any of the conditions mentioned above are not adhered to by the Principal/ Head of the Institution and the Principal Investigator, University reserves the right to take appropriate action.
17. In research proposals involving clinical trials, if any untoward incidence occurs, it is the responsibility of the Principal Investigator and the

FATHER MULLER INSTITUTIONAL ETHICS COMMITTEE

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

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

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Phone : +919880530703
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SECRETARY
Dr. Shivashankara A.R.,
Associate Professor of Biochemistry,
Father Muller Medical College
Mangalore - 575 002
Phone : +919880146133
E-mail: arshiva72@gmail.com

Ref. No : FMMC/FMIEC/4451/2017

Date : 13.11.2017

Protocol Title:" A Prospective, observational post marketing surveillance study evaluate the effectiveness and safety of secukinumab in Indian patients with moderate to severe plague psoriasis requiring systemic therapy"
Protocol No:
Principal Investigator: Dr. Jyothi Jayaraman
Name & Address of Institution : Dept. of Dermatology Father Muller Medical College, Kankanady, Mangalore – 575002
New review: Exempt review **Expedited review** **Full review ✓**
Review of Revised Submission: 11.11.2017
Date of review:11.11.2017
Date of previous review, if revised application: 19.12.2016
Decision of the Ethics Committee: > Approved ✓ > Approved with suggestions > Revision/ Resubmission > Rejected
Suggestions /Reasons/Remarks: The changes in informed consent documents are reviewed and approved.
Recommended for a period of : One Year

Please note:

> Inform Ethics Committee immediately in case of any adverse events and serious adverse events.
> Inform Ethics Committee in case of any change of study procedure, site and investigator.
> This permission is only for a period mentioned above. Annual report to be submitted to Ethics Committee.
> Members of Ethics committee have right to monitor the trial with prior intimation.

Following Members of the Committee reviewed and Approved the Research Proposal.

Dr.Ashok Shenoy	Professor of Pharmacology	Chairperson
Mr.Eric Sequeira	Lawyer	Member –legal expert; vice chairman
Dr.Shivashankara A.R.	Biochemistry faculty	Member Secretary
Dr.Sudhir Prabhu	Community Medicine Faculty	Joint Secretary
Dr.Varadraj Shenoy	Professor of Pediatrics	Member-Clinician
Dr.Safeek AT	Professor of Psychiatry	Member-Clinician
Dr .Kurian PJ	Homeopathy faculty	Member –Homeopathy Expert
Mr.Sudeep Pais	Physiotherapy Faculty	Member –Physiotherapy Expert
Fr.Dr.Leo D'Souza	Director of Applied Biology Laboratory	Member-Ethicist /Philosopher
Mrs.Veena Manoj	MA, BEd. Qualified	Member – Lay Person
Prof .Irene Alvares	Professor Nursing	Member-Nursing expert
Dr. Anup Kumar Shetty	Microbiology Faculty	Member – Basic Medical Scientist
Mrs.Anuradha Shetty	School of Social Work faculty	Member- Social Scientist

Dr. Shivashankara A R
Member Secretary
Father Muller Institutional Ethics Committee

FATHER MULLER MEDICAL COLLEGE

ACCREDITED BY NAAC WITH 'A' GRADE

(FMMC is a Unit of Father Muller Charitable Institutions)

Father Muller Road
Kankanady
Mangaluru - 575 002
Karnataka, India.

Phone : 0824-2238000 (Prime Number)
: 0824-2238331 (Office)
: 0824-2238330
Tel / Fax : 0824-2436352 (Dean)
E-mail : deanfmmc@yahoo.com
Website : www.fathermuller.edu.in

Ref. No : .....

Date : .....

FMMC/Res/001/2018

28.07.2018

Dr Venkatesh G.S.,
Director, Advance Research,
Rajiv Gandhi University of Health Sciences,
4th 'T' Block, Jayanagar,
BANGALORE 560 041.

Sir,

Sub.: Request for change of Principal Investigatorship.
Ref.: Order No. RGU:Adv.Res.:Proposal-M-53:2015-16 dated 05.01.2016.

With reference to the above, we would like to bring to your kind notice that vide Order cited above, Dr Princy Louis Palatty was the Principal Investigator of the project entitled "Mechanistic studies to decipher the pathways responsible for the skin care effects of Sandalwood (Santalum album Linn), a medicinal plant indigenous to Karnataka: cell culture and in vitro studies".

Now Dr Princy Louis Palatty has resigned from our Institutions w.e.f. 24.07.2018. Hence, she will not be continuing as the Principal Investigator of the above project. Dr Shivashankara A.R., Associate Professor of Biochemistry has agreed to take over as the Principal Investigator for the above Project, as he is involved in this study and aware of the process.

Hence, I request you to kindly transfer the Principal Investigatorship to Dr Shivashankara A.R., Associate Professor of Biochemistry for the above Project.

Thanking you,

Yours faithfully,

FATHER MULLER MEDICAL COLLEGE
KANKANADY, MANGALORE - 575 002

DEAN

Rajiv Gandhi University of Health Sciences, Karnataka
4th T Block, Jayanagar, Bangalore – 560 041

PROCEEDINGS OF THE RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES, BANGALORE

Sub: Financial assistance for Research under RGUHS sanction of grant-in-aid for various teaching faculties of affiliated institutions of RGUHS – reg.

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READ:

One of the main objectives of the University is to promote research activities in the University and also affiliated colleges. In this regard University had invited applications for financial assistance for conducting of advanced research projects for the year 2015-16. University had received 366 research proposals. The University had earmarked Rs.5.00 crores in its budget estimate for the year 2015-16 for this purpose. In order to meet this expenditure the concerned Subject Experts as suggested by the concerned BOS PG chairpersons and the Expert Committee comprising of all the BOS PG chairpersons have scrutinized the proposals and shortlisted them based on the criteria set out by the University. Such of the proposals which have fulfilled the norms have been recommended by the Expert Committee for sanction of grants.

The Syndicate in its 116th meeting held on 16th December 2015 has approved to sanction the grant-in-aid as per the recommendations of Expert Committee for 159 selected proposals in medical, dental, pharmacy, ayurveda, nursing, physiotherapy, allied health sciences and BNYS faculties for the year 2015-16.

As per the decision of the Syndicate the following orders are made.

ORDER NO. RGU: Adv. Res.:Proposal-M-53: 2015-16 DATE: 05-01-2016

Pursuant to the approval of the Syndicate, sanction is hereby accorded for release of grant-in-aid amounting to Rs. 4,61,000-00 (Rupees Four lakhs sixty one thousand only) towards research proposal "Mechanistic studies to decipher the

pathways responsible for the skin care effects of Sandalwood (Santalum album Linn), a medicinal plant indigenous to Karnataka: cell culture and in vitro studies" furnished by Dr Princy L Palatty, Chair in UNESCO Bioethics South India Unit, Professor, Department of Pharmacology, Father Muller Medical College, Mangalore 575002 for the year 2015-16. The Grant-in-aid will be released in the name of Director of Father Muller Medical College, Mangalore subject to following terms and conditions mentioned hereunder.

1. The Principal / Head of Institution shall open a separate joint account for the financial grant released by RGUHS in the name of Principal / Head of the Institution and the Principal Investigator.
2. Principal / Head of the Institution and the Principal Investigator shall be responsible for the accounts and the proper utilization of the funds. The grants released shall be used only for research purpose.
3. 50% of the grant-in-aid approved by RGUHS shall be released as 1st installment. 25% of the grant-in-aid shall be released after the Utilization Certificate for the money released in the 1st installment is given. Balance of 15% shall be released after the Utilization Certificate for the money released in the 2nd installment is given. Remaining 10% will be released after the submission of Project Report to the University. Audit report shall be submitted along with every Utilization Certificate.

   The bifurcation of grant-in-aid as per the above criteria applicable to you is as follows:

1	Total grant-in-aid sanctioned	Rs. 4,61,000-00
2.	First Installment (50%)	Rs. 2,30,000-00
3.	Second Installment (25%)	Rs. 1,16,000-00
4.	Third Installment (15%)	Rs. 69,000-00
5.	Fourth Installment (10%)	Rs. 46,000-00

4. The project shall be completed within 2 years from the time of release of 1st installment of grant-in-aid. However, the University in deserving cases may extend this time frame.
5. Principal Investigator shall furnish project status report once in six months till the completion of the project.
6. During the research work, officials of the Expert Committee along with Subject Experts shall reserve the right of inspection.

7. All the details about the conduct of research activity along with documents should be properly maintained by the Principal Investigator. He/She should submit such details of research to monitoring committee or to the University whenever it is called for.
8. ICMR and MCI guidelines especially with regard to ethical issues shall be followed strictly in the research activity.
9. Regarding ethical issues in various faculties, the guidelines prescribed in the apex bodies or any other related authorities regarding the conduct of study should strictly be adhered to.
10. Research project shall be published in national/international indexed journals after the completion of the project. During such publication it is the duty of the Principal Investigator to acknowledge the assistance given by the University as a source of funding for the research activity.
11. In case the Principal Investigator discontinues the research work under unforeseen circumstances, the co-investigator shall continue the research work and complete the project with the approval of the University. It is the responsibility of the Principal/Head of the Institution to ensure, in such circumstances, that the research is completed with the co-investigator of the research project.
12. It is the responsibility of the Principal/Head of the Institution and Principal Investigator to ensure that research work is completed within the stipulated time.
13. The grants released by the University shall not be utilized for the purpose of purchase of equipments.
14. The honorarium for the supportive staff, purchase of consumables, tests carried outside the institution because of lack of infrastructural facilities in the institution, travel grants for attending conference for presenting the research work and for publication of papers in national / indexed journals shall be met out of the grant-in-aid.
15. After the completion of the project the entire project report shall be submitted to the University and will become property of the University.
16. If any of the conditions mentioned above are not adhered to by the Principal/ Head of the Institution and the Principal Investigator, University reserves the right to take appropriate action.
17. In research proposals involving clinical trials, if any untoward incidence occurs, it is the responsibility of the Principal Investigator and the

Institution to deal with the same and the University will not take any responsibility in this regard. The Principal Investigator is advised to enter into insurance schemes to meet any such adverse eventuality as per the decision of the IEC.

Further the Principal / Head of the Institution and Principal Investigator has to submit a joint affidavit duly signed by both of the Principal / Head of the Institution and Principal Investigator which has to be notarized mentioning all the conditions from Sl.No.1 to 17 and stating that they will be abide by the conditions stipulated in this order.

Only after the receipt of Pre-receipt certificate and the affidavit as above, further process for release of research grant-in-aid will be initiated. These documents have to be submitted to the Director, Advanced Research, RGUHS (superscribing the documents as ("**Advanced Research proposal**") either in person or by post on or before 18th January 2016 **without fail.** Soft copies of these documents shall also be sent to rguhsresearch@gmail.com before 18th January 2016.

Cheque has to be collected **in person** at Advanced Research Wing of RGUHS **after the intimation from the University and no representatives are allowed to collect the cheque.**

By order

Director
Advanced Research

To

1. Diretor, Father Muller Medical College, Mangalore
2. Dr Princy L Palatty, Chair in UNESCO Bioethics South India Unit, Professor, Department of Pharmacology, Father Muller Medical College, Mangalore 575002

Copy to:

1. PA to Vice-Chancellor/Registrar/Finance Officer, RGUHS
2. Office copy.

AFFILIATION AGREEMENT FOR RESEARCHERS

This Affiliation Agreement ("**Agreement**") is made at Mumbai and entered into on _____day of_____2016, effective as of _____("**Effective Date**") by and between

Novartis Healthcare Private Limited, a company incorporated under the provisions of the Indian Companies Act, 1956 and having its registered office at Sandoz House, Dr. Annie Besant Road, Worli, Mumbai-400 018, hereinafter referred to as "**Novartis**" (which expression shall unless repugnant to meaning or context mean and include its successors and assigns) of the One Part

AND

Dr. Jyothi Jayaraman, consulting at **Father Muller Medical College Hospital, Kankanady, Mangalore-575002, Karnataka, India**, hereinafter referred to as "**Researcher**" (which expression shall unless repugnant to meaning or context mean and include his/her heirs, executors, administrators and assigns) of the Second Part.

AND

Father Muller Medical College Hospital, Father Muller Road, Kankanady, Mangalore-575002, Karnataka, India with payee name as **Father Muller Research Centre** and bearing PAN No**. AAATF0345D**, hereinafter referred to as "Institution" (which expression shall unless repugnant to the context shall mean and include its successors and permitted assigns) of the Third Part;

(Novartis, Researcher and the Institution may hereinafter be individually referred to as '**Party**' and collectively as '**Parties'**)

WHEREAS

A. Novartis is involved in research, sale and marketing of pharmaceutical products in India while the Researcher is a medically qualified doctor having expertise and longstanding

experience in the area of research on General Medicine and the Institution inter alia with other services, also provides institution facilities, necessary to carry out a clinical study in accordance with the respective study protocol**.**

B. The Researcher and the Institution are willing to conduct the study for Novartis as more particularly set out in Exhibit 1 to this Agreement ("**Study**") on the terms and conditions set forth in this Agreement.

C. The Researcher has been informed by Novartis, that prior approval of the Drugs Controller General of India (**DCGI**) for its no objection to conduct the Study has been applied (*wherever applicable as per Indian regulations)* for and will be procured prior to conducting the Study.

D. The Parties now wish to record their arrangement on the terms and conditions and in the manner hereinafter appearing.

NOW THIS AGREEMENT WITNESSETH AND IT IS HEREBY AGREED BY AND BETWEEN THE PARTIES HERETO as follows:

1. Upon obtaining the approval of the Ethics Committee and other authorities as may be prescribed under the Drugs and Cosmetics Act, 1940, the Researcher hereby agrees to conduct the Study in accordance with the Study protocol. Further the Researcher shall render timely support in the registration process of the Study with the Clinical Trial Registry of India (CTRI).

2. In consideration of the Researcher conducting the Study, Novartis shall pay the Researcher, the amount as mentioned in Exhibit 1 of this Agreement.

   Novartis shall in its sole discretion, reimburse reasonable out-of-pocket expenses actually incurred by Researcher while conducting the Study (such as for travel in accordance with Novartis' travel policy and international courier charges). Reimbursement of such expenses is subject to production of receipts or other evidence of payment and a written pre-approval of Novartis for incurring such expenses.

3. Novartis shall make payments to the Institution in accordance with Exhibit 1 herein and based on the Case Report Forms (CRF) to be provided to Novartis by the Researcher.

   Novartis shall pay all undisputed amounts within a period of sixty (60) days after receipt of the respective CRFs. All payments shall be subject to deduction of tax at source at prevailing rates. Payment by Novartis in terms of this Agreement shall be full and complete discharge of its payment obligations and Researcher shall not have any claim in connection with the same.

4. **Safety Reporting Requirements**: The Researcher hereby agrees and undertakes to follow the Novartis requirements of identifying and reporting all adverse events (**AEs**) /Serious Adverse Events (**SAEs**) and pregnancy exposures to Novartis Drug Safety & Epidemiology unit as per the process described in the Study specific protocols.

5. Any information relating to Novartis or its affiliates or any of their businesses, business plans, operations or products acquired by Researcher in the course of this Agreement, and any information generated in connection with the Services, (collectively, "**Information**") shall be kept strictly confidential by the Researcher and/or the Institution and shall not be used except as necessary to conduct the Study as contemplated hereunder. The Researcher and the Institution shall not disclose such Information to any third party without Novartis' prior written consent. These obligations shall also remain in force after expiry of term of this Agreement. Upon request of Novartis, the Researcher and/or the Institution shall promptly return to Novartis or destroy any documents and computer data containing any Information, and any materials supplied by Novartis.

   The obligations specified in this Section shall not apply to Information which the Researcher and/or the Institution can demonstrate by written evidence: (a) is (at the time of disclosure) or becomes (after the time of disclosure) known to the public through no breach of any obligations by the Researcher; (b) is disclosed to Researcher by a third party who is entitled to disclose it without breaching any confidentiality obligation; (c) was known to, or otherwise in the possession of the Researcher prior to the time of disclosure by Novartis; or (d) is developed by Researcher independently of any information disclosed by Novartis or any of its affiliates.

   However, the Researcher and/or the Institution may disclose such Information if compelled to do so by a court, administrative agency or other tribunal of competent jurisdiction; provided however, that the Researcher and/or the Institution shall first provide prompt written notice to Novartis of any such requirement so that Novartis may seek a protective order or other remedy from such court, agency or tribunal and the Researcher and/or the Institution shall only disclose that portion of the Information that, in the reasonable opinion of its legal counsel, is required to be disclosed.

6. The Researcher and/or the Institution shall not make any publication (oral or written) containing any Information without the prior written approval of Novartis. Prior to Researcher and/or the Institution making any publication, it shall provide a sixty (60) days prior written notice and a copy of the proposed publication to Novartis. Novartis shall respond to the said notice within a period of thirty (30) days from receipt of such submission and intimate its objection, if any, to the use of any Information in such publication. The Parties shall timely and in good faith discuss all disputes and issues and the Researcher and/or the Institution shall not make any publication until such dispute is resolved between the Parties.

7 This Agreement shall be effective from _____and shall remain in force until **31st August 2019** (both days inclusive) unless earlier terminated in accordance with this Section.

(a) Either Researcher or Novartis (being the Party not in breach) may terminate this Agreement forthwith

(i) Upon expiry of fourteen (14) days from the Party not in breach notifying the other Party of the breach of any of the other's obligations under this Agreement and the other Party so notified failing to remedy the breach within the said fourteen (14) days;

(ii) In the event of other Party being unable to pay its debts as they fall due, entering into any scheme of arrangement or composition with, or assignment for the benefit of all or any class or creditors, is wound up or has a liquidator, provisional liquidator, receiver and manager or statutory or other official manager appointed over all or any part of its property.

(b) Novartis alone shall be entitled to terminate this Agreement:

(i) for convenience and without any cost or liability, by prior written notice of (fifteen) 15 days to the Researcher;

(ii) forthwith and without notice in the event of any permission, licenses, approvals required for the purposes of this Agreement have been withdrawn, cancelled or not granted or if the Researcher and/or the Institution has been in breach or default of Novartis code of conduct, Anti bribery Policy.

7.1 Termination of this Agreement shall be without prejudice to any claim or right of action of either Party against the other Party for any prior breach up to date of this Agreement.

7.2 On termination or expiry of this Agreement, the Researcher and/or the Institution shall return and/or destroy all documents and Information received by it from Novartis and shall not make any copies of the same in any manner whatsoever.

8. The Researcher and/or the Institution confirms that it has no obligations towards any third party which might conflict with its obligations under this Agreement and that it has received all required approvals required to conduct the Study under this Agreement including but not limited to approvals required from the Researcher's employer and/or relevant regulatory body. The Researcher also confirms that any compliance/disclosure obligations arising herein including disclosing this contract to any regulatory authority or professional council governing the professional conduct of the Researcher including the Medical Council of India, shall be the sole responsibility of the Researcher.

9. The Researcher and the Institution acknowledge and agree (as applicable) that (a) the compensation paid for the services as enumerated in Exhibit 1 herein is consistent with the fair market value in arm's length transactions, (b) all amounts incurred are legitimate expenses or for reimbursement of such expenses and/or towards compensation for the performance of the services. The receipt of such amounts shall be in accordance with all applicable laws, regulations and policies.

10. Novartis shall be entitled to periodically monitor the progress of the Study.

11. The Researcher and the Institution hereby agrees and undertakes:

a. to provide Novartis, access to and inspection of, all data and documents relating to the Study and shall ensure co-operation during monitoring of the Study by Novartis.

b. to maintain and secure all the Study records, patient files and source data etc., for a period of 15 (fifteen) years from the end of the Study and shall provide access to the same for regular monitoring and audits by Novartis and regulatory authorities.

12. It is agreed between the Parties hereto that the commencement of the Study in terms of this Agreement, shall be subject to the written 'no objection' approval by the DCGI (*wherever applicable as per Indian regulations)*, failing which this Agreement shall stand cancelled and in that event Novartis shall have no liability whatsoever towards the Researcher and/or the Institution.

13. This Agreement constitutes the entire understanding between the Parties with respect to its subject matter and shall supersede any other prior arrangements as to the services.

14. **Assignment**. This Agreement shall not be assignable in whole or in part without the prior consent of the other Party, except that Novartis shall be entitled to assign this Agreement or any rights and obligations pertaining to this Agreement to any of its affiliates or to a company taking over all or substantially all of its business.

15. The Researcher and/or the Institution shall allow officers authorized by the Central Drug Standard Control Organization, who may be accompanied by an officer of the State Drug Control Authority concerned, to enter with or without prior notice, any premises of clinical Study sites to inspect, search and seize any record, data, documents, books, investigational drugs etc. related to clinical studies and provide adequate replies to any queries raised by the inspecting authority in relation to conduct of clinical studies.

16. **Applicable law, Venue**. This Agreement shall be construed in accordance with, and governed by, the laws of India The venue shall be at Mumbai and the competent courts at Mumbai shall have exclusive jurisdiction in that regard.

17. **Notices**. Any notice required or authorized to be served hereunder shall be deemed to have been properly served if delivered by hand, or sent by registered or certified mail, or sent by facsimile transmission confirmed by registered or certified mail, to the Party to be served at the address specified by such Party for that purpose, or, if no such address is specified, at the address given at the head of this Agreement. Notices sent by post shall be deemed to have been delivered within seven days after the date of posting. Notices sent by facsimile shall be deemed to have been delivered within 24 hours of the time of transmission.

18. **Waivers**. Neither Party shall be deemed to have waived its rights under this Agreement unless such waiver is in writing and signed by such Party and such waiver by one Party of a breach of any provision of this Agreement by the other Party shall not be deemed to be a waiver of any subsequent or continuing breach of such provision or of the breach of any other provision of this Agreement by that other Party. Any delay or omission on the part of any Party in the exercise of its strict rights hereunder will not impair those rights nor will it constitute a renunciation or waiver of those rights. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative, and none of them shall be a limitation of any other right, remedy, undertaking, obligation, or agreement of any of the Parties.

19. **Force Majeure**. Neither Party shall be liable to the other Party for any failure to perform any obligation on its part hereunder to the extent that such failure is due to circumstances beyond its control which it could not have avoided by the exercise of reasonable diligence. The affected Party shall however notify the other Party as soon as practicable of the occurrence of any such circumstance, and the Parties shall meet to consider what steps, if any, can be taken to overcome any issues.

20. The Researcher and the Institution shall be bound by Novartis Supplier Code a copy of which is annexed as **Annexure A** hereto. Researcher and the Institution represent and warrant to NOVARTIS that it has not corruptly paid, offered to pay, promised to pay and shall not corruptly pay, offer to pay, promise to pay or authorize the payment directly or indirectly of any monies, or anything of value to any foreign official, individual, institution, government official, representative or employee, or to any political party, holder of public office or a candidate for public office knowing that all or part of the payment will be offered or paid to foreign official, individual, institution, government official, representative or employee, or to any political party, holder of public office or a candidate for public office in order to retain business or to secure any improper advantage whether or not in connection with the Agreement. Researcher and the Institution further represent and warrant that in exercising its rights and performing its obligations under this Agreement, it will comply with all policies provided to it by Novartis including the Novartis Anti-Bribery policy, as amended from time to time. In the event Novartis issues additional policies in relation to the Researcher's and/or the Institutions' activities under this Agreement, Novartis will provide Researcher with a copy of the same and the Researcher and the Institution undertakes to duly comply with such thereafter. The Researcher and the Institution hereby confirms that it has read and understood the above mentioned policies and guidelines; and perform its obligations under this Agreement with high ethical and moral business and personal integrity standards.

IN WITNESS WHEREOF, the parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives.

Novartis Healthcare Private Limited	**Father Muller Medical College Hospital**
By: **Name: Dr. Apurva Gawai** **Title: Head-Medical Affairs** **Date:**	By: **Name: Dr. Jyothi Jayaraman** **Title: Researcher (Principal Investigator)** **Date**:
By: **Name: Dr. Bincy Mehta** **Title: Medical Advisor** **Date**:	By: **Name:** **Title: Institution** **Date:**

Exhibit 1

Description of Services:

A. Study Protocol No: CAIN457AIN01
B. Study Title: A prospective, observational post marketing surveillance study to evaluate the effectiveness and safety of secukinumab in Indian patients with moderate to severe plaque psoriasis requiring systemic therapy
C. Study to be conducted at Father Muller Medical College Hospital, Kankanady, Mangalore-575002, Karnataka, India
D. Total Duration of study: 17 months
E. Recruitment period:12 months
F. Total Treatment duration : 16 Weeks ± 1 week
G. No. of patients to be recruited : minimum 15
H. Study fees per completed patient in the following manner:-

Payment head	Study fee per patient per visit	Study coordinator fees
Visit 1 (Week 0)	15,000	2,500
Visit 2 (Week 1)	10,000	2,500
Visit 3 (Week 2)	10,000	2,500
Visit 4 (Week 3)	10,000	2,500
Visit 5 (Week 4)	10,000	2,500

Visit 6 (Week 8)	10,000	2,500
Visit 7 (Week 12)	10,000	2,500
Visit 8 (Week 16)	10,000	2,500
Total amount per patient	85,000	20,000

NOTE:

i. The total payment to the institution will vary depending upon the total number of eligible patients enrolled. For each eligible patient with completed eCRF the institution would be paid @ Rs. 85,000/- only.
ii. The above payment covers cost of all investigations for the patients enrolled in the study.
iii. In case of any reduction in the number of patients the corresponding amount would be reduced in the final amount payable to the institution. A minimum of 15 patients can be enrolled by the Researcher in this study.
iv. Study co-ordinator fees will be 2,500 per visit.
v. Institutional Overhead charges will be paid as 20% of researcher's fee upon submission of appropriate covering letter.
vi. No additional payment in addition to the above mentioned would be paid by Novartis.
vii. All payments are subject to TDS (subject to Government of India, Tax regulations) and service tax as applicable.
viii. Service tax will be paid on providing valid invoice with relevant details mentioning Service tax registration number on it.

Annexure A

- **Novartis Supplier Code**

ANNEXURE A
NOVARTIS SUPPLIER CODE

Novartis Supplier Code

Version 2.0
June 1, 2014

NOVARTIS

Contents

Introduction

"High Performance with Integrity" is a Novartis strategic imperative.

Novartis promotes the societal and environmental values of the United Nations Global Compact to its suppliers and third parties and uses its influence where possible to encourage their adoption. The Novartis Supplier Code (the "Supplier Code") is based on the United Nations Global Compact and other international standards or accepted good practices. The Supplier Code is aligned with the Novartis Code of Conduct.

Novartis expects its suppliers to aspire to the standards defined in its Supplier Code.

Novartis is committed to being a leader in good corporate responsibility, and this commitment is embodied in the Supplier Code. The Novartis Responsible Procurement program has been created to extend the Novartis commitment to corporate responsibility to suppliers and third parties.

Novartis is a member of the Pharmaceutical Supply Chain Initiative. The Supplier Code is consistent with the Pharmaceutical Industry Principles for Responsible Supply Chain Management (the "Principles") for ethics, labor rights, health and safety, environment and related management systems.

- Novartis supplier programs are consistent with the Principles.
- Novartis believes that society and business are best served by responsible business behaviors and practices. Fundamental to this belief is that business should not only operate in compliance with applicable laws, rules and regulations, but that our behaviors address underlying societal concerns.
- Novartis is aware that differences in cultures and laws create challenges to applying these Principles globally.
- Novartis believes the Principles are best implemented through a continual improvement approach that advances supplier performance over time.

The Supplier Code does not replace local law. Novartis expects suppliers and third parties to operate in compliance with applicable laws, rules and regulations in addition to the standards contained herein.

For the purposes of this Supplier Code, the term "suppliers" may include distributors, wholesalers, licensors, licensees, other technology partners, and other sales entities.

Links referenced on this page can be found at the end of this document.

Monitoring against our standards

Adherence to the standards contained in this Supplier Code is one of the evaluation criteria in the Novartis supplier selection process.

Novartis expects suppliers to adhere to applicable legal standards and work toward the higher standards contained herein. Under some circumstances, where the suppliers or third parties have shown and continue to show a material commitment to improvement, Novartis is willing to work with them to bring about improvements through engagement and collaboration. This may include audits, development and progress monitoring of corrective action plans, referring suppliers to external experts, and other reasonable improvement plans.

Responsible Procurement – Ethical Standards

1 Labor Rights

Suppliers shall be committed to uphold the human rights of workers and to treat them with dignity and respect. The labor elements include:

1.1 Freely Chosen Employment

Supplier Code

Suppliers shall not use forced, bonded or involuntary prison labor.

Expectations

Forced Labor - Management Systems: a nominated manager with responsibility for HR at each site follows policies and procedures to ensure that all onsite workers, including agency and temporary labor, have freely chosen to be there and are fully paid for the work they do.

Prison Labor: the use of any prison labor is voluntary and clearly communicated to Novartis, and where used, all applicable local laws or international guidance is followed.

Notice Periods: workers are free to leave their jobs after reasonable notice and are paid on time and in full for the work they have done prior to leaving.

Retention of ID/Passports: workers are not required to hand over their identity papers to secure employment unless required to do so by local law. If this is the case, workers have access to their papers at all times.

Freedom of Movement: workers are able to freely come and go from the site or onsite accommodation at all times and are not controlled by security guards (e.g., monitored during breaks, followed to the toilets, etc.).

Cash Deposits: workers do not pay "deposits" to secure a job or employer-provided accommodation, nor do they pay excessive "deposits" for tools, training or personal protective equipment necessary to carry out their jobs safely.

1.2 Child Labor and Young Workers

Supplier Code

Suppliers shall not use child labor. The employment of young workers below the age of 18 shall only occur in non-hazardous work and when young workers are above a country's legal age for employment and the age established for completing compulsory education.

Expectations

Child Labor - Management Systems: a nominated manager with responsibility for HR ensures that there are adequate policies and procedures in place to monitor the ages of workers at each site, including agency or temporary workers.

Child Labor: children below the local minimum working age, the age of compulsory education or the ages set out in the International Labor Organization Core Conventions (whichever is higher) are not employed.

A child is:

- Any young person below the ages defined in the International Labor Organization Core Conventions, which is 15 in Developed Countries or 14 in Less Developed Countries.
- Any young person below the local legal minimum working age where this is higher than 15.
- Any young person below the age of local legal compulsory education where this is higher than 15.

Remediation: if children are found working, an appropriate remediation procedure to ensure the welfare of the child is put in place. If children are found working, suppliers will:

- Remove the child from the workplace immediately.
- Put in place a suitable plan to support the child, which may involve covering the cost of formal or vocational training, accommodation or other costs as necessary.

Young Workers: young people under the age of 18, legally able to work, do not carry out any hazardous work (chemical handling, strenuous physical labor, etc.) or night shifts, and all applicable local laws are followed, including access to education, training, health checks and number of hours allowed to work, etc.

1.3 Non-Discrimination

Supplier Code

Suppliers shall provide a workplace free of harassment and discrimination. Discrimination for reasons such as race, color, age, gender, sexual orientation, ethnicity, disability, religion, political affiliation, union membership or marital status is not tolerated.

Expectations

Non-Discrimination - Management Systems: a nominated manager with responsibility for HR ensures adequate policies and procedures are in place at each facility to prevent discrimination as well as manage effective disciplinary procedures. All workers know to whom they can report incidences of discrimination.

Non-Discrimination: workers do not face harassment or discrimination at any time (from recruitment to leaving employment) for any reason such as race, color, race, age, gender, sexual orientation, ethnicity, disability, religion, political affiliation, union membership or marital status. Potential recruits are not pregnancy-tested unless required by local law and pregnant women are not discriminated against in accordance with local laws.

Trade Union Non-Discrimination: workers are not discriminated against if they seek to join a trade union or worker committee.

1.4 Fair Treatment

Supplier Code

Suppliers shall provide a workplace free of and with no threat of harsh and inhumane treatment, including any sexual harassment, sexual abuse, corporal punishment, mental or physical coercion or verbal abuse of workers.

Expectations

Fair Treatment - Management Systems: a nominated manager with responsibility for HR ensures adequate policies and procedures in are in place so that all workers receive fair treatment.

Workers understand disciplinary and grievance procedures, and fines imposed on workers as part of a disciplinary action are legal and fair.

Supervisors and managers found abusing workers are disciplined accordingly.

Harassment or Abuse: workers neither face nor are threatened with bullying, sexual harassment, sexual abuse, corporal punishment, mental or physical coercion or verbal abuse.

Role of Security Personnel: workers are not subject to unreasonable body searches, and physical security searches are only carried out by authorized bodies, according to local legal standards, and by same-sex security guards.

Fair Treatment - Bribery: workers do not have to pay other workers to avoid victimization or preferential treatment.

1.5 Wages, Benefits and Working Hours

Supplier Code

Suppliers shall pay workers according to applicable wage laws, including minimum wages, overtime hours and mandated benefits.

Suppliers shall communicate in a timely manner with workers regarding the basis upon which they will be paid. Suppliers are also expected to communicate with the worker whether overtime is required and the wages to be paid for such overtime.

Expectations

Wages and Working Hours - Management Systems: a system is in place to monitor the hours and wages paid to all agency staff onsite, and complete hours and payroll records are kept for all workers onsite at all times.

Wages: workers are not required to do unpaid work.
Workers' monthly pay, or piece rate, is at least at local legal minimum wages or industry benchmarks, and is paid regularly and in full, in accordance with local laws.

Overtime - Pay: overtime is paid according to all local laws, and where these do not exist, as a minimum at the same rate as normal pay, but ideally at a premium rate.

Benefits and Bonuses: all legally required benefits and bonuses are paid to workers on time and in full.

Working Hours: working hours are aligned with local laws or industry benchmarks.

Overtime Hours: overtime is voluntary and workers do not regularly work more than 12 hours of overtime per week.

Time-off and Breaks: workers are given time-off and breaks in accordance with local laws.

Communication: payment terms are communicated to workers before they start and confirmed in writing. Workers receive written pay slips.

Deductions: deductions for disciplinary issues, lateness and absence are only taken in accordance with local laws.

1.6 Freedom of Association

Supplier Code

Open communication and direct engagement with workers to resolve workplace and compensation issues are encouraged.

Suppliers shall respect the rights of workers, as set forth in local laws, to freely join or not join labor unions, seek representation and join workers' councils. Workers shall be able to communicate openly with management regarding working conditions without threat of reprisal, intimidation or harassment.

Expectations

Collective Bargaining: workers are able to bargain collectively and understand how to raise issues if they wish. Where collective agreements are in place, they are communicated to all workers in a language they can understand.

Trade Union/Worker Representation Rights: workers are freely able to join, or form, a trade union or worker committee without fear of reprisal or discrimination. Worker representatives are granted reasonable time, and access to facilities like meeting rooms, to carry out their role, in accordance with local laws.

Parallel Means: where local laws restrict trade unions, workers are able to form worker committees if they so choose.

Health, Safety and Environment

Given the breadth, complexity and size of the Novartis supply chain, the outlined standards in section 2 and 3 for Health, Safety and Environment (HSE) provide suppliers with basic standards and concepts that Novartis expects adherence to throughout its supply chain.

Novartis expects each supplier and third party to understand the applicable HSE standards for its specific products or services, and to augment these standards as necessary.

2 Health and Safety

Suppliers shall comply with all applicable health and safety laws and regulations by providing a safe and healthy working environment, and, if applicable, safe and healthy company living quarters. The health and safety elements include:

2.1 Risks and Process Safety

Supplier Code

Suppliers shall have systems and programs in place to identify both occupational and external hazards. They should classify such hazards and define the risk levels appropriately, and have programs and systems in place to prevent or mitigate these risks (e.g., catastrophic releases of chemicals, fumes, dust, etc.).

2.2 Worker Protection

Supplier Code

Suppliers shall have systems and processes in place to protect workers from exposure to chemical, biological and physical hazards (including physically demanding tasks) in the workplace and company-provided living quarters.

2.3 Emergency Preparedness and Response

Supplier Code

Suppliers shall develop and distribute emergency plans across their facilities and company-provided living quarters. Suppliers should minimize the potential impact of any emergency by implementing suitable emergency plans and response procedures.

2.4 Hazard Information

Supplier Code

Suppliers shall have programs and systems in place to provide workers with safety information relating to hazardous materials and education to protect them from potential hazards. Hazardous materials can include but not be limited to raw materials, isolated intermediates, products, solvents, cleaning agents, and wastes.

3 Environment

Suppliers shall comply with all applicable environmental laws and regulations. All required environmental permits, licenses, information registrations and restrictions shall be obtained, and their operational and reporting requirements followed, specifically:

3.1 Environmental Authorizations

Supplier Code

Suppliers shall have processes and systems to conform with applicable environmental laws and regulations. Required environmental permits, licenses, information registrations and restrictions shall be obtained, and their operational and reporting requirements followed.

3.2 Waste and Emissions

Supplier Code

Suppliers shall have processes and systems in place to ensure the safe handling, movement, storage, recycling, reuse, or management of waste. Any generation and disposal of waste, emissions to air and discharges to water, with the potential to adversely impact human health or the environment shall be appropriately minimized, properly managed, controlled, and/or treated prior to release into the environment.

3.3 Spills and Releases

Supplier Code

Suppliers shall have processes and systems in place to prevent and mitigate accidental and diffusive spills and releases to the environment.

3.4 Sustainability and Efficiency of Resources

Supplier Code

Suppliers shall have processes and systems in place to optimize the use of all relevant resources sustainably, such as energy, water and materials.

4 Animal Welfare

Supplier Code

Animals shall be treated respectfully, with pain and stress minimized. Animal testing should be performed after consideration to replace animals, reduce the numbers of animals used or refine procedures to minimize distress. Alternatives should be used wherever scientifically valid and acceptable to regulators.

Expectations

Novartis is committed to globally achieving high standards of Animal Welfare whenever animals are involved in a Novartis study or procedure. The Novartis Animal Welfare Standard applies to all internal and Novartis external animal studies. It corresponds with the US regulations, namely the AW Act (USC 7; 1966) and Regulations, and the US Guides for the Care and Use of Laboratory and Agricultural Animals (including all vertebrates). More stringent criteria apply for Non-Human Primates. For countries with local/national regulations that are more stringent than those of the United States, the higher standards apply.

- The welfare of animals is of primary concern.
- The Three Rs (Replace, Reduce, Refine) are applied.
- Studies are carried out by well-trained, competent and experienced personnel.
- Finished cosmetics and their ingredients will not be tested on animals.
- Only animals specifically bred for research purposes are purchased and used, except for some farm animals, companion animals used in clinical studies, and fish.
- Animals are treated respectfully and cared for in accordance with the particular needs of the given species and individual.
- Animals experience the minimum amount of discomfort, distress or pain.
- Particular care and attention is paid to the transportation of animals.
- The principles and requirements apply to Novartis-initiated studies performed at third party facilities (e.g., contract research organizations, universities and other companies).

5 Anti-Bribery and Fair Competition

5.1 Anti-Bribery

Supplier Code

Suppliers shall not bribe any public official or private person and shall not accept any bribes. No intermediaries, such as agents, advisers, distributors or any other business partners, shall be used to commit acts of bribery.

Suppliers shall comply with applicable laws and regulations and industry standards related to anti-corruption.

Expectations

Facilitation Payments: no facilitation payments are made, irrespective of whether or not local law permits them.

Gifts, Hospitality and Entertainment: gifts, hospitality, and entertainment are modest, reasonable and infrequent, so far as any individual recipient is concerned.

- Gifts, hospitality, and entertainment are never offered or provided with the intent of causing the recipient to do something favoring the supplier and/or Novartis or to refrain from doing something disadvantaging the supplier and/or Novartis.
- Gifts in the form of cash and gifts that are cash-equivalent are never given.
- No entertainment is provided to any participant to business meetings, congresses or comparable events, unless the entertainment is an appropriate and incidental part of such events. No payment is made for any side or extended trips.
- No payment is made for the entertainment, hospitality or travel costs of anyone who accompanies an invitee to a business meeting, congress or comparable event.

Grants and Donations: grants and donations are only given if the supplier and/or Novartis do not receive, and are not perceived to receive, any tangible consideration in return.

Political Contributions: if the supplier chooses to make political contributions, they must be made in compliance with all applicable laws, regulations and industry codes and standards, and must not be made with the expectation of direct or immediate return for the supplier or Novartis.

Internal Control Mechanisms: suppliers have policies or guidelines in place that define under which circumstances, or within what limits, employees are allowed to receive gifts or favors from external companies with whom the company does business.

- These are publicly available and widely disseminated to staff in an appropriate language.
- Compliance with the policies/guidelines is ensured and periodically reviewed.

Suppliers train their sales forces and any other relevant employees on anti-bribery, at their own expense.

- Such training includes the provisions of the applicable anti-corruption laws.
- Upon request from Novartis, the supplier shall promptly provide a copy of the training material and the training attendance sheets (including name and qualification of the trainer).

Reporting Potential Misconduct: all workers are encouraged to report concerns or illegal activities in the workplace, without threat of reprisal, intimidation or harassment.

- Appropriate investigation and corrections are carried out. The supplier makes such records available to Novartis on request.

Public Officials: any relationship between the supplier and public officials is in strict compliance with the rules and regulations to which they are subject (i.e. any applicable rules or regulations in the particular country relating to public officials or that have been imposed by their employer). Any benefit conveyed to a public official is fully transparent, properly documented, and accounted for.

Third-party Relationships: the supplier does not sub-contract or otherwise engage with third parties on behalf of Novartis or represent Novartis to third parties, without the prior written consent of Novartis. Similarly, there is no assignment of the contract, without prior written consent of Novartis.

Engagement as Third Party: suppliers' engagement by Novartis as third parties is never used to create an incentive or reward for prescribing Novartis products or to secure any improper business advantage for Novartis.

Books and Records: Novartis may audit the supplier at any time upon reasonable prior notice to ensure its compliance with these standards and to confirm all payments made by Novartis and to third parties.

- The supplier prepares and maintains books and records that document accurately and in reasonable detail all matters related to the supplier's business with Novartis, accounting for all payments (including gifts, hospitality and entertainment or anything else of value) made on behalf of Novartis, or out of funds provided by Novartis.
- A copy of this accounting is available to Novartis upon request.

5.2 Fair Competition

Supplier Code

Suppliers shall conduct their business consistent with fair and vigorous competition. They shall employ fair business practices, including accurate and truthful advertising.

Suppliers shall comply with all fair competition and antitrust laws and regulations.

6 Data Privacy

Supplier Code

Suppliers shall apply adequate data privacy and security protection to individuals' personal information it processes. Suppliers will operate in a manner that is consistent with applicable data protection laws.

Expectations

Proper Protection of Personal Information: suppliers shall have the proper organizational structure, processes and procedures to ensure the protection of personal information against accidental, unauthorized or unlawful loss, destruction, alteration, disclosure, use or access.

Proper Security Measures: suppliers must have adequate policies and procedures in place which address technical and organizational security and take reasonable steps to confirm compliance with those.

Compliance with Cross-Border Transfer Restrictions: suppliers must have adequate safeguards, rules and procedures to ensure that they remain in compliance with all applicable laws that govern cross-border data transmissions.

7 Identification of Concerns

Supplier Code

All workers should be encouraged to report concerns or illegal activities in the workplace, without threat of reprisal, intimidation or harassment. Suppliers shall investigate and take corrective action if needed.

8 Management Systems

Suppliers shall use management systems to facilitate continual improvement and compliance with the expectations of these principles. Elements of the management systems include:

8.1 Commitment and Accountability

Supplier Code

Suppliers shall demonstrate commitment to the concepts described in this document by allocating appropriate resources.

8.2 Legal and Customer Requirements

Supplier Code

Suppliers shall identify and comply with applicable laws, regulations, standards and relevant customer requirements.

8.3 Risk Management

Supplier Code

Suppliers shall have mechanisms to determine and manage risk in all areas addressed by this document.

8.4 Documentation

Supplier Code

Suppliers shall maintain documentation necessary to demonstrate conformance with these expectations and compliance with applicable regulations.

8.5 Training and Competency

Supplier Code

Suppliers shall have a training program that achieves an appropriate level of knowledge, skills and abilities in management and workers to address these expectations.

8.6 Continual Improvement

Supplier Code

Suppliers are expected to continually improve by setting performance objectives, executing implementation plans and taking necessary corrective actions for deficiencies identified by internal or external assessments, inspections and management reviews.

9 References and Bibliography

The following references are included for information. They are not intended to create any additional obligations beyond this Novartis Supplier Code.

General References	Novartis Code of Conduct Pharmaceutical Supply Chain Initiative United Nations Global Compact Universal Declaration of Human Rights
Labor Rights	**Freely Chosen Employment** **International Labor Organization** ("ILO") Conventions 29 and 105: http://www.ilo.org/ilolex/english/convdisp1.htm **Child Labor** ILO Conventions 138 and 182: http://www.ilo.org/ilolex/english/convdisp1.htm **Non-Discrimination** ILO Conventions 111 and 100: http://www.ilo.org/ilolex/english/convdisp1.htm International Convention on the Elimination of All Forms of Racial Discrimination: http://www2.ohchr.org/english/law/cerd.htm Convention on the Elimination of All Forms of Discrimination Against women: http://www2.ohchr.org/english/law/cedaw.htm **Wages, Benefits and Working Hours** ILO Conventions 131, 95, 14 and 1: http://www.ilo.org/ilolex/english/convdisp1.htm **Freedom of Association** ILO Conventions 87 and 98: http://www.ilo.org/ilolex/english/convdisp1.htm
Health, Safety & Environment	OHSAS 18001 ISO 14001 Environmental Management Systems standard ISO 50 000 Energy Management Systems standard Forest Stewardship Council Sustainable Palm Oil
Animal Welfare	Guide for the Care and Use of Laboratory Animals, 8th Edition (©2011) National Research Council (NRC), Washington DC, USA Guide for the Care and Use of Agricultural Animals in Agricultural Research andTeaching, 3rd Edition (2010), Federation of Animal Science Societies (FASS), Champaign IL, USA European Directive 2010/63/EU (PE-CONS 37/10) of the European Parliament and of the Council of the European Union on the Protection of Animals used for Scientific Purposes (2010)
Anti-Bribery	OECD Anti-Bribery Convention US Foreign Corrupt Practices Act 1977 UK Bribery Act 2010

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[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

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

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

Secondary IDs if Any

Secondary ID	Identifier
TPC-CLT-002	Protocol Number

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

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

Details Contact Person (Scientific Query)

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

Details Contact Person (Public Query)

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

	400604 India
Phone	02225816800
Fax	
Email	neeta@thinqcro.com

Source of Monetary or Material Support

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

Primary Sponsor

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

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

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

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

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

Details of Ethics Committee

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

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

Regulatory Clearance Status from DCGI

Status	Date
Awaited	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Oropharyngeal Candidiasis

Intervention / Comparator Agent

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

Inclusion Criteria

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

Exclusion Criteria

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

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

Primary Outcome

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

Secondary Outcome

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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ಪಕ್ಕಾ ಭರವಸೆ. ಡಾಟ್ಸ್.

GOVERNMENT OF KARNATAKA
Health and Family Welfare Services-TB Division
Revised National Tuberculosis Control Programme (RNTCP)

No LWSTC/RNTCP/ACC/92/2016-17

Office of the Joint Director (TB),
Lady Willingdon State TB Centre,
4th Main, Sampangiramanagar,
Bangalore- 27
E-mail: STOKA@rntcp .org
Phone No. 080- 22249364
Fax No. 080- 22249361.
Dated: 31.03.2017

Dear DTO's

Subject: Release of OR fund 2016-17

As you aware, OR committee has approved 8 proposals & depending on the availability of funds under 2016-17 ROP, 61% of the budgeted amount by each candidate has been released under the Line Item (H-14) Research, studies & Consultancy and this amount has to be released to candidate before 31st March 2016.

You are hereby instructed to release the amount as per the attached list to the Joint A/c of principle investigator of the study & Dean/Director of the Medical College. Remaining 39% of the OR fund's will be released to the Candidates depending on the availability of funds in coming Financial Year 2017-18 ROP.

Action taken in this regard must be committed to STO Office.

31/3/17
Joint Director (TB)

To,

DTO Gadag,
DTO BBMP,
DTO Davangere,
DTO Dakshina Kannada
DTO Bangalore Urban

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GOVERNMENT OF KARNATAKA

OFFICE OF THE JOINT DIRECTOR (TB), LADY WILLINGDON STATE TB CENTRE,
4TH MAIN ROAD, SAMPANGI RAMANAGAR, BANGALORE-560 027.
e-mail: STOKA@rntcp.org, ☎ : 080 - 22249364; Fax - 080 – 22249361

Date: 28th March 2017

Dear DTOs,

The State Operational Research (OR) Committee has approved the following eight operational research project proposals for RNTCP funding.

S. No	Name	Medical College	Topic	Amount Budgeted by PI	Amount released by state
1	Dr. Madhavi Bhargava	Yenopoya, Mangalore	Nutritional assessment of Tuberculosis patients of Mangalore Tuberculosis Unit	Rs. 1.89 Lakhs	Rs. 1.1 lakhs
2	Dr.Jannatbi	GIMS,Gadag	A cross-sectional study on health status and Quality of life of MDR-TB patients of Gadag and Koppal districts	Rs. 0.44 Lakhs	Rs. 0.3 lakhs
3	Dr.Poornima	JJM, Davangere	Assessment of cost incurred by patients undergoing treatment for tuberculosis in urban slum community – a multi centric longitudinal study.	Rs. 1.89 Lakhs	Rs. 1.1 lakhs
4	Dr.Rashmi	Sapthagiri,	Impact of structured awareness	Rs. 1.86 Lakhs	Rs.1.1 lakhs

		Bangalore	programmes in filling treatment gaps in RNTCP: An interventional study		
5	Dr.Shivalli	Yenopoya, Mangalore	Mobile phone instructional video on sputum expectoration for tuberculosis suspects to enhance case detection: A pragmatic RCT	Rs. 1.99 Lakhs	Rs.1.2 lakhs
6	Dr.Padmaja Udaykumar	FMMC, Mangalore	Comparison of TB treatment outcome and adverse reactions among non-diabetic, controlled diabetic and uncontrolled diabetic TB patients	Rs. 1.99 Lakhs	Rs.1.2 lakhs
7	Dr.Lalitha	MS Ramaiah, Bangalore	Validation of reporting of adverse drug reactions under pharmacovigilance programme of RNTCP in BBMP area - A mixed method approach	Rs. 1.99 Lakhs	Rs.1.2 lakhs
8	Dr.Hemam aheshwari	Vydehi, Bangalore	Strategy to Sensitize Private Practitioners on RNTCP through Medical Representative in Urban Slum, Bangalore: An Operational Research	Rs.1.16 Lakhs	Rs. 0.7 lakhs

31/3/17

FATHER MULLER MEDICAL COLLEGE INSTITUTIONAL ETHICS COMMITTEE

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

DCGI Re-registration No.
ECR/540/Inst/KA/2014/RR-17

Tel : 0824-2238327
e-mail: fmiethicscommittee@gmail.com

CHAIRPERSON
Dr. Ashok Shenoy
Professor of Pharmacology
KMC, Mangalore-575001
Phone : +919880530703
E-mail: ashok.shenoy@manipal.edu

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

Ref. No : Ref. NoFMMCIEC/CCM/65/2018

Date : 30.01.2018

To : Dr .Ramesh Bhat,
Professor of Dermatoology,
Father Muller Medical College Hospital,
Mangalore.

Dear Dr.Ramesh Bhat,

Your amended research proposal was reviewed and discussed in the ethics committee meeting held on 20/10/2018 and the decision is as follows:

Protocol title: "A multicenter comparative randomized double – blind study of the efficacy and safety of BCD-057(INN: Adalimumab JSC BIOCAD, Russia)and Humira ® (INN: Adalimumab , vetter Pharma) in patients with Moderate to severe plaque psoriasis"
Protocol No: BCD-057-2
Principal Investigator: Dr. Ramesh Bhat Co Investigators : Dr Meryl Sonia Dsouza
Version No., date, amendment no. of the protocol : Protocol Ver. 1.1 dated 26 Oct 2017 List of documents reviewed (for clinical trials)-clear description of these documents along with version No., and date. 1) 1) Protocol Ver 1.1 Dated 26 Oct 2017 2) Investigator Brochure Ver 1.0 Dated 21 Dec 2015 3) CRF content Version 1.1 Dated 14 Dec 2017

4) Patient Information Sheet & Informed Consent Form English ver 1.1 dated 26 Oct 17

5) Patient Information Sheet & Informed Consent Form Kannada ver 1.1 dated 15 Dec 2017 with Translation Certificate ver 1.1 dated 15 Dec 2017

6) Back Translation of Patient Information Sheet & Informed Consent Form Kannada to English ver 1.1 dated 24 Dec 2017 with translation certificate dated 24 Dec 2017

7) Patient Information Sheet & Informed Consent Form Malayalam ver 1.1 dated 15 Dec 2017 with Translation Certificate ver 1.1 dated 15 Dec 2017

8) Back Translation of Patient Information Sheet & Informed Consent Form Malayalam to English ver 1.1 dated 24 Dec 2017 with translation certificate dated 24 Dec 2017

9) Dermatology Life Quality Index (DLQI), SF-36 questionnaire & Visual analog scale for assessment of itch by the patient -English Version 1.0, dated 06-Sep-2017

10) Dermatology Life Quality Index (DLQI), SF-36 questionnaire & Visual analog scale for assessment of itch by the patient - Malayalam ver 1.0 dated 6 Sep 2017 Translated from English to Malayalam on 14/SEP/2017 with Translation certificates dated 14 Sep 2017 and Back Translation documents & certificates dated 17 Sep 17

11) Dermatology Life Quality Index (DLQI), SF-36 questionnaire & Visual analog scale for assessment of itch by the patient – Kannada ver 1.0 dated 6 Sep 2017 Translated from English to Kannada on 14/SEP/2017 with Translation certificates dated 14 Sep 2017 and Back Translation documents & certificates dated 17 Sep 17

12) Study Participant Card English Ver 1.0 Dated 26 Oct 2017

13) Study Participant Card Kannada ver 1.0 with Translation Certificate ver 1.1 Dated 19 Dec 2017

14) Study Participant Card ver 1.0 back Translated from Kannada to English Dated 24 Dec 2017

15) Study Participant Card Malayalam ver 1.0 with Translation Certificate ver 1.1 Dated 19 Dec 2017

16) Study Participant Card ver 1.0 back Translated from Malayalam to English Dated 24 Dec 2017

17) Draft CTA

18) DCGI Submission & Approval Letter

Name & Address of Institution : Father Muller Medical College Hospital, Mangalore.
New review: Full review
Review of Revised Submission: **Date of review:** 20.01.2018 **Date and type of previous review, if revised application:**
Decision of the Ethics Committee: Approved with suggestions
Suggestions /Reasons/Remarks: The identity of the patient should be concealed. Mask the patient's eyes while taking photographs.
Recommended for a period of : One Year

- The approval is valid for one year. After one year, you are instructed to submit an application requesting for continuation of ethical clearance for another one year (if required).
- You are instructed to register your trial in clinical registry (CTRI) before starting the study, and submit the necessary evidence to the IEC
- Your research work will be continuously reviewed by ethics committee during the study period.
- The investigator/s is/are instructed to carry out the research study as per the protocol approved by the ethics committee. Any protocol deviations/violations should be brought to the notice of ethics committee.
- The FMMCIEC will be monitoring the conduct of the protocol by on-site monitoring, review of study-related documents and review of progress reports.
- You are instructed to submit progress report of the research project once in every six months
- You should comply with the regulations and guidelines on biomedical research on human participants, and follow good clinical practice
- Ethics committee has the right to withdraw the approval if found necessary due to protocol violations, non-compliance to regulations and guidelines

- For any modifications/changes in protocol, investigators and study site you need to submit the proposal to ethics committee and get the approval.
- You should report any serious adverse events in your site or any other site of this clinical trial to the ethics committee
- You need to submit the final report and summary at the termination of the study.

Following members of the IEC were present and involved in decision making.

Sl. No.	Name	Role in the Committee	Affiliations to the Institution
1	Dr. Ashok Shenoy K.	Chairperson	Non-affiliated
2	Dr. Shivashankara A.R.	Member Secretary	Affiliated
3	Mr. Eric Sequeira	Legal Expert; Vice Chairperson	Non-affiliated
4	Dr. Varadaraj Shenoy K.	Member-Clinician	Affiliated
5	Dr. Safeekh AT	Member-Clinician	Affiliated
6	Dr. Sudhir Prabhu	Joint Secretary, Clinician	Affiliated
7	Dr. Anup Kumar Shetty	Member-Basic Medical Scientist	Affiliated
8	Mrs. Veena Manoj	Member-Lay Person	Non-affiliated
9	Mrs. Anuradha Shetty	Member-Social Scientist	Non-affiliated
10	Fr.Dr. Leo D'Souza	Member-Theologian/Ethicist	Non-affiliated

Members absent : Nil

Name and Signature of Member Secretary

Dr. Shivashankara A.R., PhD.
Member Secretary
Father Muller Medical College
Institutional Ethics Committee
Kankanady, Mangalore

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

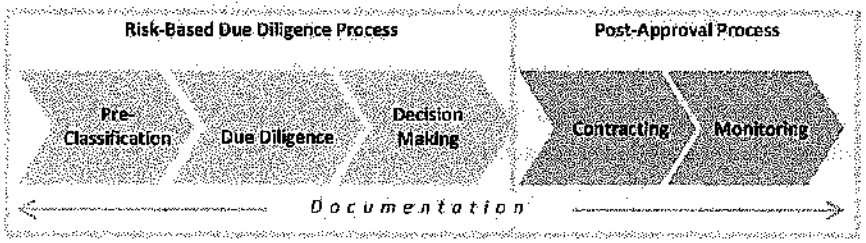
Further guidance to support the identification of Third Parties that fall within the scope of this Guideline can be found in Annex 6.

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.

NOVARTIS

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 Global Policy

Professional Practices Policy (P3)

Novartis Global Policy

March 1st, 2018

Version GIC102V1.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.

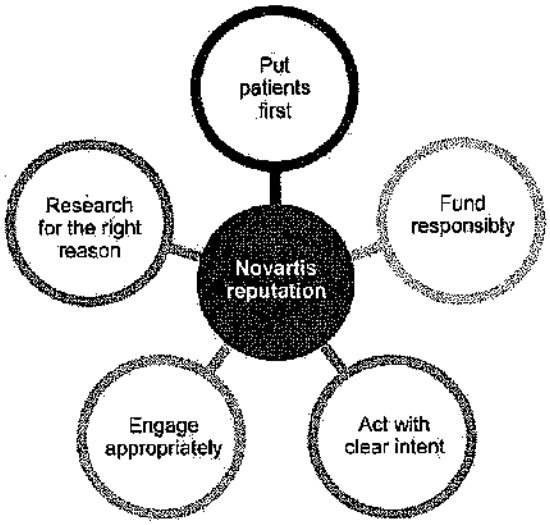
Allowable items of value, when provided to customers, must be modest, reasonable, infrequent, free from actual and perceived conflicts of interest, and disclosed where required.

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.

Executed

THE AJARA URBAN CO-OP. BANK LTD
Authorised Signatory

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157928 FEB 07 2019
Rs.0000200/-
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CLINICAL STUDY AGREEMENT

This Clinical Agreement ("Agreement") is entered into as of 1st *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 Singh

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

FULL DETAILS (Read-only) -> Click Here to Create PDF for Current Dataset of Trial

CTRI No	**CTRI/2018/11/016419** [Registered on: 26/11/2018] **Trial Registered Prospectively**
Acknowledgement Number	REF/2018/11/022336
Last Modified On:	23/11/2018
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Vaccine Biological Preventive
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	A clinical study to assess the safety and immune response with Typhoid conjugate vaccine of BE when compared with a licensed Typhoid conjugate vaccine.
Scientific Title of Study	A multicentre single blind randomised controlled Phase-II/III study to evaluate immunogenicity and safety of single intramuscular dose of Biological E's Vi-capsular Polysaccharide-CRM197 Conjugate Typhoid Vaccine in healthy infants, children and adults in comparison with a licensed comparator.
Trial Acronym	None

Secondary IDs if Any

Secondary ID	Identifier
BECT053/TCV-Phase-IIbyIII/CTP-01 Version :1.0 dated:09.07.18	Protocol Number

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

Name	Dr TSA Kishore
Designation	Associate Vice President - Clinical Development
Affliation	Biological E.Limited
Address	18/1&3, Azamabad, Hyderabad, Telangana,India Hyderabad TELANGANA 500020 India
Phone	04071216247
Fax	04027675309
Email	kishore.turaga@biologicale.com

Details Contact Person Scientific Query

Name	Dr Subhash Thuluva
Designation	Vice President- Clinical Development
Affliation	Biological E.Limited
Address	Biological E.Limited, 18/1&3, Azamabad, Hyderabad, Telangana India Hyderabad TELANGANA 500020 India
Phone	04071216000
Fax	04027675309
Email	subhash.thuluva@biologicale.com

Details Contact Person Public Query

Name	Dr Subhash Thuluva
Designation	Vice President- Clinical Development
Affliation	Biological E.Limited
Address	Biological E.Limited, 18/1&3, Azamabad, Hyderabad, Telangana India

	Hyderabad TELANGANA 500020 India
Phone	04071216000
Fax	04027675309
Email	subhash.thuluva@biologicale.com

Source of Monetary or Material Support

Biological E.Limited

Primary Sponsor

Name	Biological E Limited
Address	18/1&3, Azamabad, Hyderabad-500020, Telangana, India.
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
None	None

Countries of Recruitment

India

Sites of Study

No of Sites = **10**

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Pavan Hegde	Father Muller Medical College & Hospital	Department of Pediatrics, Ist floor,Father Muller Road, Kankanady, Mangaluru 575002, Karnataka, India Dakshina Kannada KARNATAKA	09845088116 pavanhegde@hotmail.com
Dr K Siva Ram Prasad	Gandhi Medical College & Hospital	Department of Pediatrics,Ist floor,Musheerabad, Secunderabad-500003, Telangana, India. Hyderabad TELANGANA	09440424545 ksivaramaprasad@yahoo.com
Dr Manish Narang	Guru Teg Bahadur Hospital	Department of Pediatrics, 3rd floor, Dilshad Garden, Shahdara, Delhi 110095, India North East DELHI	09811036569 manish_2710@yahoo.com
Dr Mandyam Dhati Ravi	J.S.S. Hospital	Department of Pediatrics,Ist floor, Mahathma Gandhi Road, Mysuru 570004, Karnataka, India Mysore KARNATAKA	09880629506 ravimdped@gmail.com
Dr Kapil Garg	Jay Kay Lon Hospital attached to S.M.S. Medical College	Department of Pediatrics,1st floor, JLN Marg, Jaipur-302004, Rajasthan, India. Jaipur RAJASTHAN	09829182888 drkapilgargjkl@gmail.com
Dr Sonali Kar	Kalinga Institute of	Department of community Medicine, Ist floor,KIIMS	09438423273

	Medical Sciences (KIMS)	Campus 5, KIIT University, Patia, BhubaneswarBhubaneswar – 751024, Odisha, India. Khordha ORISSA	sonsam72@yahoo.co.uk
Dr P Venugopal	King George Hospital	1st Floor, Dept.of Pediatrics, Collectorate Junction, Maharanipeta, Visakhapatnam 530002, Andhra Pradesh, India. Visakhapatnam ANDHRA PRADESH	09848027203 fbnc.amc@gmail.com
Dr Madhukar Pandey	Oriana Hospital	Department of Pediatrics,1st floor,Plot number 6, 7, 8 Ravindrapuri Extension, Lanka, Anandbagh, Bhelupur, Varanasi 221001, Uttar Pradesh Varanasi UTTAR PRADESH	09839439464 pandeymadhukar@gmail.com
Dr Savita Verma	PT. B D Sharma Post Graduate Institute of Medical Sciences & Hospital	Department of Pharmacology, 3rd floor,Near Directorate Office, Rohtak-124 001,Haryana,India Rohtak HARYANA	09812283746 savita_verma@hotmail.com
Dr Ashish Dhongade	Sant Dnyaneshwar Medical Education Research Centre	Department of Pediatrics, Ground floor, 695/A, Sadashiveth, 695/A, Sadashiv Peth, Opp. Vijay Talkies, Laxmi Road, Pune-411030, Maharashtra, India. Pune MAHARASHTRA	09011095436 adhongade1@gmail.com

Details of Ethics Committee
Clarification(s) with Reply
Modification(s)

No of Ethics Committees= **10**

Name of Committee	Approval Status	Date of Approval	Approval Document	Is IEC?
Institutional Ethics Committee,Sant Dnyaneshwar Medical Education Research Centre	Submittted/Under Review	No Date Specified	No File Uploaded	No
Ethics Committee, SMS Medical College and Attached Hospitals	Submittted/Under Review	No Date Specified	No File Uploaded	No
Guru Teg Bahadur Ethics Committee-Guru Teg Bahadur Hospital	Submittted/Under Review	No Date Specified	No File Uploaded	No
Institutional Ethics Committee, Gandhi Medical College/ Gandhi Hospital	Submittted/Under Review	No Date Specified	No File Uploaded	No
Institutional Ethics Committee, JSS Medical College & Hospital	Submittted/Under Review	No Date Specified	No File Uploaded	No
Institutional Ethics committee, Kalinga Institute of Medical Sciences	Submittted/Under Review	No Date Specified	No File Uploaded	No
Institutional Ethics Committee, Oriana Hospital	Approved	17/11/2018	Approval File	No
Institutional Ethics Committee, PT. B D Sharma Post Graduate Institute of Medical Sciences	Submittted/Under Review	No Date Specified	No File Uploaded	No

Institutional Ethics committee-Father Muller Medical College	Submittted/Under Review	No Date Specified	No File Uploaded	No
Institutional Ethics Committee-King George Hospital	Submittted/Under Review	No Date Specified	No File Uploaded	No

Regulatory Clearance Status from DCGI

Status	Date	Aproval Document
No Objection Certificate	01/11/2018	Approval File

Health Condition / Problems Studied
Clarification(s) with Reply
Modification(s)

Health Type	Condition
Healthy Human Volunteers	Preventive protection against Typhoid fever
Patients	Z23||Encounter for immunization,

Intervention / Comparator Agent

Type	Name	Details
Intervention	BioE's Typhoid Conjugate Vaccine(Monovalent)-Single Human dose-0.5mL	1. Dose: 0.5 mL single dose 2. Frequency: One dose only 3. Route of administration: intramuscular injection 4. Total duration of therapy:42 days (post single dose administration)
Comparator Agent	Typbar-TCV Single Human dose-0.5mL	1. Dose: 0.5 mL single dose 2. Frequency: One dose only 3. Route of administration: intramuscular injection 4. Total duration of therapy:42 days (post single dose administration)

Inclusion Criteria

Age From	6.00 Month(s)
Age To	64.00 Year(s)
Gender	Both
Details	1. Healthy subjects of either gender between ≥6 months to <64 years of age at the time of vaccination 2. Subject or Subject's Parent(s) or LAR who after the nature of the study has been explained to them, have given written consent according to local regulatory requirements. 3. Subject or Subject's Parent(s) or LAR's ability to understand information relevant to participation in the study and abide with the requirements of the subject diary and other study procedures; 4. Individuals in good health as determined by the outcome of medical history, physical examination based on clinical judgment of the investigator. 5. Negative to urine pregnancy test for female subjects of childbearing potential. Female of childbearing potential is defined as a pre-menopausal female capable of becoming pregnant. This does not include females who meet any of the following conditions: (1) menopause at least 2 years earlier, (2) tubal ligation at least 1 year earlier, or (3) total hysterectomy.

Exclusion Criteria

Details	1. Individuals who have a previously ascertained or suspected disease caused by Salmonella typhi; 2. Individuals who have history of household contact with/and or intimate exposure to an individual with laboratory confirmed S. typhi; 3. Individuals who have previously received any vaccines against typhoid fever (either oral live attenuated or injectable vaccines); 4. Individuals with body temperature ≥100.4°F (≥38.0°C) within 3 days of intended study immunization; 5. Individuals with any serious chronic or progressive disease according to judgment of the investigator (e.g., neurological, neoplasm, insulin dependent diabetes, cardiac, renal or hepatic disease); 6. Subject or Subject's Parent(s) or LAR unwillingness or inability to understand and follow required study procedures, keep appointments, or are planning to relocate during the study period; 7. Individuals with history of any illness or any laboratory abnormality that, in the opinion of the investigator, might interfere with the results of the study or

	pose additional risk to the subjects due to participation in the study; 8. Subject with suspected or known history of an autoimmune disorder or any other known or suspected impairment /alteration of the immune system, or under immunosuppressive therapy including use of systemic corticosteroids or chronic use of inhaled high-potency corticosteroids within the previous 30 days; 9. Subject with a known bleeding diathesis, or any condition that may be associated with a prolonged bleeding time or history of receipt of anti-coagulants in the past 3 weeks; 10. History of allergy or allergic reaction to any vaccine-related component; 11. Individuals participating in any other clinical trial within 30 days prior to first study visit or intent to participate in another clinical study at any time during the conduct of this study; 12. Women who are pregnant or breast-feeding or of childbearing age who have not used or do not plan to use acceptable birth control measures, for the duration of the study. Female of childbearing potential or age is defined as a pre-menopausal female capable of becoming pregnant. This does not include females who meet any of the following conditions: (1) menopause at least 2 years earlier, (2) tubal ligation at least 1 year earlier, or (3) total hysterectomy. 13. Any other reason that in the opinion of the investigator may interfere with the evaluation required by the study objectives.
Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	On-site computer system
Blinding/Masking	Participant Blinded

Primary Outcome

Outcome	TimePoints
1.Seroconversion rate as measured by proportion of subjects with anti-Vi IgG serum antibody concentrations above the threshold value. 2.Geometric mean concentrations (GMC) of anti-Vi IgG antibodies. 3.Fold increase in anti-Vi IgG antibody concentration.	1.at day 0 pre vaccination and at day 42 post vaccination. 2.at day 0 (pre vaccination) and at day 42 (post vaccination) 3.post-vaccination sample from pre-vaccination concentrations

Secondary Outcome

Outcome	TimePoints
Proportion of subjects with solicited adverse reactions	during first 30 minutes of post vaccination observation period and for subsequent 7 consecutive days (Day 0-6)
Proportion of subjects with unsolicited adverse events (AEs)	during the follow up period until day 42 of post vaccination.
Medically attended and/or serious adverse events (SAEs), if any	during the post vaccination 42 day follow up period.

Target Sample Size	**Total Sample Size=**"622" **Sample Size from India=**"622" **Final Enrollment numbers achieved (Total)=** "Applicable only for Completed/Terminated trials" **Final Enrollment numbers achieved (India)=**"Applicable only for Completed/Terminated trials"
Phase of Trial	Phase 2/ Phase 3
Date of First	30/11/2018

Enrollment (India)	
Date of Study Completion (India)	Applicable only for Completed/Terminated trials
Date of First Enrollment (Global)	No Date Specified
Date of Study Completion (Global)	Applicable only for Completed/Terminated trials
Estimated Duration of Trial	**Years=**"0" **Months=**"6" **Days=**"0"
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	None
Brief Summary	This is a multicentre single blind randomised, comparative, phase-II/III study to demonstrate non-inferiority in terms of seroconversion rates and safety of Biological E's Typhoid conjugate vaccine in ≥6 months to <64 year old healthy subjects in comparison with licensed Typbar-TCV vaccine at day 42. The total sample size to be enrolled would be 622 subjects in both groups put together based on the screening and enrolment criteria set in the protocol. Each subject will receive a single 0.5 mL dose of the study vaccine intramuscularly i.e., Biological E's Typhoid conjugate vaccine or Typbar-TCV vaccine, based on the treatment groups to which they are randomised for assessing the safety & Immunogenicity. Only optimal quantity of venous blood sample for immunogenicity assessment will be drawn twice during the study period. The study will be conducted in compliance with schedule Y, ICH and Indian good clinical practice guidelines in force at the time of study conduct.

FATHER MULLER MEDICAL COLLEGE INSTITUTIONAL ETHICS COMMITTEE

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

DCGI Re-registration No.
ECR/540/Inst/KA/2014/RR-17

Tel : 0824-2238327
e-mail: fmiethicscommittee@gmail.com

CHAIRPERSON
Dr. Ashok Shenoy
Professor of Pharmacology
KMC, Mangalore-575001
Phone : +919880530703
E-mail: ashok.shenoy@manipal.edu

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

Ref. No : FMMCIEC/CCM/643/2018 *Date :* 09.11.2018

Protocol title: "Elucidating the dermatophyte spectrum through rapid multiplex PCR and detection of antifungal drug resistance caused by mutations in squalene epoxidase and 14 alpha demethylase gene"
Protocol No: 496/18
Principal Investigator : Dr Jyothi Jayaraman Co Investigators : Dr.Sukumar.D, Dr. Meryl Sonia Rebello, Dr.Meena Dias, Dr.Indrani Karunasagr, Dr Meghashree G
Name & Address of Institution : Dept of Dermatology Father Muller Medical College, Kankanady, Mangalore – 575002
New review: Exempt review ✓ **Expedited review** **Full review**
Review of Revised Submission: Exempt review
Date of review:09.11.2018 **Date of previous review, if revised application:** Full Review was done on 08.11.2018
Decision of the Ethics Committee: **> Approved ✓** > Approved with suggestions > Revision/ Resubmission > Rejected
Suggestions /Reasons/Remarks: Nil
Recommended for a period of : One Year

Please note:
> Inform Ethics Committee immediately in case of any adverse events and serious adverse events.
> Inform Ethics Committee in case of any change of study procedure, site and investigator.
> This permission is only for a period mentioned above. Annual report to be submitted to Ethics Committee.
> Members of Ethics committee have right to monitor the study with prior intimation

Agreement Form to Be Signed By All IADVL-Research Grant Recipients

We commit to the following:

(i) To provide the IADVL Academy with a report on the status of the project and a financial report every quarter and before IADVL Central Council and General Body Meetings and at the conclusion of the Project

(ii) To complete the research within 2 years or the period decided at the time of submission of the proposal whichever is early.

(iii) To submit the results for presentation in DERMACON and for publication in the IJDVL or other national or international journals, with an acknowledgement of the Grant

(iv) To acknowledge the Grant in every mode of presentation, i.e. paper, poster or article

(v) To return any unused part of the grant along with any interest accrued to the IADVL on completion of the project and before the nearest CCM, AGBM or Academy meeting

(vi) To submit the financial account of the project and final report within 3 months of its completion along with invoices of purchased materials for audit

(vii) To utilize the Grant only for those aspects for which it has been sanctioned

(viii) To not apply for any grant for the same project with any other organization/institutions, public or private.

(ix) To abide by all terms and conditions related to the grant that IADVL has at the time of approving it and also those that can come into force during the study period.

(x) To accept all legal liability since IADVL is only the funding body

We declare that we have no conflict of interest in regard to the subject of this project with a pharmaceutical company or any other organization other than the IADVL.

We accept that that if we do not follow this undertaking or if there is any deviation, we will not be considered for any research grant from IADVL in future.

Dr. JYOTHI JAYARAMAN

Dr. SUKUMAR. D

Dr MEGHAJHREE. G.

Signed by all investigators

Countersign of head of institute

Dr. INDRANI KARUNASAGAR

Dr. MEENA DIAS.

Copy of Approval letter from VGST

GOVERNMENT OF KARNATAKA
Vision Group on Science and Technology
Department of Information Technology, Biotechnology and Science & Technology
Karnataka Government Secretariat, No.702, 7th Floor, 4th Stage, M. S. Building, Dr. Ambedkar Veedhi,
Bangalore-560 001
Phone: 080-2203 2013, E-mail: visiongroup.st@gmail.com Website: www.vgst.in

No /VGST/GRD -650 /2017-18 /572

23-03-2019

To,

The Principal,
Father Muller Medical College, Kankanady,
Mangalore - 575 002.

Dear Sir,

Subject: - Approval for the submission of PART – A, for purchase the Equipment. GRD 650.

***

With reference to the approval of GRD–650, **Muller Medical College, Kankanady,Mangalore** proposed by Dr. Beena Antony, Department of **Micro Biology**, under the scheme K-FIST(L2) the project titled **"Phenotypic and Genotypic Characterization of anaerobic Microbial Community Isolated from Huma Infections in the Suburban Population of Coastal Karnataka" was** released the grant of Rs.20.00 lakhs for 1st Instalment in the FY: 2017-18 (Cheque no: 384870 / 384871 Dt :10-09-2018).

As submitted the PART – A, of GRD– 650, by the Grantee Institution requesting for the purchase of Equipment for the **First Instalment** the details are as follows.

1st Instalment – Non-Recurring Budget Estimate under E-Tendering process (ETP) for the FY: 2017-18.

Sl. No	Submitted in PART –A under Non –Recurring (ETP) Budget Estimate by Grantee Institution	Amount (Rs)
1	Don Whitley Anaerobic Chamber	13,62,055.00
2	Don Whitley CO_2	4,35,000.00
	TOTAL	**17,97,055.00**

Non-Recurring Budget Estimate under Manual Tendering Process for the FY: 2017-18.

Sl. NO	Submitted in PART –A under Non –Recurring (MTP) Budget Estimate by Grantee Institution	Amount (Rs)
1	Olympus Binocular	75,000.00
2	Colony Counter	70,000.00
	TOTAL	**1,45,000.00**

1st Instalment – Recurring Budget Estimate for the FY: 2017-18.

SL. NO	Submitted in PART – A under Recurring Budget Estimate by Grantee Institution	AMOUNT (Rs)
1	Chemicals	1,20,000.00
2	Glass Ware	
3	Plastic Ware	
4	Biological Specimen	
5	Electrical and Electronic Spare Parts	15,000.00
6	Mechanical Spare Parts	15,000.00
7	Contingency	40,000.00
8	Books and Journal	10,000.00
	Totsal	**2,00,000.00**

The submitted Financial status Performa (FSP) and PART – A document details are as follows.

Grant Amount for the FY: 2016-17	20,00,000.00
TOTAL	**20,00,000.00**
NON-RECURRING (A)	
E-tendering (ETP)	17,97,055.00
Manual Tendering (MTP)	1,45,000.00
TOTAL (A)	**19,42,055.00**
RECURRING (B)	
Consumables and Contingency	2,00,000.00
TOTAL (A) + (B)	**21,42,055.00**
Approval by VGST (PART - A submitted by GI / PC)	**20,00,000.00**
Amount sponsored by the Management	**1,42,055.00**

In this view, as mentioned in the procurement document (PART-A), you may purchase the equipment through E-Tendering and Manual Tendering. Please do not deviate the purchase procedure for the procurement of equipment. Please submit the PART-B and PART-C (downloads in VGST website) to the VGST office after completion of the process . This is for your kind information.

With thanks and regards,

Yours sincerely,

(Dr.S.G.Sreekanteshwara Swamy)

Consultant

S.K.Muthagi 25/3/15

CC: Dr. Beena Antony, Department of Micro Biology, Muller Medical College, Kankanady,

Rajiv Gandhi University of Health Sciences, Karnataka
4th T Block, Jayanagar, Bangalore – 560 041

PROCEEDINGS OF THE RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES, BANGALORE

Sub: Financial assistance for Research under RGUHS sanction of grant-in-aid for various teaching faculties of affiliated institutions of RGUHS – reg.

Ref: 1. University notification No: RGUHS/Adv.Research: 2015-16 dated:29-04-2015
2. Approval of the Syndicate in its 116th meeting held on 16th December 2015.

- - -

READ:

One of the main objectives of the University is to promote research activities in the University and also affiliated colleges. In this regard University had invited applications for financial assistance for conducting of advanced research projects for the year 2015-16. University had received 366 research proposals. The University had earmarked Rs.5.00 crores in its budget estimate for the year 2015-16 for this purpose. In order to meet this expenditure the concerned Subject Experts as suggested by the concerned BOS PG chairpersons and the Expert Committee comprising of all the BOS PG chairpersons have scrutinized the proposals and shortlisted them based on the criteria set out by the University. Such of the proposals which have fulfilled the norms have been recommended by the Expert Committee for sanction of grants.

The Syndicate in its 116th meeting held on 16th December 2015 has approved to sanction the grant-in-aid as per the recommendations of Expert Committee for 159 selected proposals in medical, dental, pharmacy, ayurveda, nursing, physiotherapy, allied health sciences and BNYS faculties for the year 2015-16.

As per the decision of the Syndicate the following orders are made.

ORDER NO:RGU: Adv. Res:Proposal-M-111: 2015-16 DATE:05-01-2016

Pursuant to the approval of the Syndicate, sanction is hereby accorded for release of grant-in-aid amounting to Rs. 3,00,000-00 (Rupees Three lakhs only) towards research proposal "Analysis of Biofilm Production and Detection of

Associated Genes in Anaerobic Microbial community of Human Body" furnished by Dr Beena Antony, Professor of Microbiology, Fr.Muller Medical College, Kankanady, Mangalore,Karnataka-575002 for the year 2015-16. The Grant-in-aid will be released in the name of Director of the Fr. Muller Medical College, Kankanady, Mangalore subject to following terms and conditions mentioned hereunder.

1. The Principal / Head of Institution shall open a separate joint account for the financial grant released by RGUHS in the name of Principal / Head of the Institution and the Principal Investigator.
2. Principal / Head of the Institution and the Principal Investigator shall be responsible for the accounts and the proper utilization of the funds. The grants released shall be used only for research purpose.
3. 50% of the grant-in-aid approved by RGUHS shall be released as 1st installment. 25% of the grant-in-aid shall be released after the Utilization Certificate for the money released in the 1st installment is given. Balance of 15% shall be released after the Utilization Certificate for the money released in the 2nd installment is given. Remaining 10% will be released after the submission of Project Report to the University. Audit report shall be submitted along with every Utilization Certificate.

   The bifurcation of grant-in-aid as per the above criteria applicable to you is as follows:

1	Total grant-in-aid sanctioned	Rs.3,00,000-00
2.	First Installment (50%)	Rs. 1,50,000-00
3.	Second Installment (25%)	Rs. 75,000-00
4.	Third Installment (15%)	Rs. 45,000-00
5.	Fourth Installment (10%)	Rs. 30,000-00

4. The project shall be completed within 2 years from the time of release of 1st installment of grant-in-aid. However, the University in deserving cases may extend this time frame.
5. Principal Investigator shall furnish project status report once in six months till the completion of the project.
6. During the research work, officials of the Expert Committee along with Subject Experts shall reserve the right of inspection.

7. All the details about the conduct of research activity along with documents should be properly maintained by the Principal Investigator. He/She should submit such details of research to monitoring committee or to the University whenever it is called for.
8. ICMR and MCI guidelines especially with regard to ethical issues shall be followed strictly in the research activity.
9. Regarding ethical issues in various faculties, the guidelines prescribed in the apex bodies or any other related authorities regarding the conduct of study should strictly be adhered to.
10. Research project shall be published in national/international indexed journals after the completion of the project. During such publication it is the duty of the Principal Investigator to acknowledge the assistance given by the University as a source of funding for the research activity.
11. In case the Principal Investigator discontinues the research work under unforeseen circumstances, the co-investigator shall continue the research work and complete the project with the approval of the University. It is the responsibility of the Principal/Head of the Institution to ensure, in such circumstances, that the research is completed with the co-investigator of the research project.
12. It is the responsibility of the Principal/Head of the Institution and Principal Investigator to ensure that research work is completed within the stipulated time.
13. The grants released by the University shall not be utilized for the purpose of purchase of equipments.
14. The honorarium for the supportive staff, purchase of consumables, tests carried outside the institution because of lack of infrastructural facilities in the institution, travel grants for attending conference for presenting the research work and for publication of papers in national / indexed journals shall be met out of the grant-in-aid.
15. After the completion of the project the entire project report shall be submitted to the University and will become property of the University.
16. If any of the conditions mentioned above are not adhered to by the Principal/ Head of the Institution and the Principal Investigator, University reserves the right to take appropriate action.
17. In research proposals involving clinical trials, if any untoward incidence occurs, it is the responsibility of the Principal Investigator and the

GOVERNMENT OF KARNATAKA
OFFICE OF THE JOINT DIRECTOR (TB), LADY WILLINGDON STATE TB CENTRE,
4TH MAIN ROAD, SAMPANGI RAMANAGAR, BANGALORE-560 027.
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LWSTC/RNTCP/PPM/122 /2017-18 Date : 12.09.2018

Proceedings of the meeting held on 12th September 2018 under the chairmanship of Joint Director (TB) to discuss Development of OR and the release of Budget for the approved ORs 2017-18

Participants of the meeting

- **Dr. M. Manjula, Joint Director (TB), LWSTC, Bangalore**
- **Dr. Anil.S, Deputy Director (TB), LWSTC, Bangalore**
- **Dr. Sharath BN, Chair of State OR Committee, Bangalore**
- **Mrs. Vidya H.P State PPM Coordinator, LWSTC, Bangalore**

Meeting Agenda:

1. **Release of the second instalment of the eight Operational Research for the FY 2016-17**
2. **Mechanism of Budget release for 2017-18**
3. **Development of OR for the 2018-19**

Meeting started with the briefing of the agenda of the meeting by Dr. Sharath BN, State Chair of OR.

1. **Agenda 1- Release of the second instalment of the eight Operational Research for the FY 2016-17**

Discussed about the release of 2nd instalment for 8 Operational Research of 2016-17 for the below titles mentioned below

Sl.No	Investigator	Medical College & District	Budget approved in Lakh	1st instalment released in Lakh	2nd instalment to be released in Lakh
1	Dr. Madhavi Bargava-	Yenopoya, Dakshina Kannada	1.84	1.1	0.79
2	Dr.Jannatbi,	GIMS , Gadag	0.44	0.3	0.14

3	Dr.Poornima,	JJM Medical College ,Davanagere	1.89	1.1	0.79
4	Dr.Dr.Rashmi,	Sapthagiri Medical College ,Bangalore Urban	1.86	1.1	0.75
5	Dr.Shivalli,	Yenapoya ,Dakshina Kannada	1.99	1.2	0.79
6	Dr.Padmaja	FMMC, Dakshina Kannada	1.99	1.2	0.79
7	Dr.Lalitha	MS Ramaiah, BBMP	1.99	1.3	0.69
8	Dr Hemamaheshwari	Vydehi, Bangalore Urban	1.16	0.7	0.46

The status of the Operational Research for 2016-17 will be given by the Dr. Sharath -OR Chair

(Action: Chair OR)

Budget will be released respective Districts DTO to all 8 Operational Research of 2016-17. Budget will be released with following conditions:

- The principal investigator has to submit the fund utilization certificate for the funds received (First Instalment) to the District TB Officer. Further upon the second instalment will be released..
- The Principal Investigator should also update the progress of the research to STF Chairman, and the State Operational Research Committee Chair. The State OR Chair will submit the copy of the progress made by all investigator to Joint Director (TB).
- Hard copy of the completed research should be submitted to District TB office and State TB Office.

(Action: Dr. Anil Deputy Director(TB))

Agenda 2: Budget release for the Operational Research title finalised in 2017-18 .

All 14 Operational Research are approved with few remarks. It will be reviewed by the OR committee and reported to Dr. Anil S. Deputy Director (TB) and Dr. Sharath, State OR Chair , will facilitate for the same.

The following Operational Research Protocols from Medical College Faculty are approved by the RNTCP

State Operational Research Committee of Karnataka for funding.

S.No	Principal Investigators * & Medical College	Title	Approved Budget in Lakh	Remarks
1	Dr. Shantha Kumar, MR Medical College, Gulbarga	A study on effect of micronutrient supplementation on sputum smear conversion among pulmonary tuberculosis cases in Kalaburgi district	Rs. 1.90	Title to be reworked. If the PI wants to keep the same title then, the PI is requested to submit publications which site the micronutrients to be deficient in pulmonary TB and what would be the replacement dose and duration.
2	Dr. Panduranga, ESIC Medical College & PGIMSR, Bangalore	Granulomatous response pattern among tubercular lymphadenitis cases and their response to RNTCP treatment	Rs. 1.36	Approved.
3	Dr. Ranganath, BMC, Bangalore	Factors favoring/hindering the adherence of treatment among TB-HIV patients initiated on 99DOTS- A Cross sectional study across five districts of Karnataka	Rs. 1.90	99 DOTS is not functional in Karnataka. Hence, this study cannot be undertaken.
4	Dr. Akshaya, Yenepoya Medical College, Mangalore	Are the patients with tuberculosis in Dakshina Kannada district beneficiaries of the social welfare measures of the government? An operational research to facilitate linkages	Rs. 1.96	Approved
5	Dr. Rajani, RIMS, Raichur	Study of Proportion of Isoniazid Mono-Poly	Rs. 1.95	Approved

		resistant TB cases and Subsequent resistance to second line anti TB drugs		
6	Dr. Shilpa K, GIMS, Gadag	Validation of On Site Evaluation (OSE) checklist reported by senior TB lab supervisor (STLS) in DMCs of selected districts in Karnataka: A Multicentre study.	Rs. 1.99	Approved
7	Dr. Pracheth, Yenepoya Medical College, Mangalore	Implementation of airborne infection control in Anti-Retroviral Therapy centres of Karnataka: A mixed-methods operational research	Rs.1.95	Dr. Sharath BN to check on the methodology of assessing AIC by the PI. And the PI to add other departments like Radiology, In-patients where HIV infected and admitted for the study.
8	Dr. Kiran Chawla, KMC, Manipal	Enhancement of Detection of Pediatric TB cases (≤15 years) in Udupi TU after strengthening the skills of health care workers to perform induced sputum production	Rs. 1.99	Approved
9	Dr.Kavya, KS Hegde Medical College, Mangalore	Integrating Tuberculosis Screening into Antenatal Care: A Mixed-Methods Study in a Tertiary Care Hospital of Dakshina Kannada, Karnataka	Rs. 1.76	Budget to be reviewed.
10	Dr. Huliraj, KIMS Bangalore	Identification of ADR/SE by targeted intervention among DS-TB patients initiated on daily regimen at a tertiary medical centre, Bengaluru	Rs. 1.93	Approved

11	Dr.Tejashree, JSS Medical College, Mysore	A study of Spoligotyping patterns of MTB isolates and their drug resistance analysis among PTB patients in JSS, a tertiary care hospital, Mysore, South India	Rs.1.99	Approved
12	Dr. Roopa, GIMS, Gadag	Compare the Cough Hygiene and Sputum Disposal practices before and after additional interpersonal communication among the newly diagnosed Pulmonary Tuberculosis patients Attending District Hospital Gadag	Rs.1.99	Approved
13	Dr. Sourabh, Father Mullers Medical College, Mangalore	Effect of Sensitization about Mandatory Notification Guidelines on the Tuberculosis case notification rate by private pharmacies in Mangalore city in Dakshina Kannada district	Rs.1.60	Approved
14	Dr. Lalitha, Oxford Medical College, Bangalore	A Study on Challenges Encountered by Medical Colleges to Implement RNTCP Activities in Karnataka	Rs.1.99	Approved

Note:

- The principal investigator has to submit the fund utilization certificate to the District TB Officer as on 31st March 219.
- They should also update the progress of the project to Chairman, STF Operational Research Committee and State TB Officer every three months.
- All the PIs should attend the "Scientific paper writing module workshop" which shall be organized by State OR Committee and publish their study findings in a peer reviewed journals.
- Those who fail to complete the project should return back the funds to the programme.

- Further directives, if any, will be provided by the Chairman STF, State OR Committee Chair from time to time.

(Action: Dr. Anil S. Deputy Director (TB) & Dr, Sharath BN , OR Chair)

The Committee decided to release 100% of fund for the all approved 14 Operational Research for which Utilisation Certificate to be provided by the respective Principal Investigator before 31st of the March 2019 to concerned District TB Officers.

(Action: Dr. Anil S. Deputy Director (TB))

Agenda -3 : Development of OR for the 2018-19

New Operational Research proposal and PG thesis need to be submitted by the 15th December 2018.

(Action: Dr. Anil S. Deputy Director (TB) & Dr, Sharath BN , OR Chair)

Meeting concluded with the vote of thanks by the State PPM Coordinator.

Chairman
State Operational Research

Joint Director (TB)
LWSTC-Bangalore

NATIONAL CENTRE FOR DISEASE INFORMATICS AND RESEARCH

INDIAN COUNCIL OF MEDICAL RESEARCH

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

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

14 June 2018

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

Sir,

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

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

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

Yours faithfully,

(Ramesha N.M.)
Administrative Officer
For Director

To CMS.

21-6-18

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

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

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