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.

FATHER MULLER INSTITUTIONAL ETHICS COMMITTEE

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

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

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

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

Ref. No : FMMC/FMIEC/2893/2016 *Date* : 03.05.2016

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

Study Protocol No: 605-12

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

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

Dear Dr. Ramesh Bhat,

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

The following documents are:

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

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

The following members of the Ethics Committee were present at the meeting held on **16.04.2016 at 3:00pm in the Seminar Hall.**

Sl No.	Name	Qualification	Designation/ Title	Affiliations as to the Institution
1.	Dr. Arun Rao	MD, DGO	Chairperson (Clinician)	No
2.	Dr. Shiva Shanker	Ph.D	Joint Secretary (Scientist)	Yes
3.	Mr. Eric Sequeira	BABL	Vice Chairperson (Advocate)	No
4.	Rev. Dr. Leo D' Souza	M. Sc, Ph.D	Member(Theologian)	No
5.	Mrs. Rameela Shekar	MSW, M. Phil, (PSW), PGDHRM, Ph.D	Member (Sociology)	No
6.	Dr. P J Kurian	MD	Member (Homeopathy)	Yes

7.	Prof. Irene T.R. Alvares	M. Sc	Member (Nursing)	Yes
8.	Dr. Ashok Shenoy	MD	Member (Pharmacologist)	No
9.	Dr. Varadaraj Shenoy	MD, DCH	Member (Pediatrician)	Yes
10.	Mrs. Veena Manoj	MA, B.Ed	Member (Lay person)	No
11.	Mr. Sudeep M J Pais	MPT	Member (Physiotherapist)	Yes
12.	Dr. Jayaram Shetty	BVSc, MVSc	Member (Veterinion)	No
13.	Mr. Nikesh Shetty	BABL	Member (Advocate)	No

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

Sl No	Name	Qualification	Designation/ Title	Affiliations as to the Institution
14.	Dr. B. Sanjeev Rai	MD, DCH, MBA	Secretary (Clinician)	Yes
15.	Dr. John Mathai	MD	Member (Clinician)	Yes
16.	Ms. Bindiya Shetty	MSW	Member (Counsellor)	No

We approve the trial to be conducted in its presented form

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

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

Yours Sincerely,

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

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

FATHER MULLER INSTITUTIONAL ETHICS COMMITTEE

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

Tel : 2238399
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CHAIRPERSON
Dr. Arun Rao
Prof. of Obstetrics & Gynaecology
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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/1026/2012 *Date :* 07.12.2012

To,

Dr. Nelee Bisen

Senior Resident,

Dept. of Dermatology, Venereology & Leprosy,

Father Muller Medical College,

Mangalore.

Dear Dr. Nelee Bisen,

Subject : FMIEC approval for the Study **"A clinicoepidemiological dermoscopic and histopathological study of Dermatosis papulosa nigra in a tertiary care hospital of South India"**

Your study entitled **"A clinicoepidemiological dermoscopic and histopathological study of Dermatosis papulosa nigra in a tertiary care hospital of South India" 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

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**

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

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

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

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Karnataka, India

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

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Dr. B. Sanjeev Rai
Chief of Medical Services,
Father Muller Charitable Institutions,
Kankanady, Mangalore - 575 002
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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 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

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

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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/188/2018 *Date* 13.03.2018

To : Dr.Jacintha Martis
Professor of Dermatoology,
Father Muller Medical College Hospital,
Mangalore.

Dear Dr.Jacintha Martis,

Your amended research proposal was reviewed and discussed in the ethics committee meeting held on 10/03/2018 and the decision is as follows:

Protocol title: " A phase 2 , Multicenter, Randomozid , Double blind , Comparative Study to evaluate the reduction in incidence of scarring in acne vulgaris subjects treated with combination of Benzoyl peroxide (2.5%), Zinc oxide and Polysiloxanes compared to Benzoyl Peroxide(2.5/5%)"
Protocol No: 5267/17
Principal Investigator: Dr. Jacintha Martis Co Investigators : Dr. Ganesh Kamath H, Dr Rochelle Cheryl Monteiro
List of following amended consent forms were reviewed on 10.03.2018 • Patient informed Assent form English final version 04.1 dated 04.1 • Patient informed Consent form English final version 04.1 dated 04.1 • Patient information sheet English final version 04.1 dated 04 Nov 2017 • Patient information sheet English final version 04.1 back translated from Kannada to English On 17 November 2017 dated 04 Nov 2017

- Patient informed Assent form final version 04.1 back translated from Kannada to English 0n 16 November 2017 dated 04 Nov 2017
- Patient informed consent form English final version 04.1 back translated from Kannada to English 0n 16 November 2017 dated 04 Nov 2017
- Patient information sheet Kannada final version 04.1 back translated from English to Kannada 0n 17 November 2017 dated 04 Nov 2017
- Patient informed consent form final version 04.1 back translated from English to Kannada 0n 16 November 2017 dated 04 Nov 2017
- Patient informed Assent form final version 04.1 back translated from English to Kannada 0n 16 November 2017 dated 04 Nov 2017
- Summary of changes

Name & Address of Institution :

Father Muller Medical College Hospital,
Father Muller Road, Kankanady, Mangalore-575002

Date of Submission: 02.02.2018
Date of review: 10.03.2018

Decision of the Ethics Committee: Approved

Suggestions /Reasons/Remarks:

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. Sudhir Prabhu	Joint Secretary, Clinician	Affiliated
6	Dr. Anup Kumar Shetty	Member-Basic Medical Scientist	Affiliated
7	Mrs. Veena Manoj	Member-Lay Person	Non-affiliated
8	Mrs. Anuradha Shetty	Member-Social Scientist	Non-affiliated
9	Fr.Dr. Leo D'Souza	Member-Theologian/Ethicist	Non-affiliated

Name and Signature of Member Secretary

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

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

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

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Karnataka, India

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Associate Professor of Biochemistry,
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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 INSTITUTIONAL ETHICS COMMITTEE

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Prof. of Obstetrics & Gynaecology
Kasturba Medical College
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Phone : 9845677507

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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

FATHER MULLER INSTITUTIONAL ETHICS COMMITTEE

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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

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

Ref. No : FMMC/FMIEC/1185/2013

Date : 05.03.2013

To,

Dr. Ramesh Bhat M
Prof and HOD, Department Of Dermatology,
Father Muller Medical College Hospital,
Kankanady, Mangalore – 575002.

Dear Dr. Ramesh Bhat M,

Subject :FMIEC approval for the Study "Role of scalp cleansers in the management of Infantile seborrheic dermatitis (ISD)"

Your study entitled "Role of scalp cleansers in the management of Infantile seborrheic dermatitis (ISD)" was discussed during the meeting and it was approved.

You are not to be 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 College
Mangalore-575002

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Kankanady, Mangalore - 575 002
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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

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/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

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Karnataka, India

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Mangalore - 575 001
Phone : 9845677507

SECRETARY
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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 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

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/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

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

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CHAIRPERSON
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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/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

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 : 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

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 Non recurring	 6.25 5.20	 9.25	 7.00	 22.50 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 Recurring	2.23	2.52	1.15	5.9
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 Non recurring	 4.10 1.15	 4.28	 3.82	 12.20 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

MANGALORE BIOTECH LABORATORY (Regd)
(AN ISO 9001:2008 CERTIFIED & NABL 17025:2005 ACCREDITED LAB)
Embassy Plaza , 3rd Floor, Near Pumpwell Circle. Mangalore – 575002 **Mob :09343351143 / Tel/Fax: 0824-2242636**
Email:mangalorebiotech@yahoo.com / **Website:**www.mangalorebiotech.com
Dr.P.Tauro – Ph.D , Director

NABL Certificate No.TC-7316

Dt: 30th October 2018

Dr Jyothi Jayaraman,
Fr. Mullers Charitable Hospital
Kankanady
Managalore

Respected Madame,

Sub: PCR Testing basis Molecular Detection Methodology.

We wish to state that our Laboratory has been one of the pioneers for doing various Molecular based testing for the Extraction of DNA as well as the amplification and detection of various organisms related to humans etc at Mangalore.

Title of the Project : ELUCIDATING THE DERMATOPHYTE SPECTRUM THROUGH RAPID MULTIPLEX PCR AND DETECTION OF ANTIFUNGAL DRUG RESISTANCE CAUSED BY MUTATIONS IN SQUALENE EPOXIDASE AND 14 – DEMETHYLASE.

We also are willing you and welcome you to be part of the above titled study.

We are very much familiar with the above subject and are capable and confident of undertaking any work related to the same.

Regards

Anand
Lab Manager

THE AJARA URBAN CO-OP BANK LTD
Authorised Signatory

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CLINICAL STUDY AGREEMENT

This Clinical Agreement ("Agreement") is entered into as of 7 *Feb 2019* ("Effective Date") between Novartis Healthcare Private Limited, a company registered under the Companies Act, 1956 and having its registered office at 6th & 7th floor, Inspire BKC, G Block, Bandra Kurla Complex, Bandra (East), Mumbai - 400051("Novartis") which expression shall mean and include its successors and assigns of the ONE PART;

AND

Father Muller Medical College Hospital, located at *Mangalore* ("Institution") registered under *Father Muller Medical College Hospital(A unit of charitable Instituions) Certificate No: H-2015-0313* and having its address at *Father Muller Medical College Hospital, Father Muller Charitable Institutions, Father Muller Road, Kankanady, Mangalore 575002, Karnataka India* which expression shall mean and include its successors and assigns of the SECOND PART;

AND *Dr. Ramesh Bhat M* as clinical practitioner in the field of *Dermatology* acting in the role of principal investigator ("Principal Investigator") which expression shall mean and include his/her heirs, executors, administrators and assigns of the THIRD PART;

Novartis and Institution and Principal Investigator are hereinafter individually referred to as the "Party" and jointly as the "Parties".

RECITALS:

WHEREAS, Novartis is to perform a clinical trial (hereinafter the "Study") to evaluate the following drug *Ligelizumab (QGE031)* (hereafter the "Study Drug") in accordance with a protocol entitled *PEARL- 2 (CQGE031C2303)* and its amendments (hereinafter collectively the "Protocol") attached hereto in Annex 3, and,

WHEREAS, the Institution and the Principal Investigator having each reviewed the Protocol for the Study and sufficient information regarding the Study Drug to evaluate their interest in participating in the Study, wish to conduct in the Study and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Study,

WHEREAS, the Parties wish to set forth certain the terms and conditions under which the Study shall be conducted;

NOW THEREFORE, the Parties, in consideration of the above and the mutual promises set forth below, agree as follows:

1. CONFORMANCE WITH LAW AND ACCEPTED PRACTICE

The Institution and Principal Investigator shall carry out the Study in accordance with:

(a) the Protocol as amended from time to time,

(b) Good Clinical Practice;

(c) the Declaration of Helsinki;

(d) any applicable direction received from a regulatory authority (DCGI) or ethics committee with jurisdiction over the Study;

(e) any "**Applicable Law(s)**" being hereinafter defined as : all regional, federal, state, and local directives, laws, including but not limited to Schedule Y of Drugs and Cosmetics Act 1940, those related to anti-bribery and promotion, rules, regulations, orders, published guidelines, operating procedures applicable to the Study and/or the Parties including but not limited to, legislation applicable to clinical Studies, the Parties, medical treatment and the processing of personal and medical data.

(f) comply with all guidelines provided to it by Novartis from time to time individually but not limited to Code of Conduct, Novartis global Antibribery Policy and Professional Practices Policy

The Institution warrants that the Principal Investigator and the Institution's employees and collaborators involved in the Study will comply with all Applicable Laws.

2. PROTOCOL

2.1 The Parties agree that the Protocol, including any subsequent amendments and the Annexes form an integral part of this Agreement.

2.2 Institution and Principal Investigator agree to use their best efforts and professional expertise to perform the Study in accordance with the Protocol, all Applicable Laws, the identified timelines and the terms and conditions of this Agreement. Institution and Principal Investigator may not start the clinical trial without prior approval of the appropriate Ethics Committee and Regulatory Authority.

3. APPROVALS

The Study shall not commence until:

(a) all the necessary approvals of the relevant regulatory authority hence been obtained by Novartis and the competent Ethics Committee have been obtained in writing by the Principal Investigator. Such approvals shall be forwarded to Novartis no sooner they are obtained;

(b) the written approval of relevant authority or organisation that owns or is responsible for the administration of the facility in which the Study is to be performed has been obtained, if such authority or organisation is not the Institution.

(c) the Informed Consent Form as defined in Section 6.4 provided by Novartis, has been approved by the Principal Investigator and/or the ethic committee.

4. DURATION OF THE STUDY

The Study shall commence on *10 Sep 2018*, subject to the requirements of Section 3 have been met prior to this date. The Institution shall use its best efforts to complete the Study and to perform its obligations under this Agreement by *21 Oct 2021* or as may be extended by a formal writing between the parties in that behalf

5. TERM OF THIS AGREEMENT

5.1 This Agreement shall be effective upon *5 Feb 2019* ('Effective Date') and shall expire upon *4 Feb 2022* (both days inclusive) unless extended or terminated in terms of this Agreement.

5.2 The following provisions shall survive the termination or expiry of this Agreement: Section 12 (Intellectual Property), Section 14 (Publication) and Section 15 (Confidentiality), as well as any other provisions which by their terms are understood to survive the termination or expiry of this Agreement, including compliance with Applicable Laws.

5.3 In the event that the Principal Investigator decides to no longer conduct the Study both Principal Investigator and the Institution shall provide written notice to Novartis as soon as possible, and at the latest, within 30 days prior to such departure. It is clarified that Principal Investigator shall not be discharged of his/her obligations under this Agreement unless the Novartis and the Institution have been provided sufficient notice in terms of this clause. Upon expiry of the notice period this Agreement shall expire. Novartis shall have the right to approve any new Principal Investigator designated by Institution and parties shall execute a fresh agreement in that behalf

6. PERFORMANCE OF THE STUDY

Principal Investigator and the Institution shall jointly and severally be responsible for the performance of the Study, in particular for the following:

6.1 Principal Investigator may appoint individuals and investigational staff as they may deem appropriate as sub-investigator (the "**Sub-Investigators**") to assist in the conduct of the Study. All Sub-Investigators and investigational staff will be adequately qualified, timely appointed and an updated list will be maintained. Principal Investigator shall alone be responsible for hiring, leading, supervising and reimbursing such team of Sub-Investigators and investigational staff, who, in all respects, shall be bound by the same terms and conditions as the Principal Investigator under this Agreement. The Principal Investigator shall be responsible for the conduct of the clinical investigation in its entirety and the well-being of the study subjects ("**Study Subjects**") and undertake in particular to have it executed by competent resources.

6.2 **Study Site**

The Study shall be conducted at the premises of Institution at the ***Father Muller Medical College Hospital:*** (hereinafter the "Study Site").

6.3 **Use of Study Drug:**

Novartis shall provide *Ligelizumab* (hereinafter called "**Study Drug**") in sufficient quantity to conduct the Study. For purposes of this Agreement only, the Study Drug shall be supplied to Institution free of charge. In all events, the Study Drug shall remain the sole property of Novartis.

The Principal Investigator shall

(a) at his/her risks, costs and expenses ensure the safe receipt, handling, storage, use and administration of the Study Drug and take all reasonable measures to ensure that it is kept secure;

(b) not permit Study Drug to be used for any purpose other than the conduct of the Study in compliance with the Protocol;

(c) shall not make the Study drug available to any third party other than as specified in the Protocol without Novartis' prior written consent;

(d) shall fully comply with all the responsibilities set out under the law;

(e) keep full and accurate records of who dispenses the Study Drug, the quantity dispensed, and the quantity returned which shall be available for review and /or collection by Novartis and/or designated monitor ("Novartis Monitor") at any scheduled monitoring visit; and

(f) upon any earlier expiration or termination of this Agreement, at Novartis's expense, return any remaining quantities of the Study Drugs to Novartis.

6.4 **Study Subject consent and entry into Study**: Before entering a Study Subject into the Study, the Principal Investigator shall:

(a) Exercise independent medical judgement as to the compatibility of each prospective Study Subject with the requirements of the Protocol;

(b) advise Novartis of all instances in which, in the Principal Investigator's judgement, there is any question as to any prospective Study Subject's suitability for participation in the Study, and abide by Novartis's decision as to whether or not to enroll that Study Subject;

(c) ensure that, before their participation in the Study, the Study Subject, and/or as the case may be, her/his legal representative, are duly informed in language understandable to them, about all aspects of the Study that are relevant to them, including: (i) the purpose, duration, nature, significance, implications, potential benefits and/or risks of the Study; and (ii) the processing, auditing, and monitoring of data (including personal data) under this Agreement;

(d) ensure that, before his /her participation in the Study, each Study Subject and/or as the case may be her/his legal representative has given his or her Informed Consent on the basis of the information described in Clause 6.4. (c) by signing a consent form ("Informed Consent Form" or "ICF") in accordance with the Protocol and without the undue influence or coercion of any person directly involved in the Study, and in accordance with Applicable Laws. An example ICF is attached hereto as Annex 3;

(e) ensure that a copy of the signed Informed Consent Form be provided to the Study Subject, and/or as the case may be, his/her legal representative;

(f) acknowledge that the use of the Informed Consent Form does not release the Principal Investigator from his or her legal, regulatory and contractual obligations relating to Informed Consent, and that it remains the Principal Investigator's responsibility to ensure that those obligations are complied with;

(g) comply with the procedures described in the Protocol in relation to that Study Subject; and,

(h) provide details of the proposed Study Subject to Novartis.

6.5 **Study Subject Recruitment**

Principal Investigator has estimated that he/she can recruit the number of Study Subjects as specified in Annex 1. This target of recruitment can be increased only upon written agreement of Novartis. The Principal Investigator undertakes to comply with these limitations and conditions for further recruitment at the Study Site as required by Novartis.

Novartis will review the Study Subjects recruitment on an on-going basis to ensure that the enrollment continues at an acceptable rate. Novartis is empowered to discontinue the Study at Institution medical facilities in case of no or poor enrollment.

In a multicentre study, Novartis reserves the right, at its sole discretion, to require Institution and Principal Investigator to cease enrollment of Study Subjects prior to enrollment of the targeted number of Study Subjects. Institution and Principal Investigator undertake to cease such enrollment upon request of Novartis and further undertake not to seek any compensation therefor.

6.6 **Recordkeeping, Reporting, Access and Inspections**

(a) **Recordkeeping, Reporting**

The Institution and the Principal Investigator shall perform the following recordkeeping and reporting obligations in a timely fashion:

(i) Preparation and maintenance of complete, accurately written and electronic records, including accounts, notes, reports, Case Reports Forms, records of Study Subject identifications, medical notes, clinical observations, laboratory tests, and the receipt and disposition of the Study Drug and all supportive documentation and data for each Study Subject of this Study (hereinafter "Records").

(ii) Maintain a copy of all documents related to this Study for the longer of a) fifteen (15) years after the Study is completed or discontinued by Novartis) as required by applicable laws and regulations.

(iii) Meet with a representative of Novartis to discuss the progress of the Study; and Notify Novartis immediately upon discovering any significant violations of the Protocol.

(iv) In accordance with the procedure set out in the Protocol : Complete a Case Report Form for each Study Subject; review and sign each of the Case Report Forms to ensure and confirm their accuracy and completeness; promptly submit the Case Report Forms to Novartis following their completion,

(v) Cooperate with Novartis in all their efforts to monitor the Study and to support Novartis in all matters of data collection, verification and discrepancy resolution

(vi) Maintain all documents and other Records generated in the Study in safe keeping for such period as is required by any applicable regulations, and in any event for 15 years following termination of the Study; and obtain Novartis approval prior to disposing of any Record, provided that 'safe disposal' of any Record shall at all times be in compliance with 'Data Privacy and Protection' provisions set out in this Agreement. In the event of the insolvency or bankruptcy of Institution, Institution agrees to promptly transmit all copies of such records to Novartis in accordance with Novartis' written instructions and in line with the transfer and disclosure terms set out in the ICF signed by concerned trial participants, at Novartis' expense.

(vii) Ensure the hospital records of Study Subjects are kept safely in a known and accessible location during the period defined here-above.

(viii) Make all Records available to Novartis or its nominee promptly upon request for monitoring and/or auditing purposes;

(ix) Be responsible for making any necessary applications for registration under the data protection legislation in connection with data obtained under this Agreement, as provided in Article 27.

(b) **Access and Inspection**

It is agreed that the authorized representatives of Novartis, and regulatory authorities to the extent required by law, shall be entitled to:

(i) Examine and inspect the Institution's facilities required for performance of the Study; and

(ii) Inspect and copy all data and work products relating to the Study (including, without limitation, access to records as necessary for study monitoring or to audit the conduct of the Study in accordance with Novartis standards). Sponsor will maintain the confidentiality of any subject-identifiable medical records.

(iii) If any governmental or regulatory authorities notifies Institution or the Principal Investigator that it will inspect Institution's records, facilities, equipment, or procedures, or otherwise take action related to the Study, Institution shall promptly notify Novartis or any designated person within 24 hours, allow Novartis to be present at the inspection/action or participate in any response to the inspection/action, and provide Novartis with copies of any reports or information issued by the authority and Institution's proposed and final response.

(iv) Grant access to Novartis or its representative to visit periodically, as frequently as required for the proper performance and oversight of the Study, the Study Site in order to proceed with any and all monitoring activities required for the Study.

(v) The Institution and the Principal Investigator will use their best efforts to facilitate the performance of any audit and inspection and shall give Novartis and any person designated by them access to all necessary facilities, data and documents.

(vi) The Institution and the Principal Investigator shall take appropriate measures required by Novartis to correct without delay all observations found during the audits or inspections.

(vii) It is expressly agreed between the Parties that Novartis will not compensate the Institution or the Principal Investigator for the audits and inspection.

The rights and obligations under this Article shall remain in effect for fifteen (15) years after the end of the Study.

6.7 **Reporting:** The Principal Investigator shall, either by himself/herself or his/her duly authorized representative, on reasonable notice

(a) Meet with a representative of Novartis to discuss the progress of the Study; and

(b) Make the hospital notes and Case Report Forms for each Study Subject available for source data verification or auditing purposes by representatives of Novartis representatives and the officers of any competent authority.

(c) On discovering any significant violations of the Protocol, the Principal Investigator shall notify Novartis immediately.

6.8 **Reporting of Safety Information:**

The Principal Investigator shall notify Novartis of each Serious Adverse Event encountered in the Clinical Trial within twenty-four (24) hours of becoming aware of it in accordance with the instructions set forth in the Protocol as well as local regulatory requirements. Each such notice shall be given by telefax or e-mail on a Novartis Serious Adverse Event Report form, whether or not notification was initially given by telephone. Section 6.6 shall apply to both the original copy of each Serious Adverse Event Report form and the telefax confirmation sheet or e-mail reflecting its transmission to Novartis.

The Principal Investigator shall also ensure that any person involved in the conduct of the study shall:

(a) Immediately report to Novartis according to the procedure set out in the Protocol, any new safety findings on the Study Drug, including Serious Adverse Event or Serious Adverse Reaction affecting or which could have an impact on the safety of the Study Subject or which could result in a re-assessment of the risk-benefit ratio of the Study Drug. The Principal Investigator shall follow up such immediate reports and provide the additional information in a detailed, written manner to Novartis in accordance with the Protocol and local regulatory requirements;

(b) Report to Novartis all Adverse Events (refer definition of adverse event as per ICH E6 guidelines for Good Clinical Practice and/or as mentioned in the protocol) in accordance with the study Protocol, applicable study procedures for safety data reporting;

(c) Cooperate with and supply any further information required by Novartis and/or any relevant ethics committee or Regulatory Authority with jurisdiction over the Study.-

These reporting obligations shall survive expiration or earlier termination of the Agreement.

Novartis shall further report the adverse events to the competent Regulatory Authorities, in accordance with the current Applicable Laws. Novartis will furthermore provide the Principal Investigator with safety-related information from other investigational sites in order to inform the ethics committees IRB/IEC, as required.

After completion of the Study and evaluation of the results, Novartis will inform the Principal Investigator about relevant safety-related findings in accordance with the guidelines and Study procedures.

6.9 **Items supplied by Novartis**

Novartis shall provide directly or indirectly the Principal Investigator and/or the Institution with all necessary information, documents and materials, including but not limited to:

(a) the Investigator Brochure (IB)

(b) the Protocol,

(c) the CRF/e-CRF

(d) he Study Drug

(e) the study related equipments on returnable basis listed in Annexure 1- Payment schedule

6.10 The Principal Investigator, or coordinating investigator for multicentre studies, shall sign the clinical Study reports, which form part of the marketing authorization submission.

7. LIABILITY-INDEMNIFICATION

7.1 In the case of any injury occurring to a clinical trial subject or in the event of clinical trial related death of the subject, Novartis assumes responsibility to the extent and in the manner under the applicable laws

7.2 The Institution and Principal Investigator ("Indemnifying Party") will indemnify and hold harmless Novartis from and against any and all liabilities, claims, damages, losses, settlements, penalties, fines, costs and expenses, including attorneys' fees, (collectively, "Damages") of whatever kind or nature (but not including taxes) arising from any third party demand, investigation, claim, action or suit in the based on (i) the gross negligence, bad faith or willful or intentional misconduct of the Indemnifying Party (ii) a material breach by the Indemnifying Party of any term of this Agreement, or (iii) a violation of any relevant law, rule or regulation by the Indemnifying Party in the performance of its duties under this Agreement.

8. INSURANCE

The Institution warrants that it has appropriate and adequate professional indemnity insurance to cover claims or damages including those arising out of negligence of the Principal Investigator for which it shall be liable under this Agreement. The Institution shall provide evidence of its insurance upon request by Novartis.

Novartis warrants that it has insurance for the Study Subjects included in the Study in place at Study start.

9. COMPENSATION

9.1 In consideration for the satisfactory performance of the Study according to this Agreement and the Protocol, The Principal Investigator agrees to Payment Schedule attached hereto as Annex 1.

9.2 Novartis reserves the right to terminate the Agreement immediately if no subjects have been recruited at the Study Site by *4 Feb 2022.*

9.3 Subjects not completing the Study will be paid for on a prorated basis according to the number of completed visits. All payment will be made for subject visits according to the above Payment Schedule attached as Annex 1. No payment will be made for any Study Subject excluded from analysis because of Protocol violations that were within the Institution or Principal Investigator's control. Reimbursement for expenses related to screening failures, patient travel, and local lab test will be made according to the Payment Schedule in Annex 1.

9.4 The Principal Investigator shall send the invoices to:

Ms. Jayshree Bagul

Novartis Healthcare Private Limited

GDO Trial Monitoring, India

Novartis Healthcare Private Limited

Inspire BKC, 'G' Block,

6 & 7 Floor, BKC Main Road,

Bandra Kurla Complex,

Bandra (E) Mumbai 400051, India

9.5 Each invoice shall specify the Study Code. Novartis shall make payments into the account indicated by the Institution and Principal Investigator within 60 (sixty) days of receipt of an invoice from the Institution.

10. EQUIPMENT

10.1 If necessary and based upon Novartis' assessment of Institution existing equipment, Novartis may provide equipment (the "**Equipment**") to the Institution and/or Investigator strictly on a returnable basis as detailed in Annex 1 The Equipment shall remain the sole and exclusive property of Novartis. It shall be used exclusively by the Institution and/or the Investigator: The Equipment shall only be used for the conduct of the Study in accordance with the Protocol, Novartis instructions and until the Study is completed or discontinued.

10.2 If Novartis, or its designee, provides the Institution and/or Investigator with Equipment for the purpose of this Study, the Institution and Investigator agree that the Equipment shall remain in the same condition during the Study, with the exception of ordinary depreciation.

10.3 During the term of the Study, Institution and/or Investigator shall be responsible for immediately notifying Novartis of any malfunctioning Equipment.

10.4 Following completion of the Study or upon discontinuation of the Study for any reason, the Institution and/or Investigator, as the case may be, shall return the Equipment to Novartis or alternatively, in the event the Equipment remains with the Institution and/or Investigator, the cost of such Equipment will be deducted from the last payment(s) to be made to either the Institution or Investigator, as the case may be.

11. TERMINATION

11.1 Either party may terminate this Agreement for any safety and/or efficacy concerns or other ethical grounds by giving written notice to the other party with immediate effect. In case of early termination the ***Institution/Principal Investigator*** shall notify the relevant Ethics Committee of the early termination, and Novartis shall notify the regulatory authorities and any other competent authorities as relevant and appropriate within specified timelines

11.2 Novartis may terminate this Agreement for convenience by giving written notice to the Institution with immediate effect.

11.3 If Novartis terminates this Agreement, Novartis shall have no obligations under this Agreement except to reimburse the Institution for such reasonable costs and non-cancellable obligations which has been approved by Novartis incurred in the performance of the Study prior to receiving notice of termination.

11.4 The termination or expiry of this Agreement shall not affect the rights and obligations of the parties which accrue prior to the date of termination. In particular, the Institution/Principal Investigator shall provide all outstanding Case Report Forms to Novartis and return to Novartis all documents and Equipment provided by Novartis under this Agreement.

12. INTELLECTUAL PROPERTY

12.1 All data, information and documents provided to the Institution by or on behalf of Novartis, whether in paper, oral, electronic or other form, shall remain the sole property of Novartis.

12.2 All data, information, documents, inventions and discoveries, resulting from or developed in the performance of the Study or this Agreement shall be the sole property of Novartis and may be used and/or transferred by Novartis in its sole discretion with no further payment or other obligation to the Institution. The Institution shall have no rights whatsoever therein.

12.3 The Institution agrees to, and to cause its employees and collaborators and the Principal Investigator to, execute promptly all documents and take all such other action as may reasonably be requested by Novartis to enable Novartis to obtain the benefit of its rights under this Agreement. This includes without limitation taking all necessary steps for the transfer of ownership of all data, information, documents, inventions and discoveries to Novartis in accordance with this Agreement, and assisting Novartis in the preparation and prosecution of patent applications. Furthermore, Institution and Investigator shall execute, or procure the execution of, and enforce all documents and deeds and do, or procure the doing of, all things as Novartis including but not limited to assignment of any and all rights, title and interest in resulting intellectual property in Novartis.

12.4 The Institution shall ensure that the Principal Investigator and the Institution's employees and collaborators involved in the Study will comply with its obligations under this Agreement.

13. TAXES AND SOCIAL SECURITY CONTRIBUTIONS

It shall be the Institution's responsibility to comply with all obligations in respect of taxes and social security contributions, if applicable, which relate to the subject matter of this Agreement, including without limitation those which relate to the Principal Investigator, the Institution and its employees and/or collaborators.

14. PUBLICATION

14.1 Novartis recognizes the Institution's interest in making publications and presentations relating to the Study in journals, at meetings or otherwise, and may therefore permit such publications and presentations, provided however that the Institution shall provide to Novartis any proposed presentation at least 15 (fifteen) working days prior to being disclosed and any other proposed publication at least 45 (forty-five) working days prior to being disclosed, and provided that Novartis shall have the right to require amendments to any such proposed presentation or publication on reasonable grounds including without limitation:

(a) to ensure the accuracy of the presentation or publication;

(b) to ensure that proprietary information is not inadvertently divulged;

(c) to enable intellectual property rights to be secured;

(d) to enable relevant supplementary information to be provided.

14.2 Authorship of any publications relating to the Study shall be determined by mutual agreement.

14.3 Novartis may require any proposed publication or presentation to be delayed for up to 4 (four) months to enable a patent application to be prepared and filed. The 4 (four) month period shall commence on the date of receipt of the proposed publication or presentation, or from the date when all relevant data from the Study are made available to Novartis, whichever is later.

14.4 If the Study is a multi-centre study, the first publication of data shall be based on consolidated data from all centres analysed according to the Protocol, unless otherwise agreed in writing by all the Principal Investigators involved in the Study and Novartis.

14.5 Except as otherwise required by law or regulation, neither Party shall release or distribute any materials or information containing the name of the other Party or any of its officers, agents or employees without the prior written consent by an authorised representative of the non-releasing Party.

15. CONFIDENTIALITY

15.1 All information and data, trade secrets, privileged records and other confidential or proprietary information (including but not limited to the Protocol, CRFs and information on password-protected Novartis websites) disclosed to or collected or developed by the Institution, the Principal Investigator and/or the Institution's employees and/or collaborators in connection with this Agreement or the Study (collectively "**Information**") shall be treated as confidential. The Institution and/or the Principal Investigator agree not to disclose to any third parties or to use any Information for any purpose other than the performance of the Study. The Institution and/or the Principal Investigator shall ensure that the Institution's employees and collaborators are bound by confidentiality obligations not less strict than those set out herein prior to receiving any Information.

15.2 Upon termination or expiry of this Agreement, the Institution and / or Principal Investigator shall safely destroy (as set in the Data Privacy and Protection annexure to this Agreement) or return to Novartis, as per Novartis' request, all documents, samples and material containing or relating to Information, except for one copy of Information which is to be retained in the confidential files of the Institution for record purposes only. If requested by Novartis, such safe destruction shall be promptly confirmed in writing by the Institution to Novartis.

15.3 The confidentiality obligations set out above shall not apply to:

(a) Information which is, at the time of disclosure, in the public domain or thereafter becomes part of the public domain otherwise than by the act or omission of the Institution, the Principal Investigator, or the Institution's employees and/or collaborators;

(b) Information that the Institution can demonstrate by written evidence was in its possession prior to its disclosure by Novartis or that said information, its collection or creation did not occur during or in connection with the Study;

(c) Information which the Institution received from any third party not engaged in the activities which are the subject of this Agreement, where such information is not subject to an obligation of confidentiality in favour of Novartis or any of its affiliates.

16. NOTICES

Any notice given in connection with this Agreement shall, unless otherwise provided herein, be in writing and shall be delivered personally, or sent by registered mail or facsimile to the address given in this Agreement

Mr. K. Murugananthan

GDO Trial Monitoring,

Novartis Healthcare Private Limited

Inspire BKC, 'G' Block,

6 & 7 Floor, BKC Main Road,

Bandra Kurla Complex,

Bandra (E) Mumbai 400051, India

Email: murugananthan.k@novartis.com

or to such other address as may have notified to the other party in writing.

17. ASSIGNMENT

Neither Party may assign its rights and obligations under this Agreement without the other Party's prior written consent, except that Novartis may (a) assign its rights and obligations under this Agreement or any part hereof to one or more of its Affiliates; or (b) assign this Agreement in its entirety to a successor to all or substantially all of its business or assets to which this Agreement relates. Any permitted assignee will assume all obligations of its assignor under this Agreement (or related to the assigned portion in case of a partial assignment). Any attempted assignment in contravention of the foregoing will be void. Subject to the terms of this Agreement, this Agreement will be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

18. SUBCONTRACTING

The Institution and /or Principal Investigator shall not retain any subcontractor to perform any of its obligations under this Agreement without the prior written consent of Novartis. Any such consent shall not relieve the Institution and/or Principal Investigator of its obligations hereunder.

19. SEVERABILITY

The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision hereof.

20. WAIVER

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

21. ENTIRE AGREEMENT

This Agreement (including the Protocol) represents the entire understanding between the parties with respect to the subject matter hereof. No amendment to this Agreement will be effective or binding unless it is in writing signed by both parties and refers to this Agreement.

22. DEBARMENT

Neither the Principal Investigator nor the Institution, nor any person employed thereby nor any collaborator who is involved in the performance of the Study has been debarred under the law including but not limited to provisions of the Indian Medical Council Act, 1956 as amended, Drug and Cosmetics Act, 1940 and no debarred person will in the future be employed or engaged by the Institution in connection with any work to be performed for or on behalf of Novartis. If at any time after the execution of this Agreement, the Institution becomes aware that the Principal Investigator or the Institution or any person employed or engaged thereby is debarred, or is in the process of being debarred, the Institution hereby certifies that the Institution will so notify Novartis at once.

23. CONFLICT OF INTEREST, FINANCIAL DISCLOSURE

The Institution and the Principal Investigator confirm that there is no conflict of interests between the Parties that would inhibit or affect their performance of the work specified in this Agreement. The Institution and the Principal Investigator further certify that they will promptly inform Novartis in the event any conflict of interests arises during the performance of this Agreement and certify that their performance hereunder does not violate any other agreement they may have with any other third party.

24. TRANSPARENCY/DISCLOSURE

24.1 In all materials relating to Services intended for an external audience, Principal Investigator shall disclose:

(a) that Novartis has retained Principal Investigator for professional services in relation to the conduct of the Study; and

(b) any other relationships that Novartis has with Principal Investigator which a reasonable and ethical person would expect to be disclosed.

24.2 Both parties agree to make all other disclosures and/or notifications as may be required in connection with entering into, performing, or receiving compensation under this Agreement, and Principal Investigator shall follow all Applicable Laws in this respect, including those relating to Principal Investigator's professional relationships with decision-making authorities or bodies (if any), such as, for instance, recusal from any votes, discussions or recommendations regarding investigational or marketed products of Novartis, regardless of whether such are subject to the Services.

24.3 The Institution and Principal Investigator understand and agree that Novartis may be required to disclose certain information to governmental agencies in different jurisdictions in order to comply with local laws regulating clinical trials. The Institution and Principal Investigator consent to the disclosure of certain information that otherwise may constitute personal data in order to comply with laws regulating clinical trials, including but not limited to the Institution's and/or Principal Investigator's name, clinical trial Study Site contact information, name of the clinical trial, sponsor, copy of the Agreement, and costs and fees relating to Study Site's activities performed under the Agreement. Novartis will provide upon written request a list of any such disclosure made regarding the Institution and/or the Principal Investigator.

25. JURISDICTION AND APPLICABLE LAW

This Agreement shall be governed by and construed in accordance with the laws of India. The parties hereby submit to the exclusive jurisdiction of the competent courts of Mumbai, India without restricting any right of appeal.

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

NOVARTIS HEALTHCARE PRIVATE LIMITED

By: _____

Name: Sealini Sujit

Title: Head - CTO

Date: 7th Feb 2019

FATHER MULLER MEDICAL COLLEGE HOSPITAL

By: _____

Name: Rev. Fr. Richard Aloysius Coelho

Title: Director of Father Muller Charitable Institutions

Date: 12-02-2019

FATHER MULLER CHARITABLE INSTITUTIONS
KANKANADY
MANGALORE
575 002

DR. RAMESH BHAT M.

By: _____

Name: Dr. Ramesh Bhat M

Title: Professor of dermatology department

Date: _____

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

ANNEX 1: PAYMENT SCHEDULE

STUDY NUMBER: CQGE031C2303

STUDY NAME: PEAR- 2

Investigator's Name: DR. RAMESH BHAT M.

Institute Name: FATHER MULLER MEDICAL COLLEGE HOSPITAL

Payee Name: Father Muller Research Centre

Pan Card Number: AAATF0345D

GSTIN: 29AAATF0345D1Z4

Committed Number of Study Subjects: 05

List of Equipments provided to Institution / Principal Investigator:

- AV recording camera used for study AIN457F2366 can be used, to be retrieved during study close out
- ERT log pads- to be retrieved during study close out
- Hard disk
- DVD for AV consenting storage
- ERT machine- to be retrieved during study close out

Payment Schedule:

	Screening		Double blind treatment												
Visit	1	20	110	120	130	140	150	160	170	180	190	200	210	220	230
Week	-4	-1	R	4	8	12	16	20	24	28	32	36	40	44	48
Protocol Procedures	9300	2800	6000	5000	5000	5000	3500	3500	5000	3500	3500	3500	3500	3500	3500
Investigator Fees	4000	3000	5000	3000	3000	3000	3000	3000	3000	3000	3000	3000	3000	3000	3000
Coordinator Fees	1000	1000	1500	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000
Unblinded Pharmacist fee			1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000
Institutional Overhead @ 30%	5434	2584	5130	3800	3800	3800	3230	3230	3800	3230	3230	3230	3230	3230	3230
TOTAL (INR)	19734	9384	18630	13800	13800	13800	11730	11730	13800	11730	11730	11730	11730	11730	11730

post treatment follow up			
240/EoT/TD	310	320	1999/EOS/PSD
52	56	60	64
6200	5000	5000	5700
4000	3000	3000	4000
1000	1000	1000	1000
1000	1000	1000	1000
4636	3800	3800	4446
16836	13800	13800	16146
TOTAL COST 1 PT			257370

Payment Terms:

- A start -up cost of Rs. 30,000/- will be paid after the EC submission and EC approval is obtained. Invoice needs to be submitted for processing the start- up cost.
- The amount of payment due to the Institution/Investigator will be calculated in respect of each patient visit according to the attached budget schedule.
- The screening cost will be paid only for randomized subjects. No separate screen failure cost will be provided
- Any other third parties designated by the Institution/Investigator that would receive remuneration, will be managed by & paid by the Institution/Investigator.
- The work performed by the hospital laboratory in addition to budget schedule shall be paid based on actuals. It is the Investigators responsibility to liaise with the hospital laboratory.
- Sponsor shall reimburse patient's travel cost per protocol visit as per actuals for which institution/PI shall provide original invoice along with the supporting bills.
- The Ethics committee charge will also be paid via Novartis, and this cost is not included in the budget schedule.
- Unscheduled visits covers subject visits that are not expressly set forth in the Study Schematic of the Protocol, but are otherwise required for the study. Medically necessary procedure, test performed during unscheduled visits would be paid as per actual bills. Payment for unscheduled visits will be payable to the institution within 60 days of receipt of original, itemized invoice by Novartis.
- All payments are based on actual patient visits.
- All values are in INR. All budget schedule payments are subject to TDS (subject to Government of India, Tax regulations) and GST as applicable. GST will be paid on providing valid tax invoice with relevant details mentioning GST registration number on it.

ANNEX 2: PRINCIPAL INVESTIGATOR – PERSONAL DATA DISCLOSURE FORM

Novartis wants to ask your permission to include certain elements of your personal data in a database maintained by a third party. The Grant Plan database, which is maintained and provided to pharmaceutical research sponsors by a company called TTC in the United States, is intended to assist research sponsors with transparency relating to clinical trial expenses. The database is used to support country specific forecasts for clinical trial costs and to provide benchmarking information in order to achieve transparency and fairness in setting costs for performing clinical trials.

The information is entered into the database in such a way that it is not possible for anybody except the personnel of TTC to view your name or link your site to a particular clinical trial or sponsor company.

In that regard, Novartis is asking for your permission to submit your name, clinical trial site contact information, name of the clinical trial, sponsor, copy of the clinical trial agreement, and costs and fees relating to your site's retention, to a third party administrator of this database. This information will be maintained in that database for five years. If you are conducting research for Novartis in countries other than the United States, such as those in Europe, you should note that the United States does not offer the same standards of privacy protection as those offered in Europe. You are not required to give consent to this disclosure in order to proceed with this clinical study. However, by doing so, you are helping to collect information on fair costs in clinical trials.

☑ Yes, I hereby agree that Novartis may disclose my personal data in connection with the Grant Plan database.

☐ No, I do not give my permission to disclose my personal data in connection with the Grant Plan database.

Place and Date: _____

Name: Dr. Ramesh M. Bhat

Principal Investigator

Data Privacy and Protection

Provisions regarding any Personal Information Processed by Institution under this Agreement:

Defined Terms. For the purposes of this Section, the following terms shall have the meanings given below:

"Personal Information or Data" means any information that relates to an identified or identifiable person including without limitation electronic data and paper based files that include such information such as: (a) name or initials; (b) home or other physical address; (c) work, cell or home telephone number; (d) work or home email address or online identifier associated with the individual; (e) identification code; (f) credit card number; and (e) employment information, that is Processed directly or indirectly, by Institution on behalf of Novartis in connection with this Agreement.

"Sensitive Personal Information or Data" – constitutes a subset of Personal Information and relates to of an individual's (a) physical, physiological or mental characteristics, (b) economic status, (c) racial or ethnic origin, (d) political, ideological, religious opinions or philosophical beliefs, (e) trade union membership, (f) health or medical information including information related to payment for health services, (g) sex life or sexual preference, (h) genetic material or information, (i) human biological samples or cells, (j) unique biometric data, (k) Personality Profiles or (ii) an individual's name in combination with the individual's (a) Social Security number, (b) alien registration number, (c) driver's license number, (d) passport number, visa number or other government identifier, (e) credit card, debit card, or other financial account numbers, with or without any associated code or password that would permit access to such account, or (f) mother's maiden name; and as applicable under local laws.

"Data Subject" – and identified or identifiable person who's Agreement Personal Data are processed, accessed, received, transmitted, or maintained by the Supplier. An identifiable perosn is one sho can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological ,mental, economic, cultural or social identity.

"Processing" means any operation or set of operations which is performed upon personal information, whether or not by automatic means, such as collection, recording, organisation, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction or any other operation or set of operations otherwise defined in applicable Data Privacy Laws. This also includes the processing of personal information in structured manual files.

"Institution Third Parties" – any third party that assists Institution in performing its obligations under the Agreement, including an affiliate or direct or indirect subcontractor of Supplier.

General Obligations of Institution:

a. Compliance with Applicable Laws and Permitting Processing. Institution will, and will cause all Institution Third Parties to, hold Personal Information in confidence, use Process such data only for the benefit of Novartis and its Affiliates and Process such information in compliance with (i) all Applicable Data Protection Laws, (ii) the Agreement, (iii) any consent, authorization of a Data Subject or other authorized participant, such as subject's legal representative, (iv) industry standards, and (v) this Data Privacy and Protection Exhibit; provided, however, that Institution (or Institution's Third Party) may Process Personal Information only under the written instructions of an authorized signatory of Novartis.

To the extent that the Agreement involves the processing of personal information owned by or licensed to Institution prior to or separately from the Services, Institution represents and warrants that such data has been obtained in compliance with applicable laws and regulations, including Applicable Data Protection Laws and all necessary consents and authorizations, including those of any patient, if applicable. Institution further represents and warrants that Institution and/or Novartis is authorized to use such data as contemplated by this Agreement.

b. Obligations with respect to the Data Subjects participating in trials:
Institution shall take reasonable steps to ensure that each individual whose Personal Information were, or are, in its possession is able to assert his or her rights under local law, including but not limited to right of access to view and correct his or her Personal Data, right to withdraw consent and file complaint or grievance if any, with the Institution.

c. Obligations with Respect to Institution's Third Parties.

Within seven (7) business days of Novartis' written request, Institution will produce clear and accurate information stating who is holding and processing Agreement Personal Data, and in what country they are located. In all such arrangements, Supplier will enter into agreements with Supplier Third Party(ies) that are substantially similar to this Data Privacy Exhibit. Supplier shall provide copies of such agreements to Novartis within seven (7) business days following a written request from Novartis therefor.

Data Safeguards. The parties agree to comply with the following:

(a) Without limitation of any provision of this Agreement, the parties agree to comply with all applicable Laws governing the privacy and security of Personal Information that Institution shall create, acquire, access or receive as a result of this Agreement, to the extent that such Laws apply to either party.

(b) Institution agrees to implement administrative, technical and physical security measures to protect Personal Information, from (i) unauthorised or accidental destruction, (ii) theft, forgery or loss, (iii) technical faults, (iv) forgery, theft or unlawful use (v) unauthorised alteration, copying access; or (vi) any other unauthorised processing.

(c) Security measures implemented by Institution must take into account (i) the purpose of the data processing, (ii) nature and extent of the processing, (iii) assessment of possible risks to the data subject; and (iv)current industry best practices and state of the art technologies, including but not limited to encryption of information at rest and in transit. Security measures shall be reviewed on a periodic basis and updated as required.

(d) All email communication with Novartis, especially those involving trial related information should happen via secure 'Institutional email Ids'. Exceptions (i.e. use of non-institutional email Ids), if any must be discussed with Novartis and a secure communication solution, as mutually agreed and in line with Novartis' security standards, is implemented.

(e) Institution shall not sub-contract any of its rights or obligations without the prior written notification to Novartis. In the event that any Institution Subcontractor shall have access to Personal Information, such access shall be permitted under a need-to-know basis and only to the extent required for the due performance of Institution's obligations. Institution shall enter into Agreements with its' subcontractors that contain privacy and security provisions that are equivalent to the provisions under this Agreement.

(f) Institution shall ensure that personnel who will be undertaking the Processing of Novartis Personal Information, including that by Institution's Third Party (if any) have appropriate skills and privacy and security training to handle Sensitive Personal Information.

(g) If Institution disposes of any paper, electronic or other record containing Agreement Personal Data, Supplier shall do so by taking all reasonable steps to destroy the information by (a) shredding; (b) permanently erasing and deleting; (c) degaussing; or (d) otherwise modifying the Agreement Personal Data in such records to make it unreadable, un-reconstructable and indecipherable.

(h) Institution shall maintain procedures to detect and respond to a Data Security Breach. Institution shall notify Novartis of any Data Security Breach within 24 hours of discovery of a data security breach. Institution shall promptly make available to Novartis details of the Data Security Breach and shall use commercially reasonable efforts to investigate and prevent the recurrence of such Data Security Breach. The parties shall reasonably cooperate to remediate a Data Security Breach and prevent any recurrence. Novartis, at its sole discretion, after consultation with Institution, shall determine whether and when to notify any individuals or persons (including Governmental Authorities) regarding any Data Security Breach affecting Novartis Personal Information. Institution, as determined in its sole discretion, shall comply with all applicable Laws to which it is subject with regard to the Data Security Breach.

ANNEX 3: NOVARTIS POLICIES & STUDY DOCUMENTS

'e, 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.

'ather 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

Government of Karnataka
Revised National TB control Programme

Minutes of State Task Force-Operational Research (STF-OR) Committee Meeting held at State TB Cell, Bangalore on 7th January 2016

The State Task Force Operational research committee meeting was held at state TB Cell, Bangalore on 7th January 2016. Initially, Dr. Anil S, the state TB officer of Karnataka and member secretary of STF-OR committee welcomed the members of the newly constituted committee (Appendix-1).He briefed about the objectives of the meeting which were intended (1) To discuss and endorse the standard operating procedures (SOP) for STF OR Committee, Karnataka (2)To discuss and review the thesis and operational research protocols submitted to the state (3) to discuss the plan on building the capacity of medical colleges in operational research.

The Standard Operating Procedures (SOPs) for State Task Force Operational Research Committee was presented by Dr Sharath BN. It was deliberated that the SOP was the first of its kind in the country and would be useful tool to the committee to drive the operational research agenda at medical colleges in a systematic manner.The SOP was discussed in detail and there were few constructive comments made by the committee members which shall be incorporated and re-circulated amongst the members before final approval.

To build the capacity of Medical college faculty in Operational Research, Dr Ajay Kumar suggested a model of one faculty and one student forming a team and submitting the concept notes. The top ten notes will be selected and OR priorities will be decided by the state team which the teams will work over a period of one year during

subsequent workshops.Dr Balu opined that it would be wise to offer such courses on a nominal/subsidized rate to the faculty.Dr Balu also suggested that one day CME including all core committee members and unit heads must be undertaken in all Medical colleges for which an initiative of instructing the medical colleges through a DO letter from Director of Medical Education (DME) may be undertaken .

All the committee members reviewed the thesis received from the various medical colleges and the decision of approving the thesis for funding was made. The decision of the committee members for the submitted thesis is as shown in appendix –II. The committee members reviewed the 7 OR proposals received from the state. However, a decision was made to review the OR proposals individually and discuss during the next meeting. The committee decided to meet during the last week of March 2016.

The meeting ended with vote of thanks.

Appendix-I

S.No	Name and Institution	Designation
1	Dr Sharath BN, ESIC Medical College and PGIMSR,Bangalore	Chairman, STF OR Committee
2	Dr Anil S, State TB Officer, Karnataka	Member Secretary, STF OR Committee
3	Dr Balu, JJM Medical College, Davanagere	STF Chairman and Member, STF OR Committee
4	Dr Ashwini, KMC Manipal, Udupi	Member, STF OR Committee
5	Dr Akshaya, Yenopoya Medical College, Mangalore	Member, STF OR Committee
6	Dr Ashok Dorle, SN Medical College, Bagalkot	Member, STF OR Committee
7	Dr VenkateshNaik, RIMS, Raichur	Member, STF OR Committee
8	Dr Ajay Kumar, The Union, New Delhi	Member, STF OR Committee
9	Dr Reynold Washington, KHPT, Bangalore	Member, STF OR Committee
10	Dr Suresh Shastri, State TB Cell, Karnataka	Member, STF OR Committee
11	Dr MallikarjunaSwamy, State TB Cell, Karnataka	Member, STF OR Committee
12	Dr Shazia Anjum, RNTCP Consultant, Karnataka	Ex-officio Member, STF OR Committee

Appendix-II

S.no	Name and Institution	Title of the thesis	Status(80% fund to be given)
1	Dr.HasbullaShameer.U , PG student, Dept of paediatrics,KMCHubli,Dharawad District	Drug resistant TB in children in a tertiary care hospital	Approved
2	Dr.Mamatha.J.Kurdekar,PGstudent,Dept of Community Medicine, BIMS Belagum	Epidemiological determinants among the suspects of MDR TB at DMC,BIMS,Belgavi.	Approved
3	Dr.ViquarAhmed,PG Community Medicine, Yenepoya Medical College, Dakshina Kannada	A case control study on factors associated with defualt among TB patients in DK ,Karnataka	Approved (100% fund to be given)
4	Dr. Neethu Susan Philip, PG Resident Dept of Microbiology, Father Muller Medical College Mangalore	Identification and speciation of non-tuberculous mycobacteria in acid fast bacilli positive clinical specimens at a tertiary	Approved

		care centre in mangalore.	
5	Dr.KoreKavita .S Postgraduate, Dept. of Pulmonary Medicine Navodaya Medical College Raichur	Combined efficacy of pleural fluid Lymphocyte Neutrophil ratio and pleural fluid adenosine deaminase for the diagnosis of Tubercular Pleural effusion	Approved
6	Dr.Afaq Ahmed, PG Studen.Dept. of Gen Medicine KIMS Hubli	Study of adverse drug reactions in multidrug resistant TB therapy.	Approved
7	Dr.Sachin Kumar Patil, 1st yr PG Student. Dept. of Community Medicine KIMS Hubli	To assess the factors affecting treatment outcome in Pulmonary TB patients under RNTCP in Dharwad District	Approved
8	Dr. UmerFarooq , 1st year PG Resident, Dept of Community medicine, Yenepoya Medical college Mangalore	TB case notification to RNTCP by the private practitioners in Dakshina Kannada District Karnataka	Approved
9	Dr. Harisree .S. Department of microbiology, St john's medical college, Bangalore-34	Estimation of second line anti-tubercular drug susceptibility to mycobacterium tuberculosis in clinical isolates.	Approved
10	Dr NeethuKishor Department of microbiology	Rapid detection of mycobacterium tuberculosis complex and rifampicin	Approved

	Father muller medical college, Kankanady Mangalore– 575002.	resistance in pulmonary and extra pulmonary tuberculosis using cartridge based nucleic acid amplification test in mangalore"	
11	Dr Manumita Deb KMC	TB Lymphadenitis	Approved
12	Manu S JJMMC,Davangere	Delay in TB Diagnosis	Approved

Copy to:

1. DDG-TB, Central TB Division, New Delhi
2. All District TB Officers, Karnataka
3. All Medical Colleges, Karnataka

APPLICATION ATTESTATION FORM (AAF) STS 2014

Reference ID: 2014 – 02931

Name of the Student: THEJASHWINI.SI

Name of the Guide: Dr B. REKHA

Name of Medical College: FATHER MULLER MEDICAL COLLEGE

Title of the STS Proposal: Screening for anti-methicillin resistant Staphylococcus aures bacteriocin producing bactena in clinical specimen. and environmental specimen.

Certificate to be signed by the Student

I certify that the information provided by me in the online application form for STS 2014 is best to my knowledge and I am submitting only one application for STS 2014. In the event any information is found to be false, my studentship may be cancelled. I also certify that the research proposal is an original work prepared under the guidance of my Guide. I understand that after evaluation of my proposal, I may or may not be selected and I shall abide by the decision of ICMR.

If selected, I shall follow all instructions provided on ICMR website for carrying out the research, preparation and submission of STS report. I also understand that if I am unable to complete my project & submit the report before the last date, no certificate or stipend will be awarded to me. I have gone through all the Instructions and Terms & Conditions for STS 2014 provided on ICMR website and will abide by them.

Signature of Student: _____ Name of the Student: THEJASHWINI.S.I

Date: 24/01/2014

Certificate to be signed by the Guide

I agree to accept the applicant ~~Mr.~~/Ms. THEJASHWINI. S.I studying in MBBS/~~BDS~~/II/III. I certify that he/she is not an intern and will offer him/her all facilities and guidance for carrying out research. I also certify that the proposal is an original submission prepared by the student under my guidance. I am forwarding only one STS 2014 student application. If my student is selected, I shall facilitate early completion of research work in any two given months, so that the report is submitted before the last date.

Signature of Guide: _____

Name: Dr B Rekha.

Designation: Prof & Head

Department: Microbiology

Attested By

Signature of Head of Department

Dr B Rekha

(Name in Block letters with seal)

H. O. D. MICROBIOLOGY
Fr. Muller's Medical College
MANGALORE-575002

Signature of Head of Medical College

DR. JAYAPRAKASH ALVA
DEAN
Father Muller Medical College
Mangalore 575 002

(Name in Block letters with seal)

Fill form completely & check it before submission

FATHER MULLER INSTITUTIONAL ETHICS COMMITTEE
FATHER MULLER MEDICAL COLLEGE
Father Muller Road, Kankanady, Mangalore-575002

FMMC/FMIEC/1598/2014 23.01.2014

Ms. Thejashwini S. I.
MBBS Phase II,
Father Muller Medical College,
Kankanady, Mangalore - 575002.

Dear Ms. Thejashwini,

Subject: Institutional Ethics Committee approval for the conducting a study.

Your proposal "Screening for Anti-Methicillin Resistant Staphylococcus aureus Bacteriocin Producing Bacteria in Clinical Specimens" was approved by the Institutional Ethics Committee.

Yours Sincerely,

Secretary
Father Muller Institutional Ethics Committee

FATHER MULLER INSTITUTIONAL ETHICS COMMITTEE
FATHER MULLER MEDICAL COLLEGE
Father Muller Road, Kankanady, Mangalore-575002

FMMC/FMIEC/1589/2014 22.01.2014

Ms. Ashika Retnaswamy
MBBS (3rd Term)
Father Muller Medical College
Kankanady, Mangalore - 575002.

Dear Ms. Ashika,

Subject: Institutional Ethics Committee approval for the conducting a study.

Your proposal "Detection of Vancomycin susceptibility from Methicillin resistant Staphylococcus aureus" was approved by the Institutional Ethics Committee.

Yours Sincerely,

Secretary
Father Muller Institutional Ethics Committee

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-

Date: 16 MAY 2014

OFFICE MEMORANDUM

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

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

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

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

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

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

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

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

3. The expenditure involved is debitable to:

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

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

Sd/-
(D. K. Dalal)

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

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

Copy forwarded to:

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

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

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

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

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

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

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

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

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

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

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

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

i) The Department will issue a fresh sanction for the third and subsequent years after receiving the recommendation of the BRNS after scrutiny of the Renewal Application in Form PRA.

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

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

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

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

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

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

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

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

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

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

a) Claim Form-II,

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

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

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

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

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

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

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

Dalal

(D. K. Dalal)

** **Note:**

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

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/ 1139-71 Date: 21 JUL 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.

In continuation of this Department's Office Memorandum no. 34/14/18/2014-BRNS/310 dated 16/05/2014, on the recommendations of Board of Research in Nuclear Sciences (BRNS), I am pleased to convey the administrative approval of the President of India to incur an **additional** expenditure of **₹1,37,600/- (Rupees one lakh thirty seven thousand six hundred only)** as detailed below:-

	Item of expenditure	Amount
#	Staff JRF (1)	1,28,000
$	Overheads	9,600
	Total:	1,37,600

\# Salary for JRF for 8 months during 2014-15. JRF salary is payable @16000/- in 1st and 2nd year and on redesignation by Committee in 3rd year as SRF @18000/-.

$ Overheads calculated @ 7.5% of the other heads except contingency. The remaining 7.5% towards overheads (**₹9,600/-**) shall be released only on meeting the requirements specified **(See Annex-B)**.

2. With this amount, the total amount sanctioned for 2014-15 will be **₹9,71,000/-** and total staff for the project will be **2 JRFs**.

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	Grants-in-aid

4. The other Terms and Conditions of the sanction letter of even number dated 16/05/2014 will remain unchanged.

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

Sd/-
(D. K. Dalal)

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

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

Copy forwarded to:

1. Director of Audit, Scientific Department, AEAP, OYC, CSM Marg, Mumbai - 400 001.
2. Joint Secretary (R&D), DAE, Anushakti Bhavan, CSM Marg, Mumbai-400 001.
3. Dean, Father Muller Medical College, Kankanady, Mangalore 575 002.
4. ** Principal Investigator (PI): Dr. J. P. Alva, Professor of Medicine, Father Muller Medical College, Kankanady, Mangalore 575 002 – the payment will be made by Pay and Accounts Officer, DAE through ECS directly into **Account no.02392160000136** of Father Muller Research Centre at Syndicate Bank, Father Muller Medical College Branch, **IFSC code – SYNB0000239**.
5. AAO (Bills-II), DAE Anushakti Bhavan, CSM Marg, Mumbai - 400 001 – With a request that the amount granted may be released immediately.
6. Member Secretary, ATC : Dr. P. V. A. Padmanabhan, Head, Plasma Spray Technologies Section, L & PTD, BARC, Trombay, Mumbai-400 085.
7. Co-Investigator (CI): Dr. B. Sanjeev Rai, Professor of Pediatrics, Father Muller Medical College, Kankanady, Mangalore 575 002.
8. Principal Collaborator (PC): Mr. R. K. Jain & Mr. Vineet Sinha, Electronics Division, BARC, Trombay, Mumbai-400 085.

(D. K. Dalal)

** **Note:**

1. Please quote the Sanction No. **34/14/18/2014-BRNS** in all your correspondence with BRNS.
2. If you do not receive the money please contact AAO (Bills II), DAE **on 022-22862709.**

Fwd: An intelligent medical support through speech summarization

Inbox x

Anil Shetty <anilshettyk@hotmail.com> 7/24/17

to me

Sent from my iPhone

Begin forwarded message:

From: "Konga Gopikrishna Scientist D, DST, Min. of Science & Technology" <k.gopikrishna@nic.in>
Date: 14 June 2017 at 4:18:26 PM IST
To: <koolagudi@nitk.ac.in>, <anilshettyk@hotmail.com>
Subject: An intelligent medical support through speech summarization

Dr. Konga Gopikrishna
Scientist – 'D'
Science for Equity Empowerment and Development Division
E – Mail: k.gopikrishna@nic.in Phone: 011 – 26590298

SEED/TIDE/016/2017 **14th June 2017**

BY SPEED POST/E-MAIL

Sub: 14th Meeting of the Programme Advisory & Monitoring Committee (PA&MC) for 'Technology Interventions for Disabled and Elderly' (TIDE) Programme

Ref: Your project titled *"An intelligent medical support through speech summarization"*

Dear Sir

The above mentioned project proposal submitted by you to this Department for financial assistance under TIDE Programme will be considered by the PA&MC in its meeting scheduled to be held on 13th July 2017 at Indian National Science Academy (INSA), Bahadur Shah Zafar Marg, New Delhi – 110 002 starting at 9:30 Hrs. The address of the venue is given below.
Indian National Science Academy (INSA)
2, Bahadur Shah Zafar Marg,
ITO Cross, Delhi-110002

www.insaindia.res.in/
Tele: 011 – 2322 1931 – 2322 1950 (20 lines)

You are requested to make a presentation of the proposal before the Committee on 13th July 2017. Please prepare a neat presentation using MS power point. The investigators are required to present the project proposal in 10 minutes time using not more than 12 slides. The presentation should highlight the "problem identification" and the relevance of the innovation to the "user group". The presentation may emphasize on innovative aspects, S&T component, novelty in delivery of the interventions, list of deliverables, etc. Kindly note that time should not be wasted on the state-of-art/ background of the project during presentation. The presentation should also accentuate on industry partnerships (Government/Private/NGO) and standing tie ups with end users, if any for dissemination/implementation of developed technologies.

Traveling Allowance will be reimbursed by DST restricted to AC 2 tier either to the Investigator or the Co-Investigator on production of travel documents. You had to make your own arrangements for reaching the Venue of the meeting.

You had to make your own arrangement for your stay during the meeting. Though not guaranteed, limited reimbursement towards accommodation charges may be considered on production of relevant bills as per extant norms of DST. Kindly confirm your participation to the undersigned on the E- Mail given above.

Kind Regards

Yours
Sincerely
(Konga Gopikrishna)

To

Dr. Shashidhar G. Koolagudi
National Institute Technology Karnataka
Surathkal, Mangalore - 575 025
Karnataka

FORMATS FOR SUBMISSION OF PROJECTS

UNDER RADIATION HAZARDS

(To be filled by applicant)

1. Project Title-Cancer and proximity to mobile phone towers

2. Broad Subject:- Life Sciences

3. Duration in months- Twelve

4. Total cost-6,30,540

5. FE Component- Nil

6. Principal Inv.-Dr Anil Shetty K

7. Designation- Associate Professor

8. Department-Paediatrics

9. Institute Name-Fr Muller Medical College

10. Address- Department of Paediatrics,

Fr Muller Medical College

Kankanady

Mangalore-575002

11. Date of Birth: Sex (M/F) 19-05-1974 Male

12. Telephone Fax Gram e-mail 9886392043(mobile), 0824– 2238000(Landline), 0824 - 2437402 / 2436352(Fax) anilshettyk@hotmail.com

13. Co-Investigator NA

14. Designation NA

15. Department NA

16. Institute Name NA

17. AddressNA

18. Date of Birth: Sex (M/F) NA

19. Telephone Fax Gram e-mail NA

(Repeat 13 to 19 for additional Co-Investigators, if any, as 13.1-19.1, 13.2-19.2,.)

20. Project summary

One of the biggest fears associated with cell phone towers is the apprehension that they cause cancer. This has led to many communities opposing the setting up of cell phone towers in urban residential localities or in the vicinity of schools. While there is no conclusive evidence implicating cell phone towers in the causation of cancer, the public at large remains skeptical and there are several misconceptions about cell phone tower radiation. Many studies have collected data and information about radiation and its effect in the vicinity of towers. Our study proposes a different approach. We use addresses of past patients in our cancer center and triangulate their location and proximity to cell phone towers using specially developed software and maps. This will aid us and demonstrate whether proximity and location of cell phone towershave any bearing on the incidence of cancer.

21. Key words Cancer, Cellphone Tower Proximity

22. Technical details

22.1. Introduction

22.1.1. Origin of the proposal

Teledensity in India is 79.28% (May 2012), the vast majority of these phones are cell phones, (930,000,000). To serve the spectrum needs of this huge number of cell phones, cell phone towers are also seeing an exponential growth. There has been much public debate, controversies and in some cases mass hysterical reactions about the health hazards about cell phones in general and cell phone towers in particular. While there is no consensus in the scientific and health community about the effects, the biggest fear however is whether cell phones and towers have a role in the etiology of cancer. Most studies have focused on detecting cases of cancer in the vicinity of the tower's . In our opinion this is akin to looking for a needle in a haystack and we propose to do the reverse, i.e. use data and addresses of cancer patients using the facility's in our hospital and co relate it to the proximity of towers to their home addresses.

22.1.2. Definition of the problem

Media coverage of residents and resident associations waging a campaign against cell phone tower installation has received wide coverage and shaped public perception. There are about 25 lakh existing cancer cases in India, 7 lakh new cases are added every year, every year nearly 5 lakh deaths occur due to cancer. In 2012 there were 7,36,654 mobile phone towers in India. Some of the statistics on cancer will be attributed by the public to the proliferating number of these cell phone towers.

22.1.3. Objective

1.Toinvestigate the risk of cancers associated with exposure to radiofrequency from proximity to cell phone towers.

2. To determine if proximity to cell phone towers increases the incidence of cancer, i.e. closer the tower, more the incidence.

22.2. Review of status of Research and Development in the subject

22.2.1. International status

While there are a few studies that studied the effect of cell phones like the interphone study (http://www.iarc.fr/en/media-centre/pr/2010/pdfs/pr200_E.pdf), there are fewer studies of cancer and cell phone tower radiation. Elliot.P et al British Medical Journal,2010, 340, c3077 studied 'Mobile phone base stations and early childhood cancers, case control study' concluded that there was no association between cell phone towers and childhood cancers.

Another study was conducted by Wood A.W. et al in the Archives of disease in childhood, vol 91, April 2006, pp361-66 and a study by Bethele J.F. et al in the British Medical Journal 2010,340 c 3015 came to similar conclusions. ' Sciences economiques&sociales de la santé &traitment de l'informationmedicale' a French journal studied the risk perception of the general public of cell phone tower radiation and cancer risk and revealed an increased perception of risk to 68.9% in 2010 from 48.5% in 2005.

22.2.2. National status

There are very few studies if any of the effect of cell phone tower radiation in India. There is a current study by the W.H.O. in many countries supported by the I.T.U. There is a study by Prof Girish Kumar of the Electrical Engineering department of I.I.T Bombay. A search on pubmed on 'cell phone tower radiation and cancer in India' did not reveal any results.

22.2.3. Novelty Importance of the proposed project in the context of current status

The Unique selling proposition of our study is that we are approaching the problem in a reverse direction, rather than cause-effect, we are proceeding in the effect-cause(?) direction. Our Hospital was the first one in the region to be equipped with a linear accelerator and other cutting edge technology in the treatment of cancer. Because of these advanced facilities the number of cancer patients availing our services both on an outpatient and inpatient basis increased rapidly. As a result we have access to a lot of data including their home addresses in our Medical Records Department. For the purpose of this study we propose to tie up with 'Code Craft Technologies' a company that develops apps, medical software and location software. (www.codecraft.co.in). A combination of these two valuable assets, our access to patient addresses, data and Codecraft's technological expertise will help us to plot the location of our patients and cell phone towers and determine association if any. This study can also be treated as a pilot study and if successful can be replicated in multiple centers.

22.2.4. if the project Is location specific, basis for selection of location

Since most patients who were treated in our hospital would be from the same geographical sprawl, the data available would also be of the same local geographical area. This data will be matched against the location of cell phone towers in the vicinity of these areas and the information analyzed.

23. Target beneficiaries of the proposed work

Every individual living in the vicinity of cell phone towers, and especially people apprehensive about these towers.

24. Review of expertise available with the PI, the proposed investigating group/institution in the subject of the project

Fr Muller Medical College was the first Hospital in the region to use a linear accelerator to treat cancer, Our hospital has treated a huge number of patients and has a radiotherapy, oncology and onco-surgery department.

Our Technical partner 'Codecraft' has technical expertise in medical and location based software.

25. Patent details (domestic and international), if applicableNA

26. Environmental impact assessment and risk analysisNA

27. Proposed impact assessmentNA

28. Sustainability: Issues relating to sustainability, including stakeholder commitment, operation and maintenance of assets after project completion, and other related issues

The only asset to be procured is a laptop and few other ancillaries, the location software will be developed independently.

29. Work plan

Source of Data – Patients treated for cancer at Fr Muller Medical College Hospital from 2006.

Number- 500-1000 cases

Inclusion criteria- Patients whose addresses are in the vicinity of Mangalore, and the surrounding towns and districts.Patients with a confirmed diagnosis of cancer.

Exclusion Criteria- Patients whose address details are inadequate, or had a diagnosis ofcancer prior to the setting up of any cell phone tower in their neighbourhood.

29.1. Methodology

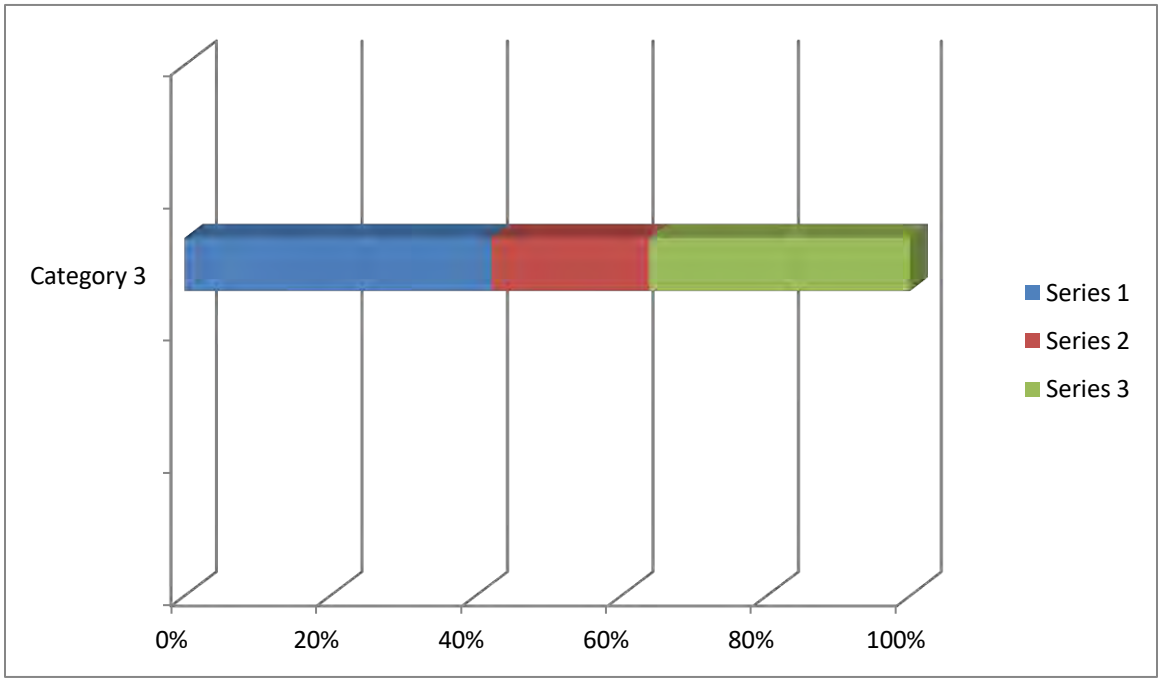
Data collected from patients in the last six years in the Medical Records Department will be analyzed, only addresses and diagnosis of the patients will be recorded in an excel file, no other information will be collected. Principal Investigator and junior research assistant will go through the data and confirm the veracity and details such as diagnosis will be checked, data will be entered by a data entry assistant Our Technical partners Codecraft have expertise in medical and location based software, they will export the data from the excel file and by reverse geo coding, plot the location on map. Information on the location of cell phone towers, their frequency, number of antennas per tower and the date and year

in which they were set up will be accessed. Using Map View-with plotters the cell phone tower location and patient location will be plotted showing people in the zone of the cellular towers. The final report will be devised using line graph to display how many (if) are in close proximity for the mobile tower's and people away from the towers. The type of cancer will be also plotted and information will be similarly compared with cell phone tower location. The data and information can also be matched against a similar number ofnormal controls

29.2. Organization of work elements

Data on addresses will be collected initially, the data will be entered into an excel file format. Information on location of cell phone towers will be collected. The excel file will be used to plot locations on a map and cross matched against location of cell phone towers.

29.3. Time schedule of activities giving milestones



1- collection of data

2-entry and verification

3-data analysis and results

29.4. Do the physical and financial targets (given in section 300-351) match with each other -yes

29.5. Suggested plan of action for utilization of research outcomeexpected from the project.

The plan for utilization will depend on the outcome, if the study reveals no association then it can be used to allay the fears of the general public. If the study reveals an association then further extensive

studies will need to be carried out. The study can also be utilized as a pilot study and as a template for replication on a larger scale involving multiple centers.

30. The development "Outcomes" and "Outputs' of the project31. Economic implications of the proposed work, if any.

Outcomes will depend on the results, whether any association is present or not, outcome will be dependent on final results.

(32.) BUDGET ESTIMATES: SUMMARY

	Item	Budget	(In Rupees)
		One Year Duration	
A	Recurring		
	1.Salaries/Wages	3,60,000	3,60,000
	2.Consumables	15,000	15,000
	3.Travel	40,000	40,000
	4.Other Cost	168,540 (Software)	168,540 (Software)
B	Equipment	47000	47000
	Grand total (A+B)	6,30,540	6,30,540

33. BUDGET FOR SALARIES/WAGES

		Budget	(In Rupees)
		One year duration	
Designation & number of persons	Monthly Emoluments		
Junior Research Assistant	20,000	2,40,000	2,40,000
Data Entry and recording	10,000	1,20,000	1,20,000
Total	30,000	3,60,000	3,60,000

34. Justification for the manpower requirement.NA

35. BUDGET FOR CONSUMABLE MATERIALS

		Budget	(In Rupees)
Item			
Paper/ storage almirah	Quantity or number	2000/1	15,000
	Budget		
Total	Budget		

36. Justification for costly consumable (if not provided for in Section 231 i.e. Methodology)NA

37. BUDGET FOR TRAVEL

Budget	40,000
Total	40,000

38. Justification for intensive travel, if any. NA

39. BUDGET FOR OTHER COSTS/CONTINGENCIES

	Budget	(in Rupees)
	One year duration	
Other costs/contingency costs	40,000	

40. Justification for specific costs under other costs, if any.NA

41. BUDGET FOR EQUIPMENT

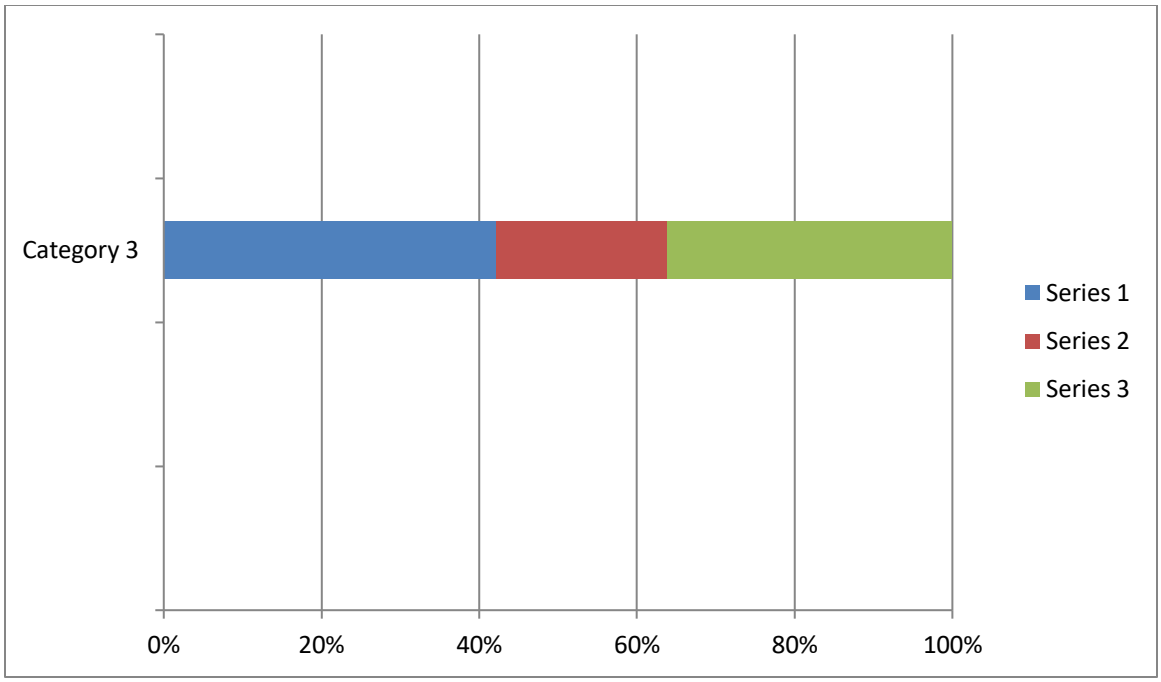
Si No	Generic name of the equipment along with make & model	Imported/indigenous	Estimated cost	Spare time for other users (in %)
1	laptop	indigenous	47,000	

42. Justification for the proposed equipment.

Laptop for entry and record data and also for the specialized software developed by technical partners

43. Reliability of Cost Estimates. Accurate

44. Time Schedule of Activities through BAR Diagram



1- collection of data

2-entry and verification

3-data analysis and results

45. List of facilities being extended by parent institution(s) for the project

implementation.

A) Infrastructural Facilities:

S.No.	Infrastructural Facility	Yes/No/not required
1	Workshop Facility	Not Required
2	Water & Electricity	Yes
3	Laboratory Space/Furniture	No/Yes
4	Power Generator	Not Required
5	AC Room or AC	Not Required
6	Telecommunication including e mail & fax	Not Required
7	Transportation	Not Required
8	Administrative/Secretarial support	Yes
9	Information facilities like internet/Library	Yes
10	Computational Facilities	Not Required
11	Animal/ Glass House	Not Required
12	Any other specialty being provided	None

B. Equipment available with the Institute/ Group/ Department/ Other Institutes for

the project:

Equipment available with	Generic name of the equipment	Model, make & year of purchase	Remarks
PI & his group	NA		
PI's department	NA		
Other Inst in the region	NA		

46. Detailed Bio-data of the Investigator

NameDr Anil Shetty

DOB 19-05-1974

Designation Associate Professor, Department of Paediatrics, Fr Muller Medical College, Mangalore

Institution address Fr Muller's road Kankanady. Mangalore- 575002

Teaching Experience 10 years

Qualification MD Paediatrics

Undergraduate qualification MBBS, from Kasturba Medical College, Mangalore.(1999) University – Manipal University, Manipal.

Post Graduate qualification MD from Fr Muller Medical College, Mangalore (2003) University- Rajiv Gandhi University of Health Sciences, Bangalore.

Postgraduate Thesis 'Congenital anomalies in Olighydramnios and Polyhydramnios', was awarded the best thesis in Fr Muller Medical College 2003.

Academic accomplishments- Post Graduate Thesis guide since 2010, Have guided 2 MD postgraduate thesis's so far.

Undergraduate MBBS Examiner since 2009, been internal examiner toFr Muller Medical College, KVG Medical College Sullia, K S Hegde Medical College Mangalore (all Rajiv Gandhi University of Health Sciences) and External Examiner at Kasturba Medical College Mangalore (Manipal University)

Publications

1. Prevention of Renal Diseases in Children Karnataka Paediatric Journal – Vol.19, No. 2 & 3 April – Sept. 2005

2.Anil Shetty, B. SanjeevRai, Habib Khan, K. VaradarajShenoy Role of Antenatal ultrasound in oligohydramnios and polyhydramnios Karnataka Paediatric Journal - Vol. 23, No. 2 April-June 2009, Page 3-5

3.Anil Shetty, B. SanjeevRai, K.V. Shenoy, Merlin Pinto, GeetanjaliDambalkar, DeepaRavindran, T.S. Ananthakrishnan, G.D. JindalAnu-Photo Rheography in NeonatesKarnataka Pediatric Journal – Vol.23, No.3, July-September 2009, Page No.3-5

4.Sanjeev Rai B, K. VaradarajShenoy, Anil Shetty, Sushanth SPitfalls in the diagnosis of urinary tract infection in childrenMuller Journal of Medical Sciences & Research Vol.1, No.1, March 2010, Page No. : 41-44

5.Detection of congenital anomalies in oligohydramnios and polyhydramniosJournal of Perinatology

6.Peter G, Manuel AL, Shetty A. Study comparing the clinical profile of complicated cases of Plasmodium falciparum malaria among adults and children Asian Pacific Journal of Tropical disease 2011 ; 1 : 35 – 37 (indexed) (International)

47. **Details of Research Projects completed/ submitted by the Investigator**

Project TitleAnu Photo Rheography in neonates

Project Status: completed,

period2007 to 2010

funding agency-Board of Research in Nuclear Sciences, Bhaba Atomic Research Centre, Trombay, Mumbai.

total cost 16 lakhs

Summary of the project

The study was done to Validate theAnu Photo Rheograph in neonates atFrMuller Medical College, Mangalore in Collaboration withBARC, Mumbai. In our study the bloodflow assessment, oxygen saturation andphysiological variability of heart rate weredone in 250 newborns and the data wascompiled. The graphs for Blood flowassessment, blood flow variability and heartrate variability were

obtained. Theseparameters are used to plot thenormoograms for Term, pre term neonates.This normogram can be used as standardsfor evaluation of sick neonates.

Major Results/ Highlights of the project including achievement (publications,

patents etc.), for completed projects

Anil Shetty, B. SanjeevRai, K.V. Shenoy, Merlin Pinto, GeetanjaliDambalkar, DeepaRavindran, T.S. Ananthakrishnan, G.D. Jindal Anu-Photo Rheography in Neonates Karnataka Pediatric Journal – Vol.23, No.3, July-September 2009, Page No.3-5

48. Any other relevant matter.

None

Fw: IMPRINT Preliminary Proposal Evaluation - Phase I

shashidhar koolagudi

Tue 6/7, 2016 11:17 AM

Anil Shetty <anilshettyk@hotmail.com>, Vikas <vikasm@gmail.com>;

Dear All,
The proposal we had submitted to IMPRINT is through in the first round.
Let us hope for the final approval. This is for your information
With regards

Shashidhar G.Koolagudi
Assistant Professor, CSE
National Institute of Technology Karnataka, Surathkal
Sreenivasanagar, Mangalore-575 025
Karnataka, India
Ph.: 91-824-2473413

On Tuesday, 7 June 2016 3:54 PM, no-reply <no-reply@imprint-india.org> wrote:

Dear Shashidhar G. Koolagudi,

We thank you for submission of your 5-page preliminary proposal number 6822 titled 'Infant cry analysis for identifying the early symptoms of dyslexia and autism in children' for financial support under the MHRD sponsored initiative IMPRINT.

The Domain Expert Committee for your domain has completed the Phase I of the evaluation process of the proposal and your proposal has been ACCEPTED for further review in Phase II (by domain experts).

The results of Phase II of the evaluation process of the proposals will be announced in a couple of weeks time. If your proposal is selected in Phase II, you will be invited to submit the full proposal in due course for final assessment.

We will send you another mail after Phase II of the evaluation process to inform the status of your proposal.

Thanks again and regards,

Team IMPRINT

Preliminary Proposal MHRD (IMPRINT)

Title (< 25 words): Infant cry analysis for identifying the early symptoms of dyslexia and autism in children

Domain and theme(s) (menu driven)

Abstract (< 100 words)**:** Lot of research has been going on since the late nineteenth century on the utility of cry of neonates/infants for predicting morbidities and disorders. Studies have shown that the cry of an infant can be a window into its brain, especially before it acquires social skills. There are already some well-known syndromes easily identifiable by infant cry, cri-du-chat being a case in point. Studies have shown promises that the conditions like autism, down's syndrome, can also be identified by analyzing an infant's cry. More research especially in the Indian context is required.

Aim and objective (< 50 words): To record the cry of both healthy and suspected/verified unhealthy infants, track their development for 5 years (minimum) and study their vocal excitations during that period to identify any traits that can help provide early medical solutions. The methodology is non-invasive and hence has exciting prospects.

Motivation and genesis (< 150 words): Even though research in this field has started in nineteenth century, very little study has been conducted in India. Local research is important because genetic factors are relevant when it comes to healthcare. Researchers have recorded and spectrally analyzed the cry of an infant in hunger and when experiencing pain. The results of such analysis have shown that the acoustic features of waveforms such as pitch, energy etc. are different in both healthy and unhealthy infants and are easily discernable even by naked eyes, promising that sustained research can yield actionable outcomes. Also earlier studies were usually headed by pediatricians, whereas our study will be led by an engineer there by

providing more technical skills on this front. Since the methodology is non-invasive, hope is that a solution it will be more acceptable and accessible even in rural areas.

Current status and open questions (< 200 words): This is a relatively nascent field with a lot of scope of study and there are no practical tools/procedures which can be used by healthcare professionals to accurately identify any abnormalities or deficiencies based on infant cry spectrograms. Studies have shown that the cry of an infant can be a window into its brain, especially before it acquires social skills and realizes that crying can be a tool to invite attention. Researchers in US are in the process of developing a tool "A Flexible Analysis Tool for the Quantitative Acoustic Assessment of Infant Cry – Brian Reggiannini et al" which should help researchers and health care professionals an easy access to a tool that can analyze infant's cry patterns. Even after such a tool is available, using it as a diagnostic aide is quite far away in the future and is the holy grail that researchers are after.

Plan of work including proposed methodology (< 500 words): The project aims to record the cry of healthy and sick babies. An initial infant cry database will be created with at least a few hundred samples. At the time of data collection other pertinent information like Age of the baby, its gender, whether it's a term or pre-term baby, birth weight of the baby, weight of the baby at the time of recording, whether the baby is suffering from any disease, whether the baby has any siblings, has any of the siblings died, if yes, the cause of death, educational qualification of the parents etc., also would be collected. Once the database is collected we intend to compare the cry of healthy and sick infants on acoustic characteristics for various reasons. Such as:

- to study effect of mother tongue on the cry pattern of neonates
- identifying the difference between cry patterns of healthy and unhealthy babies
- characterizing the cry patterns for specific health issues if possible

- analyzing and generalizing this characterization for different kinds of ailments
- mapping the early cry symptoms with the health issues of grown up children (up to 6 years)
- designing a prediction engine that predicts possible health issues like dyslexia and autism during early infancy
- developing a mechanism that improves the reliability of these predictions.

Method of recording: High precision noise suppression recording devices, which can record a frequency range beyond 20 kHz. (Sony, Ahuja..). Recording is done with the sampling frequency of 16 kHz. using 16 bits' storage per sample.

Analysis :

- A expert would note a possible reason for a cry, while recording cry samples
- Acoustic analysis of these cry patterns are conducted for various spectral and prosodic information
- Acoustically extracted patterns are studied for different children, possibly with the same reason of cry
- A track of a child for its cry pattern and health conditions is kept for a long time (at least up to 6 years) to acoustically map possible health disorders and cry patterns

Outcome :

- identifying cry patterns of children during early days of their birth for dyslexia and autism disorders
- suggesting remedial medication
- counseling of specific parents for parenting the disabled child

Justification and novelty – 'what is new' (< 50 words):

- No solution exists anywhere in the world
- Very little research in the Indian context
- Because of the non-invasive nature, a tool, if developed, can be easily available to the masses
- Research headed by an Engineer specializing in study of speech technology

Milestones and time frame (< 100 words):

Benchmark and specifications of the product (< 100 words):

Deliverables and beneficiary industry/sector (< 50 words): The ultimate aim is to develop a tool that can analyze infant cry and list possibilities for a healthcare professional to carry out further investigations or (maybe) even prescribe medications. Applications will be in the healthcare sector.

Industry, Institution or Agency partners (< 50 words): Hunting for partners from the pharma, medical industry. No partners signed up so far.

Tentative budget with year and item wise breakup (< 100 words):

Rough estimate:

Sl. no.	**Item**	**Quantity**	**Price**	**Total (In Rs.)**
01	Senior research fellow	01	Rs 28,000 per month for 6 years	20,16,000
02	Junior research fellow	02	Rs 25,000 per month for 6 years	36,00,000
03	Equipments High end PCs High end laptops Recording devices Printer	 02 02 03 01	 40,000 70,000 40,000 40,000	 80,000 1,40,000 1,20,000 40,000
04	Database collection	01	For six years	8,00,000
05	Contingency	For six years		9,00,000
06	Travelling	Meetings, Conference, workshop, training For six years		15,00,000
07	Consumables	For six years		4,20,000
08	Training and expert visits	For six years		3,00,000
09	Institutional overhead	For six years		10,00,000
09	**Total**			**1,09,16,000**

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
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Details Contact Person Public Query

Name	Dr Subhash Thuluva
Designation	Vice President- Clinical Development
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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

(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/ 0310-14 Date: 07 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 INSTITUTIONAL ETHICS COMMITTEE

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

DCGI Re-registration No.
ECR/340/Inst/KA/2014/RR-17

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

CHAIRPERSON
Dr. Ashok Shenoy
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Phone +919880530703
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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/188/2019 Date 29.07.2019

Dr. Prema D'Cunha
Professor of OBG
Father Muller Medical College Hospital,
Father Muller Road, Kankanady,
Mangalore-575002, Karnataka, India.

Dear Madam,

Your research proposal was discussed in the ethics committee meeting held on 27.07.2019. (Venue: Research Centre – Ground floor of Indoor stadium building Father Muller Road, Kankanady Mangalore, Karnataka, India at 3.00 PM.)

" A double- blind, randomized adaptive design, controlled clinical trial to evaluate the efficacy and safety of saroglitazar 2mg and 4mg tablets versus placebo for treating women with PCOS"
FMMCIEC Protocol No: 154/19
Principal Investigator: Dr. Prema D'Cunha Co Investigator : Dr. Archana Bhat
Name & Address of Institution : Department of OBG Father Muller Medical College Hospital, Father Muller Road, Kankanady, Mangalore-575002, Karnataka, India.

List of documents reviewed:

1. Investigators Brochure (Version 10.0; Dated 08 May 2019)
2. Protocol SARO 18.001.03 (version 3.0;Dated 18Dec 2018)
3. Protocol Appendix 2: Declaration of Helsinki; Dated Oct 2013
4. Protocol Appendix 3: List of Investigators
5. Protocol Appendix 4: Informed Consent Form (Eng) Version 3.0; Dated 18 Dec 2018
6. Protocol Appendix 5: Case Report Form- Screening (Version 3.0; Dated 26 Dec 2018)
7. Protocol Appendix 5: Case Report Form- Enrolment (Version 3.0; Dated 26 Dec 2018)
8. Protocol Appendix 6: Normal laboratory value.
9. Insurance policy #21230036180500000007 Validity 20 Mar 2019 to 20 Mar 2020 (Version 21230036180500000007 Dated; 20 Mar 2019)
10. Insurance Policy # 21230036180500000007 Coverage Details (Version 21230036180500000007 Dated; 20 Mar 2019)
11. Insurance Policy # 21230036180500000007 Clinical Trials Coverage Details (Version 21230036180500000007 Dated; 20 Mar 2019)
12. Additional Endorsement Document for Clinical Trials Liability (CT) Insurance Policy (Version 21230036180500000007 Dated; 04 June 2019)
13. DCGI Approval letter (NOC) Version SND/CT/18/000001; Dated 16 April 2019
14. DCGI Notification (Administrative Changes to protocol 3.0) Version SND/CT/18/000001; Dated 22 May 2019
15. CTRI Registration Number ; CTRI/2019/05/019156; Dated 30 June 2019
16. ICF Translation –Kannada (Version 3.0 Dated 16 Jan 2019)
17. ICF back Translation – Kannada to English (Version 3.0 Dated 22 Jan 2019)
18. ICF Translation Certificate –Kannada
19. ICF back Translation-Malayalam (Version 3.0 Dated 16 Jan 2019)
20. ICF back Translation – Malayalam to English(Version 3.0 Dated 22 Jan 2019)
21. ICF Translation Certificate –Malayalam
22. Patient Diary- English
23. Patient Diary Translation- Kannada
24. Patient Diary Back Translation- Kannada to English
25. Patient Diary Translation Certificate – Kannada
26. Patient Diary Translation- Malayalam
27. Patient Diary Back Translation-Malayalam to English
28. Patient Diary Translation Certificate- Malayalam
29. eCRF version 1.0 ; Dated 25 Apr 2019

30. Data Entry Guideline, Version 1.0; Dated 15 May 2019
31. USG Imaging Operating guideline, Version 1.0; Dated 10 May 2019
32. Draft Clinical Trial Agreement between the Sponsor, Investigators ans the Head of the Institution
33. PI CV of Dr Prema D'Cunha; Dated 012 Jan 2019
34. PI MRC of Dr Prema D'Cunha
35. PI GCP (E6 R2 trained) of Dr Prema D'cunha
36. Investigators Undertaking ;Dated 20 Dec 2018
37. Protocol signature Page of Dr Prema D'Cunha;Dated 05 Mar 2019

New review: Exempt review / Expedited review/ Full review✓

Review of Revised Submission: Nil

Date of previous review, if revised application: Nil

Decision of the Ethics Committee:

> Approved

> **Approved with Conditions ✓**

> Revision/ Resubmission

> Rejected

Suggestions /Reasons/Remarks: Approved with Conditions. Urine pregnancy test should be done in every visit. In case of any study participant becoming pregnant, the ethics should be informed about within 24 hours by the PI. The IEC should be informed during the recruitment of first participant, and there will be onsite monitoring. More clarity required on compensation for congenital anomalies in baby born to the study participant. If a study participant gets pregnancy during the study period and opts for medical termination of pregnancy (MTP), who will take care of the expenses of the procedure and will it be done in FMMCH? As FMMCH does not do MTP, will be the expenses of MTP in another hospital will be born by the sponsor? The clinical trial agreement should answer the query on MTP as above.
Contact details of FMMCIEC need to be mentioned in the patient information sheet.
The clinical trial is approved per se subjected to the fulfilment of above queries/conditions.

Recommended for a period of: 1 Year

- The FMMCIEC should be informed during the recruitment of the first subject. The informed consent process and recruitment of the first subject shall be witnessed by a subcommittee of the FMMCIEC. Only after approval of the same, the trial will be allowed to continue.
- The clinical trial will be periodically reviewed by ethics committee during the study period. The FMMCIEC will be monitoring the conduct of the protocol by on-site monitoring, review of study-related documents and review of progress reports. The on-site monitoring with prior intimation to the principal investigator, will be done during the recruitment of first subject, during the progress and at the closure of the study. The FMMCIEC may conduct surprise checks of the clinical trial.
- The investigator/s is/are instructed to carry out the research study as per the protocol and the informed consent documents approved by the ethics committee. Any amendments should be brought to the notice of the IEC and the study should continue only after the approval of the amended protocol and protocol-related documents by the IEC.
- Any protocol deviations/violations should be promptly and at the earliest brought to the notice of ethics committee.
- You should report the subject withdrawals (if any) within a month of the occurrence.
- You are instructed to submit progress report of the clinical trial once in every six months
- You should comply with the regulations and guidelines on biomedical research on human participants, and follow good clinical practice
- You should report any serious adverse events in your site or any other site of this clinical trial to the ethics committee . The SAE reporting should follow the timeline as per GCP guidelines of CDSCO.
- You need to submit the final report and summary at the termination of the study.
- You should take all the necessary measures to protect the rights and safety of the study subjects and confidentiality of the information collected from them.
- The subjects should be made know of their rights and responsibilities.

- Ethics committee has the right to withdraw the approval if found necessary due to protocol violations, non-compliance to regulations and guidelines

Following members were involved in the decision of Ethics Committee:

Sl. No.	Name of Member	Role/Designation in Ethics Committee
1.	Dr. Ashok Shenoy K.	Chairperson
2.	Dr. Shivashankara A.R.	Member Secretary
3.	Dr. Varadaraj Shenoy K.	Member – Clinician
4.	Dr. Safeekh AT	Member - Clinician
5.	Dr. Anup Kumar Shetty	Member - Basic Medical Scientist
6.	Mrs. Anuradha Shetty	Member - Social Scientist
7.	Fr. Leo D'Souza	Member – Theologian
8.	Mrs. Veena Manoj	Member – Lay Person
9.	Mr. Sushanth F.Sequeira	Member – Legal Expert
10.	Dr Arun Rao	Subject Expert

Name and Signature of Member Secretary

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

FMIEC/CCM/31/2019

Date:11.03.2019

Protocol Title: Ankle brachial pressure index and ankle peak systolic flow velocity in diabetes mellitus patients with ischemic stroke – A case control study.
Protocol No: 24/19
Principal Investigator : Dr Archana Bhat Co Investigators : Dr Krishna Kiran Karanth, Dr Akshatha Rao Aroor
Name & Address of Institution : Dept of General Medicine Father Muller College Kankanady, Mangaluru – 575002
New review: Exempt review **Expedited review** **Full review** ✓
Review of Revised Submission: Nil
Date of review: 09.03.2019 **Date of previous review, if revised application:** Nil
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, and renewal of approval has to be requested.
> Members of Ethics committee have right to monitor the study with prior intimation

Following members were present and were involved in the decision of Ethics Committee:

Sl. No.	Name of Member	Role/Designation in Ethics Committee
1	Dr. Shalini Shenoy	Chairperson
2	Dr. Shivashankara A.R.	Member Secretary
3	Mrs. Anuradha Shetty	Vice Chairperson; Member – Social Scientist
4	Dr. Devina F.Rodrigues	Member –Nursing Expert and Joint Secretary
5	Dr. K Shreedhara Avabratha	Member-Clinician
6	Dr. Nicole Pereira	Member-Basic Medical Scientist
7	Fr. Roque Victor D'Sa	Member - Theologian
8	Mr. Sushanth F.Sequeira	Member – Legal Expert
9	Dr Kurian P.J	Member – Homeopathy Expert
10	Mrs Sheril Maria D' Souza	Member- Lay Person
11	Dr Vivek Sakthidharan	Member – Homeopathy Expert
12	Dr Santhosh Kumar	Member – Speech and Hearing Expert

Dr. Shivashankara A R

Member Secretary
Father Muller Institutional Ethics Committee

FATHER MULLER RESEARCH CENTER
(A unit of Father Muller Charitable Institutions)
Father Muller Road, Kankanady, Mangaluru – 575002

Ref No.: FMRC/ FMMC/ ST/02/19-20

Date: 30.01.2019

Dr K Sundara Bhat
Dept of General Medicine

Dear Doctor,

Sub: Sanction of FMRC research grant - 2019-20

Congratulations to you!

I am pleased to inform you that your research proposal titled **"Correlation of Thyroid Hormone Profile with the Acute Physiology and Chronic Health Evaluation II Score (APACHE II) as a Prognostic Indicator in Patients with Sepsis in the Intensive Care Unit"** has been approved. A research grant of ₹ **66,000** has been sanctioned. The details of grant are as follows:

Investigations	Consumables	Equipments	Stationary*	Travel#	Miscellaneous@	Total ₹
TFT(T3,T4,Ft4,TSH) (80*650) Ft3 (80*175) ₹ 66,000	-	-	-	-	-	66,000

You are required to

- ✓ Initiate the project within 3 months of date of grant sanction.
- ✓ The grant amount will be released periodically as per the progress / needs of the project
- ✓ Register your project with CTRI and the registration number should be submitted before starting the project.
- ✓ Submit two quotations each for equipments / test kits/ Chemicals etc. for the needful.(if to be purchased from outside)
- ✓ Collect Investigation forms/Test Kits from the Research center for In house Investigations
- ✓ All experimental works to be done in Father Muller Laboratory except those with prior permission.
- ✓ * Purchase all stationeries from Father Muller Co- operative Society. (Library building Ground Floor)
- ✓ # Travel expenses will be reimbursed on production of receipt as per institutional guidelines
- ✓ @ Submit item wise details for Miscellaneous expenses
- ✓ Submit interim project report with fund utilization to the FMRC through proper channel through the Head of the institution at 3 rd monthly interval till the completion of the project.
- ✓ Complete the project on or before December 2019.
- ✓ Seek permission if an extension of duration is required to complete the project, through proper channel / Head of the Institution at least two months before the originally scheduled completion of the project.
- ✓ Submit a final report to the FMRC within three months of completion of the project.
- ✓ Submit at least one manuscript for publication from this research project to an indexed (MCI /UGC Approved Journals) journal.
- ✓ You are requested to write a follow-up research proposal and submit to an external agency for funding.
- ✓ Understand that during the research work, officials of the FMRC shall reserve the right of inspection.
- ✓ Maintain and record all the details of the conduct of research work along with documents properly (by the principal investigator). Such documents should be submitted whenever called for by the FMRC.
- ✓ In case the principal investigator discontinues the research work, the co-investigator shall continue and complete the work within the stipulated time with permission from the head of the institution, with intimation to the FMRC.
- ✓ On completion of the research project the entire report of the project will become the property of FMRC.
- ✓ Failure to adhere to any of the above conditions, FMRC reserves the right to take appropriate action and cancel the project including the recovery of fund utilized.
- ✓ You are bound by the rules and guidelines framed by Father Muller research Center from time to time

(sd....)

Dr B Sanjeev Rai
Chief of Research
FMRC

Cc: Dean, FMMC, HOD- General Medicine, Finance Dept, Accounts Dept

FATHER MULLER RESEARCH CENTER
(A unit of Father Muller Charitable Institutions)
Father Muller Road, Kankanady, Mangaluru – 575002

Ref No.: FMRC/ FMMC/ ST/04/19-20

Date: 30.01.2019

Dr Archana Bhat
Dept of General Medicine

Dear Doctor,

Sub: Sanction of FMRC research grant - 2019-20

Congratulations to you!

I am pleased to inform you that your research proposal titled " **Ankle brachial pressure index (ABI) and ankle peak systolic flow velocity (PSV) in diabetes mellitus patients with ischemic stroke – A case control study**" has been approved. A research grant of ₹ **2, 67,500** has been sanctioned.

The details of grant are as follows:

Investigations	Consumables	Equipments	Stationary *	Travel#	Miscellaneous@	Total ₹
Ankle peak Systolic velocity (100*800) MRI DWI Brain (50*3750) ₹ 2,67,500	-	-	-	-	-	2,67,500

You are required to

- ✓ Initiate the project within 3 months of date of grant sanction.
- ✓ The grant amount will be released periodically as per the progress / needs of the project
- ✓ Register your project with CTRI and the registration number should be submitted before starting the project.
- ✓ Submit two quotations each for equipments / test kits/ Chemicals etc. for the needful.(if to be purchased from outside)
- ✓ Collect Investigation forms/Test Kits from the Research center for In house Investigations
- ✓ All experimental works to be done in Father Muller Laboratory except those with prior permission.
- ✓ * Purchase all stationeries from Father Muller Co- operative Society. (Library building Ground Floor)
- ✓ # Travel expenses will be reimbursed on production of receipt as per institutional guidelines
- ✓ @ Submit item wise details for Miscellaneous expenses
- ✓ Submit interim project report with fund utilization to the FMRC through proper channel through the Head of the institution at 3 rd monthly interval till the completion of the project.
- ✓ Complete the project on or before December 2019.
- ✓ Seek permission if an extension of duration is required to complete the project, through proper channel / Head of the Institution at least two months before the originally scheduled completion of the project.
- ✓ Submit a final report to the FMRC within three months of completion of the project.
- ✓ Submit at least one manuscript for publication from this research project to an indexed (MCI /UGC Approved Journals) journal.
- ✓ You are requested to write a follow-up research proposal and submit to an external agency for funding.
- ✓ Understand that during the research work, officials of the FMRC shall reserve the right of inspection.
- ✓ Maintain and record all the details of the conduct of research work along with documents properly (by the principal investigator). Such documents should be submitted whenever called for by the FMRC.
- ✓ In case the principal investigator discontinues the research work, the co-investigator shall continue and complete the work within the stipulated time with permission from the head of the institution, with intimation to the FMRC.
- ✓ On completion of the research project the entire report of the project will become the property of FMRC.
- ✓ Failure to adhere to any of the above conditions, FMRC reserves the right to take appropriate action and cancel the project including the recovery of fund utilized.
- ✓ You are bound by the rules and guidelines framed by Father Muller research Center from time to time

(sd....)

Dr B Sanjeev Rai
Chief of Research
FMRC

Cc: Dean FMMC, HOD- General Medicine, Finance Dept, Accounts Dept

FMMCIEC/CCM/475/2018

11.09.2018

Protocol Title: " Clinical and radiological correlation of pulmonary manifestations in rheumatoid arthritis"
Protocol No: 374/18
Principal Investigator : Dr Srilakshmi Prbhu **Co Investigators** : Dr. Peter George, Dr Ram Shenoy Basti
Name & Address of Institution : Dept. of General Medicine Father Muller Medical College, Kankanady, Mangalore – 575002
New review: Exempt review **Expedited review** **Full review** ✓
Review of Revised Submission:
Date of review: 06.09.2018
Date of previous review, if revised application: Nil
Decision of the Ethics Committee: > Approved > **Approved with suggestions** ✓ > Revision/ Resubmission > Rejected
Suggestions /Reasons/Remarks: Have a relook at the Kannada version of patient information sheet and informed consent form and correct the errors.
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

Following members were present and were involved in the decision of Ethics Committee:

Dr Ashok Shenoy	Chairperson
Dr.Shivashankara A.R.	Member Secretary
Dr Varadaraj Shenoy	Member-Clinician
Dr.Sudhir Prabhu	Joint Secretary; Member-Clinician
Dr.Safeek AT	Member-Clinician
Dr. Anup Kumar Shetty	Member -Basic Medical scientist
Mrs.Veena Manoj	Member – Lay Person
Mrs.Anuradha Shetty	Member- Social Scientist

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

Fwd: An intelligent medical support through speech summarization

Inbox x

Anil Shetty <anilshettyk@hotmail.com> 7/24/17

to me

Sent from my iPhone

Begin forwarded message:

From: "Konga Gopikrishna Scientist D, DST, Min. of Science & Technology" <k.gopikrishna@nic.in>
Date: 14 June 2017 at 4:18:26 PM IST
To: <koolagudi@nitk.ac.in>, <anilshettyk@hotmail.com>
Subject: An intelligent medical support through speech summarization

Dr. Konga Gopikrishna
Scientist – 'D'
Science for Equity Empowerment and Development Division
E – Mail: k.gopikrishna@nic.in Phone: 011 – 26590298

SEED/TIDE/016/2017 **14th June 2017**

BY SPEED POST/E-MAIL

Sub: 14th Meeting of the Programme Advisory & Monitoring Committee (PA&MC) for 'Technology Interventions for Disabled and Elderly' (TIDE) Programme

Ref: Your project titled *"An intelligent medical support through speech summarization"*

Dear Sir

The above mentioned project proposal submitted by you to this Department for financial assistance under TIDE Programme will be considered by the PA&MC in its meeting scheduled to be held on 13th July 2017 at Indian National Science Academy (INSA), Bahadur Shah Zafar Marg, New Delhi – 110 002 starting at 9:30 Hrs. The address of the venue is given below.
Indian National Science Academy (INSA)
2, Bahadur Shah Zafar Marg,
ITO Cross, Delhi-110002

www.insaindia.res.in/
Tele: 011 – 2322 1931 – 2322 1950 (20 lines)

You are requested to make a presentation of the proposal before the Committee on 13th July 2017. Please prepare a neat presentation using MS power point. The investigators are required to present the project proposal in 10 minutes time using not more than 12 slides. The presentation should highlight the "problem identification" and the relevance of the innovation to the "user group". The presentation may emphasize on innovative aspects, S&T component, novelty in delivery of the interventions, list of deliverables, etc. Kindly note that time should not be wasted on the state-of-art/ background of the project during presentation. The presentation should also accentuate on industry partnerships (Government/Private/NGO) and standing tie ups with end users, if any for dissemination/implementation of developed technologies.

Traveling Allowance will be reimbursed by DST restricted to AC 2 tier either to the Investigator or the Co-Investigator on production of travel documents. You had to make your own arrangements for reaching the Venue of the meeting.

You had to make your own arrangement for your stay during the meeting. Though not guaranteed, limited reimbursement towards accommodation charges may be considered on production of relevant bills as per extant norms of DST. Kindly confirm your participation to the undersigned on the E- Mail given above.

Kind Regards

Yours
Sincerely
(Konga Gopikrishna)

To

Dr. Shashidhar G. Koolagudi
National Institute Technology Karnataka
Surathkal, Mangalore - 575 025
Karnataka

FORMATS FOR SUBMISSION OF PROJECTS

UNDER RADIATION HAZARDS

(To be filled by applicant)

1. Project Title-Cancer and proximity to mobile phone towers

2. Broad Subject:- Life Sciences

3. Duration in months- Twelve

4. Total cost-6,30,540

5. FE Component- Nil

6. Principal Inv.-Dr Anil Shetty K

7. Designation- Associate Professor

8. Department-Paediatrics

9. Institute Name-Fr Muller Medical College

10. Address- Department of Paediatrics,

Fr Muller Medical College

Kankanady

Mangalore-575002

11. Date of Birth: Sex (M/F) 19-05-1974 Male

12. Telephone Fax Gram e-mail 9886392043(mobile), 0824– 2238000(Landline), 0824 - 2437402 / 2436352(Fax) anilshettyk@hotmail.com

13. Co-Investigator NA

14. Designation NA

15. Department NA

16. Institute Name NA

17. AddressNA

18. Date of Birth: Sex (M/F) NA

19. Telephone Fax Gram e-mail NA

(Repeat 13 to 19 for additional Co-Investigators, if any, as 13.1-19.1, 13.2-19.2,.)

20. Project summary

One of the biggest fears associated with cell phone towers is the apprehension that they cause cancer. This has led to many communities opposing the setting up of cell phone towers in urban residential localities or in the vicinity of schools. While there is no conclusive evidence implicating cell phone towers in the causation of cancer, the public at large remains skeptical and there are several misconceptions about cell phone tower radiation. Many studies have collected data and information about radiation and its effect in the vicinity of towers. Our study proposes a different approach. We use addresses of past patients in our cancer center and triangulate their location and proximity to cell phone towers using specially developed software and maps. This will aid us and demonstrate whether proximity and location of cell phone towershave any bearing on the incidence of cancer.

21. Key words Cancer, Cellphone Tower Proximity

22. Technical details

22.1. Introduction

22.1.1. Origin of the proposal

Teledensity in India is 79.28% (May 2012), the vast majority of these phones are cell phones, (930,000,000). To serve the spectrum needs of this huge number of cell phones, cell phone towers are also seeing an exponential growth. There has been much public debate, controversies and in some cases mass hysterical reactions about the health hazards about cell phones in general and cell phone towers in particular. While there is no consensus in the scientific and health community about the effects, the biggest fear however is whether cell phones and towers have a role in the etiology of cancer. Most studies have focused on detecting cases of cancer in the vicinity of the tower's . In our opinion this is akin to looking for a needle in a haystack and we propose to do the reverse, i.e. use data and addresses of cancer patients using the facility's in our hospital and co relate it to the proximity of towers to their home addresses.

22.1.2. Definition of the problem

Media coverage of residents and resident associations waging a campaign against cell phone tower installation has received wide coverage and shaped public perception. There are about 25 lakh existing cancer cases in India, 7 lakh new cases are added every year, every year nearly 5 lakh deaths occur due to cancer. In 2012 there were 7,36,654 mobile phone towers in India. Some of the statistics on cancer will be attributed by the public to the proliferating number of these cell phone towers.

22.1.3. Objective

1.Toinvestigate the risk of cancers associated with exposure to radiofrequency from proximity to cell phone towers.

2. To determine if proximity to cell phone towers increases the incidence of cancer, i.e. closer the tower, more the incidence.

22.2. Review of status of Research and Development in the subject

22.2.1. International status

While there are a few studies that studied the effect of cell phones like the interphone study (http://www.iarc.fr/en/media-centre/pr/2010/pdfs/pr200_E.pdf), there are fewer studies of cancer and cell phone tower radiation. Elliot.P et al British Medical Journal,2010, 340, c3077 studied 'Mobile phone base stations and early childhood cancers, case control study' concluded that there was no association between cell phone towers and childhood cancers.

Another study was conducted by Wood A.W. et al in the Archives of disease in childhood, vol 91, April 2006, pp361-66 and a study by Bethele J.F. et al in the British Medical Journal 2010,340 c 3015 came to similar conclusions. ' Sciences economiques&sociales de la santé &traitment de l'informationmedicale' a French journal studied the risk perception of the general public of cell phone tower radiation and cancer risk and revealed an increased perception of risk to 68.9% in 2010 from 48.5% in 2005.

22.2.2. National status

There are very few studies if any of the effect of cell phone tower radiation in India. There is a current study by the W.H.O. in many countries supported by the I.T.U. There is a study by Prof Girish Kumar of the Electrical Engineering department of I.I.T Bombay. A search on pubmed on 'cell phone tower radiation and cancer in India' did not reveal any results.

22.2.3. Novelty Importance of the proposed project in the context of current status

The Unique selling proposition of our study is that we are approaching the problem in a reverse direction, rather than cause-effect, we are proceeding in the effect-cause(?) direction. Our Hospital was the first one in the region to be equipped with a linear accelerator and other cutting edge technology in the treatment of cancer. Because of these advanced facilities the number of cancer patients availing our services both on an outpatient and inpatient basis increased rapidly. As a result we have access to a lot of data including their home addresses in our Medical Records Department. For the purpose of this study we propose to tie up with 'Code Craft Technologies' a company that develops apps, medical software and location software. (www.codecraft.co.in). A combination of these two valuable assets, our access to patient addresses, data and Codecraft's technological expertise will help us to plot the location of our patients and cell phone towers and determine association if any. This study can also be treated as a pilot study and if successful can be replicated in multiple centers.

22.2.4. if the project Is location specific, basis for selection of location

Since most patients who were treated in our hospital would be from the same geographical sprawl, the data available would also be of the same local geographical area. This data will be matched against the location of cell phone towers in the vicinity of these areas and the information analyzed.

23. Target beneficiaries of the proposed work

Every individual living in the vicinity of cell phone towers, and especially people apprehensive about these towers.

24. Review of expertise available with the PI, the proposed investigating group/institution in the subject of the project

Fr Muller Medical College was the first Hospital in the region to use a linear accelerator to treat cancer, Our hospital has treated a huge number of patients and has a radiotherapy, oncology and onco-surgery department.

Our Technical partner 'Codecraft' has technical expertise in medical and location based software.

25. Patent details (domestic and international), if applicableNA

26. Environmental impact assessment and risk analysisNA

27. Proposed impact assessmentNA

28. Sustainability: Issues relating to sustainability, including stakeholder commitment, operation and maintenance of assets after project completion, and other related issues

The only asset to be procured is a laptop and few other ancillaries, the location software will be developed independently.

29. Work plan

Source of Data – Patients treated for cancer at Fr Muller Medical College Hospital from 2006.

Number- 500-1000 cases

Inclusion criteria- Patients whose addresses are in the vicinity of Mangalore, and the surrounding towns and districts.Patients with a confirmed diagnosis of cancer.

Exclusion Criteria- Patients whose address details are inadequate, or had a diagnosis ofcancer prior to the setting up of any cell phone tower in their neighbourhood.

29.1. Methodology

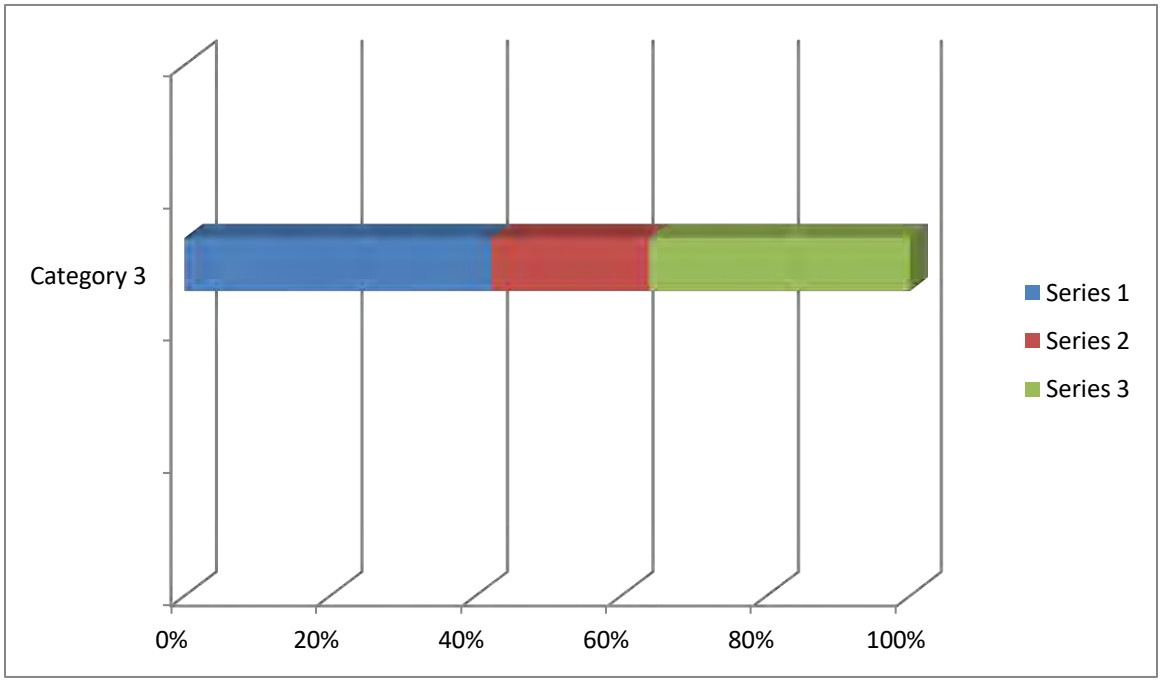
Data collected from patients in the last six years in the Medical Records Department will be analyzed, only addresses and diagnosis of the patients will be recorded in an excel file, no other information will be collected. Principal Investigator and junior research assistant will go through the data and confirm the veracity and details such as diagnosis will be checked, data will be entered by a data entry assistant Our Technical partners Codecraft have expertise in medical and location based software, they will export the data from the excel file and by reverse geo coding, plot the location on map. Information on the location of cell phone towers, their frequency, number of antennas per tower and the date and year

in which they were set up will be accessed. Using Map View-with plotters the cell phone tower location and patient location will be plotted showing people in the zone of the cellular towers. The final report will be devised using line graph to display how many (if) are in close proximity for the mobile tower's and people away from the towers. The type of cancer will be also plotted and information will be similarly compared with cell phone tower location. The data and information can also be matched against a similar number ofnormal controls

29.2. Organization of work elements

Data on addresses will be collected initially, the data will be entered into an excel file format. Information on location of cell phone towers will be collected. The excel file will be used to plot locations on a map and cross matched against location of cell phone towers.

29.3. Time schedule of activities giving milestones



1- collection of data

2-entry and verification

3-data analysis and results

29.4. Do the physical and financial targets (given in section 300-351) match with each other -yes

29.5. Suggested plan of action for utilization of research outcomeexpected from the project.

The plan for utilization will depend on the outcome, if the study reveals no association then it can be used to allay the fears of the general public. If the study reveals an association then further extensive

studies will need to be carried out. The study can also be utilized as a pilot study and as a template for replication on a larger scale involving multiple centers.

30. The development "Outcomes" and "Outputs' of the project31. Economic implications of the proposed work, if any.

Outcomes will depend on the results, whether any association is present or not, outcome will be dependent on final results.

(32.) BUDGET ESTIMATES: SUMMARY

	Item	Budget	(In Rupees)
		One Year Duration	
A	Recurring		
	1.Salaries/Wages	3,60,000	3,60,000
	2.Consumables	15,000	15,000
	3.Travel	40,000	40,000
	4.Other Cost	168,540 (Software)	168,540 (Software)
B	Equipment	47000	47000
	Grand total (A+B)	6,30,540	6,30,540

33. BUDGET FOR SALARIES/WAGES

		Budget	(In Rupees)
		One year duration	
Designation & number of persons	Monthly Emoluments		
Junior Research Assistant	20,000	2,40,000	2,40,000
Data Entry and recording	10,000	1,20,000	1,20,000
Total	30,000	3,60,000	3,60,000

34. Justification for the manpower requirement.NA

35. BUDGET FOR CONSUMABLE MATERIALS

		Budget	(In Rupees)
Item			
Paper/ storage almirah	Quantity or number	2000/1	15,000
	Budget		
Total	Budget		

36. Justification for costly consumable (if not provided for in Section 231 i.e. Methodology)NA

37. BUDGET FOR TRAVEL

Budget	40,000
Total	40,000

38. Justification for intensive travel, if any. NA

39. BUDGET FOR OTHER COSTS/CONTINGENCIES

	Budget	(in Rupees)
	One year duration	
Other costs/contingency costs	40,000	

40. Justification for specific costs under other costs, if any.NA

41. BUDGET FOR EQUIPMENT

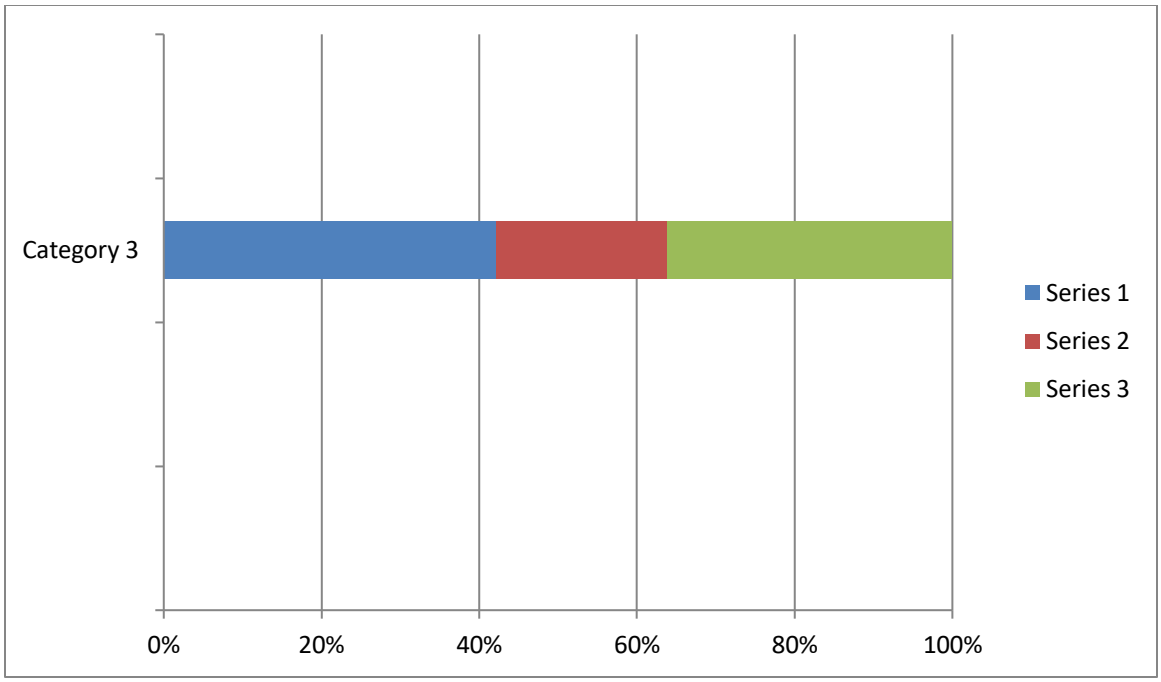
Si No	Generic name of the equipment along with make & model	Imported/indigenous	Estimated cost	Spare time for other users (in %)
1	laptop	indigenous	47,000	

42. Justification for the proposed equipment.

Laptop for entry and record data and also for the specialized software developed by technical partners

43. Reliability of Cost Estimates. Accurate

44. Time Schedule of Activities through BAR Diagram



1- collection of data

2-entry and verification

3-data analysis and results

45. List of facilities being extended by parent institution(s) for the project

implementation.

A) Infrastructural Facilities:

S.No.	Infrastructural Facility	Yes/No/not required
1	Workshop Facility	Not Required
2	Water & Electricity	Yes
3	Laboratory Space/Furniture	No/Yes
4	Power Generator	Not Required
5	AC Room or AC	Not Required
6	Telecommunication including e mail & fax	Not Required
7	Transportation	Not Required
8	Administrative/Secretarial support	Yes
9	Information facilities like internet/Library	Yes
10	Computational Facilities	Not Required
11	Animal/ Glass House	Not Required
12	Any other specialty being provided	None

B. Equipment available with the Institute/ Group/ Department/ Other Institutes for

the project:

Equipment available with	Generic name of the equipment	Model, make & year of purchase	Remarks
PI & his group	NA		
PI's department	NA		
Other Inst in the region	NA		

46. Detailed Bio-data of the Investigator

NameDr Anil Shetty

DOB 19-05-1974

Designation Associate Professor, Department of Paediatrics, Fr Muller Medical College, Mangalore

Institution address Fr Muller's road Kankanady. Mangalore- 575002

Teaching Experience 10 years

Qualification MD Paediatrics

Undergraduate qualification MBBS, from Kasturba Medical College, Mangalore.(1999) University – Manipal University, Manipal.

Post Graduate qualification MD from Fr Muller Medical College, Mangalore (2003) University- Rajiv Gandhi University of Health Sciences, Bangalore.

Postgraduate Thesis 'Congenital anomalies in Olighydramnios and Polyhydramnios', was awarded the best thesis in Fr Muller Medical College 2003.

Academic accomplishments- Post Graduate Thesis guide since 2010, Have guided 2 MD postgraduate thesis's so far.

Undergraduate MBBS Examiner since 2009, been internal examiner toFr Muller Medical College, KVG Medical College Sullia, K S Hegde Medical College Mangalore (all Rajiv Gandhi University of Health Sciences) and External Examiner at Kasturba Medical College Mangalore (Manipal University)

Publications

1. Prevention of Renal Diseases in Children Karnataka Paediatric Journal – Vol.19, No. 2 & 3 April – Sept. 2005

2.Anil Shetty, B. SanjeevRai, Habib Khan, K. VaradarajShenoy Role of Antenatal ultrasound in oligohydramnios and polyhydramnios Karnataka Paediatric Journal - Vol. 23, No. 2 April-June 2009, Page 3-5

3.Anil Shetty, B. SanjeevRai, K.V. Shenoy, Merlin Pinto, GeetanjaliDambalkar, DeepaRavindran, T.S. Ananthakrishnan, G.D. JindalAnu-Photo Rheography in NeonatesKarnataka Pediatric Journal – Vol.23, No.3, July-September 2009, Page No.3-5

4.Sanjeev Rai B, K. VaradarajShenoy, Anil Shetty, Sushanth SPitfalls in the diagnosis of urinary tract infection in childrenMuller Journal of Medical Sciences & Research Vol.1, No.1, March 2010, Page No. : 41-44

5.Detection of congenital anomalies in oligohydramnios and polyhydramniosJournal of Perinatology

6.Peter G, Manuel AL, Shetty A. Study comparing the clinical profile of complicated cases of Plasmodium falciparum malaria among adults and children Asian Pacific Journal of Tropical disease 2011 ; 1 : 35 – 37 (indexed) (International)

47. **Details of Research Projects completed/ submitted by the Investigator**

Project TitleAnu Photo Rheography in neonates

Project Status: completed,

period2007 to 2010

funding agency-Board of Research in Nuclear Sciences, Bhaba Atomic Research Centre, Trombay, Mumbai.

total cost 16 lakhs

Summary of the project

The study was done to Validate theAnu Photo Rheograph in neonates atFrMuller Medical College, Mangalore in Collaboration withBARC, Mumbai. In our study the bloodflow assessment, oxygen saturation andphysiological variability of heart rate weredone in 250 newborns and the data wascompiled. The graphs for Blood flowassessment, blood flow variability and heartrate variability were

obtained. Theseparameters are used to plot thenormoograms for Term, pre term neonates.This normogram can be used as standardsfor evaluation of sick neonates.

Major Results/ Highlights of the project including achievement (publications,

patents etc.), for completed projects

Anil Shetty, B. SanjeevRai, K.V. Shenoy, Merlin Pinto, GeetanjaliDambalkar, DeepaRavindran, T.S. Ananthakrishnan, G.D. Jindal Anu-Photo Rheography in Neonates Karnataka Pediatric Journal – Vol.23, No.3, July-September 2009, Page No.3-5

48. Any other relevant matter.

None

Fw: IMPRINT Preliminary Proposal Evaluation - Phase I

shashidhar koolagudi

Tue 6/7, 2016 11:17 AM

Anil Shetty <anilshettyk@hotmail.com>, Vikas <vikasm@gmail.com>;

Dear All,
The proposal we had submitted to IMPRINT is through in the first round.
Let us hope for the final approval. This is for your information
With regards

Shashidhar G.Koolagudi
Assistant Professor, CSE
National Institute of Technology Karnataka, Surathkal
Sreenivasanagar, Mangalore-575 025
Karnataka, India
Ph.: 91-824-2473413

On Tuesday, 7 June 2016 3:54 PM, no-reply <no-reply@imprint-india.org> wrote:

Dear Shashidhar G. Koolagudi,

We thank you for submission of your 5-page preliminary proposal number 6822 titled 'Infant cry analysis for identifying the early symptoms of dyslexia and autism in children' for financial support under the MHRD sponsored initiative IMPRINT.

The Domain Expert Committee for your domain has completed the Phase I of the evaluation process of the proposal and your proposal has been ACCEPTED for further review in Phase II (by domain experts).

The results of Phase II of the evaluation process of the proposals will be announced in a couple of weeks time. If your proposal is selected in Phase II, you will be invited to submit the full proposal in due course for final assessment.

We will send you another mail after Phase II of the evaluation process to inform the status of your proposal.

Thanks again and regards,

Team IMPRINT

Preliminary Proposal MHRD (IMPRINT)

Title (< 25 words): Infant cry analysis for identifying the early symptoms of dyslexia and autism in children

Domain and theme(s) (menu driven)

Abstract (< 100 words)**:** Lot of research has been going on since the late nineteenth century on the utility of cry of neonates/infants for predicting morbidities and disorders. Studies have shown that the cry of an infant can be a window into its brain, especially before it acquires social skills. There are already some well-known syndromes easily identifiable by infant cry, cri-du-chat being a case in point. Studies have shown promises that the conditions like autism, down's syndrome, can also be identified by analyzing an infant's cry. More research especially in the Indian context is required.

Aim and objective (< 50 words): To record the cry of both healthy and suspected/verified unhealthy infants, track their development for 5 years (minimum) and study their vocal excitations during that period to identify any traits that can help provide early medical solutions. The methodology is non-invasive and hence has exciting prospects.

Motivation and genesis (< 150 words): Even though research in this field has started in nineteenth century, very little study has been conducted in India. Local research is important because genetic factors are relevant when it comes to healthcare. Researchers have recorded and spectrally analyzed the cry of an infant in hunger and when experiencing pain. The results of such analysis have shown that the acoustic features of waveforms such as pitch, energy etc. are different in both healthy and unhealthy infants and are easily discernable even by naked eyes, promising that sustained research can yield actionable outcomes. Also earlier studies were usually headed by pediatricians, whereas our study will be led by an engineer there by

providing more technical skills on this front. Since the methodology is non-invasive, hope is that a solution it will be more acceptable and accessible even in rural areas.

Current status and open questions (< 200 words): This is a relatively nascent field with a lot of scope of study and there are no practical tools/procedures which can be used by healthcare professionals to accurately identify any abnormalities or deficiencies based on infant cry spectrograms. Studies have shown that the cry of an infant can be a window into its brain, especially before it acquires social skills and realizes that crying can be a tool to invite attention. Researchers in US are in the process of developing a tool "A Flexible Analysis Tool for the Quantitative Acoustic Assessment of Infant Cry – Brian Reggiannini et al" which should help researchers and health care professionals an easy access to a tool that can analyze infant's cry patterns. Even after such a tool is available, using it as a diagnostic aide is quite far away in the future and is the holy grail that researchers are after.

Plan of work including proposed methodology (< 500 words): The project aims to record the cry of healthy and sick babies. An initial infant cry database will be created with at least a few hundred samples. At the time of data collection other pertinent information like Age of the baby, its gender, whether it's a term or pre-term baby, birth weight of the baby, weight of the baby at the time of recording, whether the baby is suffering from any disease, whether the baby has any siblings, has any of the siblings died, if yes, the cause of death, educational qualification of the parents etc., also would be collected. Once the database is collected we intend to compare the cry of healthy and sick infants on acoustic characteristics for various reasons. Such as:

- to study effect of mother tongue on the cry pattern of neonates
- identifying the difference between cry patterns of healthy and unhealthy babies
- characterizing the cry patterns for specific health issues if possible

- analyzing and generalizing this characterization for different kinds of ailments
- mapping the early cry symptoms with the health issues of grown up children (up to 6 years)
- designing a prediction engine that predicts possible health issues like dyslexia and autism during early infancy
- developing a mechanism that improves the reliability of these predictions.

Method of recording: High precision noise suppression recording devices, which can record a frequency range beyond 20 kHz. (Sony, Ahuja..). Recording is done with the sampling frequency of 16 kHz. using 16 bits' storage per sample.

Analysis :

- A expert would note a possible reason for a cry, while recording cry samples
- Acoustic analysis of these cry patterns are conducted for various spectral and prosodic information
- Acoustically extracted patterns are studied for different children, possibly with the same reason of cry
- A track of a child for its cry pattern and health conditions is kept for a long time (at least up to 6 years) to acoustically map possible health disorders and cry patterns

Outcome :

- identifying cry patterns of children during early days of their birth for dyslexia and autism disorders
- suggesting remedial medication
- counseling of specific parents for parenting the disabled child

Justification and novelty – 'what is new' (< 50 words):

- No solution exists anywhere in the world
- Very little research in the Indian context
- Because of the non-invasive nature, a tool, if developed, can be easily available to the masses
- Research headed by an Engineer specializing in study of speech technology

Milestones and time frame (< 100 words):

Benchmark and specifications of the product (< 100 words):

Deliverables and beneficiary industry/sector (< 50 words): The ultimate aim is to develop a tool that can analyze infant cry and list possibilities for a healthcare professional to carry out further investigations or (maybe) even prescribe medications. Applications will be in the healthcare sector.

Industry, Institution or Agency partners (< 50 words): Hunting for partners from the pharma, medical industry. No partners signed up so far.

Tentative budget with year and item wise breakup (< 100 words):

Rough estimate:

Sl. no.	**Item**	**Quantity**	**Price**	**Total (In Rs.)**
01	Senior research fellow	01	Rs 28,000 per month for 6 years	20,16,000
02	Junior research fellow	02	Rs 25,000 per month for 6 years	36,00,000
03	Equipments High end PCs High end laptops Recording devices Printer	 02 02 03 01	 40,000 70,000 40,000 40,000	 80,000 1,40,000 1,20,000 40,000
04	Database collection	01	For six years	8,00,000
05	Contingency	For six years		9,00,000
06	Travelling	Meetings, Conference, workshop, training For six years		15,00,000
07	Consumables	For six years		4,20,000
08	Training and expert visits	For six years		3,00,000
09	Institutional overhead	For six years		10,00,000
09	**Total**			**1,09,16,000**

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

(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/ 0310-14 Date: 07 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

ACCREDITED BY NAAC WITH 'A' GRADE

(FMMC is a Unit of Father Muller Charitable Institutions)

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

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: 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
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.

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-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.

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

FATHER MULLER MEDICAL COLLEGE HOSPITAL

(Unit of Father Muller Charitable Institutions)

Father Muller Road, Kankanady, Mangalore - 575 002, INDIA

Phone : 0824-2238000
E-mail : mullerhospital@gmail.com
Website: www.fathermuller.com

Fax : 0824 - 2436661
2437402

ESTD 1880

Ref. No : .....

Date : .....

Date : 22.10.2015

To,

The Chairman
Father Muller Institutional Ethics Committee
Father Muller Medical College Hospital
Father Muller Road, Kankanady
Mangalore – 575002, Karnataka, India

Subject : Documents for Ethics Committee submission & approval

Study No : 175-14

Study title : A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, THREE-ARM, PARALLEL GROUP, MULTI-CENTRIC, CLINICAL STUDY TO EVALUATE THE THERAPEUTIC BIO-EQUIVALENCE OF TWO TACROLIMUS 0.1% TOPICAL OINTMENT FORMULATIONS IN ADULT PATIENTS WITH MODERATE TO SEVERE ATOPIC DERMATITIS

Dear Sir,

With reference to the above mentioned study, hereby we are submitting the **Final version-03 Patient Diary Card** in English and it's vernacular with back translations and certificates for submission in upcoming ethics committee review and approval.

Thanking you,

Yours sincerely,

Dr. Ramesh Bhat M

Principal Investigator

I acknowledge the receipt and notification of above study document to Father Muller Institutional Ethics Committee – Fr. Muller Medical College

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

Date : 23/10/2015

Chairman/ Member Secretary – Father Muller Institutional Ethics Committee – Father Muller Medical College

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/2652/2015 *Date :* 15.12.2015

To,

Dr. Ramesh Bhat M

Prof & HOD, Dept of Dermatology

Father Muller Medical College Hospital

Mangalore - 575002, Karnataka, India

Study No : 175-14

Study title : "A randomized, double-blind, placebo-controlled, three-arm, parallel group, multi-centric, clinical study to evaluate the therapeutic bio-equivalence of two tacrolimus 0.1% topical ointment formulations in adult patients with moderate to severe atopic dermatitis"

Subject: Ethics Committee approval of Patient Dairy Card (Version 03) for above mentioned clinical trial.

Dear Sir,

The Father Muller Institutional Ethics Committee, Father Muller Medical College reviewed and approved **patient diary card; version 03 dated 26-Aug-2015 in the meeting held on 14th November 2015 at 3:00pm in the Seminar Hall.**

Yours sincerely,

Member Secretary
Father Muller Institutional Ethics Committee

Secretary
Father Muller Institutional Ethics Committee

FATHER MULLER MEDICAL COLLEGE HOSPITAL

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Website: www.fathermuller.com

Fax : 0824 - 2436661
2437402

ESTD 1880

Ref. No : .....

Date : 1-8-15

To,

The Chairman

Father Muller Institutional Ethics Committee

Father Muller Medical College Hospital

Father Muller Road, Kankanady

Mangalore – 575002, Karnataka, India

Subject : Documents for Ethics Committee submission

Study No : 175-14

Study title : A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, THREE-ARM, PARALLEL GROUP, MULTI-CENTRIC, CLINICAL STUDY TO EVALUATE THE THERAPEUTIC BIO-EQUIVALENCE OF TWO TACROLIMUS 0.1% TOPICAL OINTMENT FORMULATIONS IN ADULT PATIENTS WITH MODERATE TO SEVERE ATOPIC DERMATITIS

Dear Sir,

With reference to the above mentioned study, we are submitting 14 copies of following documents to ethics committee for review and approval.

Sr. No.	Document	Version No. & Date
01	Study Protocol	02 dated 18 Sep 2014
02	Informed consent document in English	01 Dated 06 Oct 2014
03	Informed consent documents in Regional languages 3.1 Informed consent documents in Kannada translated on 17-Jun-15 3.2 Informed consent documents in Malayalam translated on 10-Jun-15	01 Dated 06 Oct 2014
04	Back translations of Informed consent documents 4.1 Back translation of Informed consent documents in English from Kannada on 17-Jun-15 4.2 Back translation of Informed consent documents in English from Malayalam on 17-Jun-15	01 Dated 06 Oct 2014
05	Patient Diary Card in English	02 Dated 18 Sep 2014
06	Patient Diary Card in Regional Languages 6.1 Patient Diary Card in Kannada translated on 15-Jun-15 6.2 Patient Diary Card in Malayalam translated on 15-Jun-15	02 Dated 18 Sep 2014
07	Back translations of Patient Diary Card 7.1 Back translation of Patient Diary Card in English from Kannada on 15-Jun-15 7.2 Back translation of Patient Diary Card in English from Malayalam on 15-Jun-15	02 Dated 18 Sep 2014

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Fax : 0824 - 2436661
2437402

ESTD 1880

Ref. No : .....

Date : .....

Sr. No.	Document	Version No. & Date
10	Back translation of patient Instruction card 10.1 Back translation of patient Instruction card in English from Kannada on 15-Jun-15 10.2 Back translation of patient Instruction card in English from Malayalam on 13-Jun-15	01 Dated 02 Jun 2015
11	Draft e-Case Record Form	00 Dated 19-Jul-14
12	Principal investigators Current Curriculum Vitae	-
13	Investigator Brochure	02 dated 18 Sep 2014
14	Insurance Certificate	----
15	Drugs Controller General (India) [DCG(I)] clearance	Dated 25-June-2015
16	Investigator's agreement with sponsor	-
17	Investigator's undertaking to DCG(I)	-
18	CTRI Reference Number	-

Thanking you,

Yours sincerely,

DR. RAMESH BHAT M.
KMC Reg. No. 26364
Father Muller Medical College Hospital
Mangalore-575002

Dr. Ramesh Bhat M

Principal Investigator

I acknowledge the receipt and notification of above study document to Father Muller Institutional Ethics Committee – Fr. Muller Medical College

Signature .....

Date : 03/08/2015.

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

Chairman/ Member Secretary – Father Muller Institutional Ethics Committee – Father Muller Medical College

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/2413/2015 *Date :* .....09.09.2015.....

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: 175-14
Protocol Title: "A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, THREE-ARM, PARALLEL GROUP, MULTI-CENTRIC, CLINICAL STUDY TO EVALUATE THE THERAPEUTIC BIO-EQUIVALENCE OF TWO TACROLIMUS 0.1% TOPICAL OINTMENT FORMULATIONS IN ADULT PATIENTS WITH MODERATE TO SEVERE ATOPIC DERMATITIS"

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 175-14
entitled "A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, THREE-ARM, PARALLEL GROUP, MULTI-CENTRIC, CLINICAL STUDY TO EVALUATE THE THERAPEUTIC BIO-EQUIVALENCE OF TWO TACROLIMUS 0.1% TOPICAL OINTMENT FORMULATIONS IN ADULT PATIENTS WITH MODERATE TO SEVERE ATOPIC DERMATITIS" on 08.08.2015.

The following documents are:

Sr. No.	Document	Version No. & Date
01	Study Protocol	02 dated 18 Sep 2014
02	Informed consent document in English	01 Dated 06 Oct 2014
03	Informed consent documents in Regional languages 3.1 Informed consent documents in Kannada translated on 17-Jun-15 3.2 Informed consent documents in Malayalam translated on 10-Jun-15	01 Dated 06 Oct 2014
04	Back translations of Informed consent documents 4.1 Back translation of Informed consent documents in English from Kannada on 17-Jun-15 4.2 Back translation of Informed consent documents in English from Malayalam on 17-Jun-15	01 Dated 06 Oct 2014
05	Patient Diary Card in English	02 Dated 18 Sep 2014
06	Patient Diary Card in Regional Languages 6.1 Patient Diary Card in Kannada translated on 15-Jun-15 6.2 Patient Diary Card in Malayalam translated on 15-Jun-15	02 Dated 18 Sep 2014
07	Back translations of Patient Diary Card 7.1 Back translation of Patient Diary Card in English from Kannada on 15-Jun-15 7.2 Back translation of Patient Diary Card in English from Malayalam on 15-Jun-15	02 Dated 18 Sep 2014
08	Patient Instruction card in English	01 Dated 02 Jun 2015
09	Patient Instruction card in Regional Languages 9.1 Patient Instruction Card in English from Kannada Translated on 15-Jun-15 9.2 Patient Instruction Card in English from Malayalam Translated on 13-Jun-15	01 Dated 02 Jun 2015
10	Back translation of patient Instruction card 10.1 Back translation of patient Instruction card in English from Kannada on 15-Jun-15 10.2 Back translation of patient Instruction card in English from Malayalam on 13-Jun-15	01 Dated 02 Jun 2015
11	Draft e-Case Record Form	00 Dated 19-Jul-14
12	Principal investigators Current Curriculum Vitae	-
13	Investigator Brochure	02 dated 18 Sep 2014

Sr. No.	Document	Version No. & Date
14	Insurance Certificate	----
15	Drugs Controller General (India) [DCG(I)] clearance	Dated 25-June-2015
16	Investigator's agreement with sponsor	-
17	Investigator's undertaking to DCG(I)	-
18	CTRI Reference Number	-

The following members of the Ethics Committee were present at the meeting held on **8th August 2015 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.	Rev. Dr. Leo D' Souza	M. Sc, Ph.D	Member(Theologian)	No
6.	Dr. John Mathai	MD	Member (Clinician)	Yes
7.	Dr. Ashok Shenoy	MD	Member (Pharmacologist)	No
8.	Dr. Shivaprasad	MD	Member (Homeopathy)	Yes
9.	Ms. Bindiya Shetty	MSW	Member (Counsellor)	No
10.	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
11.	Dr. Varadaraj Shenoy	MD, DCH	Member (Pediatrician)	Yes
12.	Dr. Jayaram Shetty	BVSc, MVSc	Member (Veterinion)	No
13.	Prof. Irene T.R. Alvares	M. Sc	Member (Nursing)	Yes
14.	Mrs. Rameela Shekar	MSW, M. Phil, (PSW), PGDHRM, Ph.D	Member (Sociology)	No
15.	Mrs. Veena Manoj	MA, B.Ed	Member (Lay person)	No
16.	Mrs. Kavitha Vishal	MPT	Member (Physiotherapist)	Yes

We approve the trial to be conducted in its presented form

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

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

Yours Sincerely,

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

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

CLINICAL STUDY AGREEMENT

This Clinical Agreement ("**Agreement**") is entered into as of 15th Feb 2019 ("**Effective Date**") between **Novartis Healthcare Private Limited, a company registered under the Companies Act, 1956** and having its registered office at 6 & 7 floor , Inspire BKC, G Block, BKC Main Road, Bandra Kurla Complex, Bandra (East), Mumbai – 400051 ("**Novartis**") which expression shall mean and include its successors and assigns of the ONE PART;

AND

Father Muller Medical College Hospital, located at **Mangalore** ("**Institution**") registered under Father Muller Medical College Hospital (A unit of charitable Institutions) Certificate No: H-2015-0313 and having its address at **Father Muller Medical College Hospital, Father Muller Charitable Institutions, Father Muller Road, Kankanady, Mangalore 575002, Karnataka** India which expression shall mean and include its successors and assigns of the SECOND PART;

AND

Dr Ramesh Bhat M. as clinical practitioner in the field of **Professor, Department of Dermatology** acting in the role of principal investigator ("**Principal Investigator**") which expression shall mean and include his/her heirs, executors, administrators and assigns of the THIRD PART;

Novartis and Institution and Principal Investigator are hereinafter individually referred to as the "**Party**" and jointly as the "**Parties**".

RECITALS:

WHEREAS, Novartis is to perform a clinical trial (hereinafter the "Study") to evaluate the following drug: Secukinumab, AIN457M (hereafter the "Study Drug") in accordance with a protocol entitled _**A randomized, double-blind, multicenter study assessing short (16 weeks) and long-term efficacy (up to 1 year), safety, and tolerability of 2 subcutaneous secukinumab dose regimens in adult patients with moderate to severe hidradenitis suppurativa (SUNSHINE), AIN457M2301** and its amendments (hereinafter collectively the "Protocol") attached hereto in Annex 3, and,

WHEREAS, the Institution and the Principal Investigator having each reviewed the Protocol for the Study and sufficient information regarding the Study Drug to evaluate their interest in participating in the Study, wish to conduct in the Study and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Study,

WHEREAS, the Parties wish to set forth certain the terms and conditions under which the Study shall be conducted;

NOW THEREFORE, the Parties, in consideration of the above and the mutual promises set forth below, agree as follows:

1. CONFORMANCE WITH LAW AND ACCEPTED PRACTICE

The Institution and Principal Investigator shall carry out the Study in accordance with:

(a) the Protocol as amended from time to time,

(b) Good Clinical Practice;

(c) the Declaration of Helsinki;

(d) any applicable direction received from a regulatory authority (DCGI) or ethics committee with jurisdiction over the Study;

(e) any "**Applicable Law(s)**" being hereinafter defined as : all regional, federal, state, and local directives, laws, including but not limited to Schedule Y of Drugs and Cosmetics Act 1940, those related to anti-bribery and promotion, rules, regulations, orders, published guidelines, operating procedures applicable to the Study and/or the Parties including but not limited to, legislation applicable to clinical Studies, the Parties, medical treatment and the processing of personal and medical data.

(f) comply with all guidelines provided to it by Novartis from time to time individually but not limited to Novartis global Antibribery Policy and Professional Practices Policy

The Institution warrants that the Principal Investigator and the Institution's employees and collaborators involved in the Study will comply with all Applicable Laws.

2. PROTOCOL

2.1 The Parties agree that the Protocol, including any subsequent amendments and the Annexes form an integral part of this Agreement.

2.2 Institution and Principal Investigator agree to use their best efforts and professional expertise to perform the Study in accordance with the Protocol, all Applicable Laws, the identified timelines and the terms and conditions of this Agreement. Institution and Principal Investigator may not start the clinical trial without prior approval of the appropriate Ethics Committee and Regulatory Authority.

3. APPROVALS

The Study shall not commence until:

(a) all the necessary approvals of the relevant regulatory authority hence been obtained by Novartis and the competent Ethics Committee have been obtained in writing by the Principal Investigator. Such approvals shall be forwarded to Novartis no sooner they are obtained;

(b) the written approval of relevant authority or organisation that owns or is responsible for the administration of the facility in which the Study is to be performed has been obtained, if such authority or organisation is not the Institution.

(c) the Informed Consent Form as defined in Section 6.4 provided by Novartis, has been approved by the Principal Investigator and/or the ethic committee.

4. DURATION OF THE STUDY

The Study shall commence on ***1 Mar 2019*** subject to the requirements of Section 3 have been met prior to this date. The Institution shall use its best efforts to complete the Study and to perform its obligations under this Agreement by ***31 Mar 2023*** or as may be extended by a formal writing between the parties in that behalf

5. TERM OF THIS AGREEMENT

5.1 This Agreement shall be effective upon 01-Mar-2019 ('Effective Date') and shall expire upon 28-Feb-2022 (both days inclusive) unless extended or terminated in terms of this Agreement.

5.2 The following provisions shall survive the termination or expiry of this Agreement: Section 12 (Intellectual Property), Section 14 (Publication) and Section 15 (Confidentiality), as well as any other provisions which by their terms are understood to survive the termination or expiry of this Agreement, including compliance with Applicable Laws.

5.3 In the event that the Principal Investigator decides to no longer conduct the Study both Principal Investigator and the Institution shall provide written notice to Novartis as soon as possible, and at the latest, within 30 days prior to such departure. It is clarified that Principal Investigator shall not be discharged of his/her obligations under this Agreement unless the Novartis and the Institution have been provided sufficient notice in terms of this clause. Upon expiry of the notice period this Agreement shall expire. Novartis shall have the right to approve any new Principal Investigator designated by Institution and parties shall execute a fresh agreement in that behalf

6. PERFORMANCE OF THE STUDY

Principal Investigator and the Institution shall jointly and severally be responsible for the performance of the Study, in particular for the following:

6.1 Principal Investigator may appoint individuals and investigational staff as they may deem appropriate as sub-investigator (the "**Sub-Investigators**") to assist in the conduct of the Study. All Sub-Investigators and investigational staff will be adequately qualified, timely appointed and an updated list will be maintained. Principal Investigator shall alone be responsible for hiring, leading, supervising and reimbursing such team of Sub-Investigators and investigational staff, who, in all respects, shall be bound by the same terms and conditions as the Principal Investigator under this Agreement. The Principal Investigator shall be responsible for the conduct of the clinical investigation in its entirety and the well-being of the study subjects ("**Study Subjects**") and undertake in particular to have it executed by competent resources.

6.2 **Study Site**

The Study shall be conducted at the premises of Institution at the **Dermatology Department, Father Muller Medical College Hospital, Father Muller Road, Kankanady, Mangalore - 575002, Karnataka:** (hereinafter the "**Study Site**").

6.3 **Use of Study Drug:**

Novartis shall provide **Secukinumab** (hereinafter called "**Study Drug**") in sufficient quantity to conduct the Study. For purposes of this Agreement only, the Study Drug shall be supplied to Institution free of charge. In all events, the Study Drug shall remain the sole property of Novartis.

The Principal Investigator shall

(a) at his/her risks, costs and expenses ensure the safe receipt, handling, storage, use and administration of the Study Drug and take all reasonable measures to ensure that it is kept secure;

(b) not permit Study Drug to be used for any purpose other than the conduct of the Study in compliance with the Protocol;

(c) shall not make the Study drug available to any third party other than as specified in the Protocol without Novartis' prior written consent;

(d) shall fully comply with all the responsibilities set out under the law;

(e) keep full and accurate records of who dispenses the Study Drug, the quantity dispensed, and the quantity returned which shall be available for review and /or collection by Novartis and/or designated monitor ("Novartis Monitor") at any scheduled monitoring visit; and

(f) upon any earlier expiration or termination of this Agreement, at Novartis's expense, return any remaining quantities of the Study Drugs to Novartis.

6.4 **Study Subject consent and entry into Study:** Before entering a Study Subject into the Study, the Principal Investigator shall:

(a) Exercise independent medical judgement as to the compatibility of each prospective Study Subject with the requirements of the Protocol;

(b) advise Novartis of all instances in which, in the Principal Investigator's judgement, there is any question as to any prospective Study Subject's suitability for participation in the Study, and abide by Novartis's decision as to whether or not to enroll that Study Subject;

(c) ensure that, before their participation in the Study, the Study Subject, and/or as the case may be, her/his legal representative, are duly informed in language understandable to them, about all aspects of the Study that are relevant to them, including: (i) the purpose, duration, nature, significance, implications, potential benefits and/or risks of the Study; and (ii) the processing, auditing, and monitoring of data (including personal data) under this Agreement;

(d) ensure that, before his /her participation in the Study, each Study Subject and/or as the case may be her/his legal representative has given his or her Informed Consent on the basis of the information described in Clause 6.4. (c) by signing a consent form ("Informed Consent Form" or "ICF") in accordance with the Protocol and without the undue influence or coercion of any person directly involved in the Study, and in accordance with Applicable Laws. An example ICF is attached hereto as Annex 3;

(e) ensure that a copy of the signed Informed Consent Form be provided to the Study Subject, and/or as the case may be, his/her legal representative;

(f) acknowledge that the use of the Informed Consent Form does not release the Principal Investigator from his or her legal, regulatory and contractual obligations relating to Informed Consent, and that it remains the Principal Investigator's responsibility to ensure that those obligations are complied with;

(g) comply with the procedures described in the Protocol in relation to that Study Subject; and,

(h) provide details of the proposed Study Subject to Novartis.

6.5 **Study Subject Recruitment**

Principal Investigator has estimated that he/she can recruit the number of Study Subjects as specified in Annex 1. This target of recruitment can be increased only upon written agreement of Novartis. The Principal Investigator undertakes to comply with these limitations and conditions for further recruitment at the Study Site as required by Novartis.

Novartis will review the Study Subjects recruitment on an on-going basis to ensure that the enrollment continues at an acceptable rate. Novartis is empowered to discontinue the Study at Institution medical facilities in case of no or poor enrollment.

In a multicentre study, Novartis reserves the right, at its sole discretion, to require Institution and Principal Investigator to cease enrollment of Study Subjects prior to enrollment of the targeted number of Study Subjects. Institution and Principal Investigator undertake to cease such enrollment upon request of Novartis and further undertake not to seek any compensation therefor.

6.6 **Recordkeeping, Reporting, Access and Inspections**

(a) **Recordkeeping, Reporting**

The Institution and the Principal Investigator shall perform the following recordkeeping and reporting obligations in a timely fashion:

(i) Preparation and maintenance of complete, accurately written and electronic records, including accounts, notes, reports, Case Reports Forms, records of Study Subject identifications, medical notes, clinical observations, laboratory tests, and the receipt and disposition of the Study Drug and all supportive documentation and data for each Study Subject of this Study (hereinafter "Records").

(ii) Maintain a copy of all documents related to this Study for the longer of a) fifteen (15) years after the Study is completed or discontinued by Novartis) as required by applicable laws and regulations.

(iii) Meet with a representative of Novartis to discuss the progress of the Study; and Notify Novartis immediately upon discovering any significant violations of the Protocol.

(iv) In accordance with the procedure set out in the Protocol : Complete a Case Report Form for each Study Subject; review and sign each of the Case Report Forms to ensure and confirm their accuracy and completeness; promptly submit the Case Report Forms to Novartis following their completion,

(v) Cooperate with Novartis in all their efforts to monitor the Study and to support Novartis in all matters of data collection, verification and discrepancy resolution

(vi) Maintain all documents and other Records generated in the Study in safe keeping for such period as is required by any applicable regulations, and in any event for 15 years following termination of the Study; and obtain Novartis approval prior to disposing of any Record, provided that 'safe disposal' of any Record shall at all times be in compliance with 'Data Privacy and Protection' provisions set out in this Agreement. In the event of the insolvency or bankruptcy of Institution, Institution agrees to promptly transmit all copies of such records to Novartis in accordance with Novartis' written instructions and in line with the transfer and disclosure terms set out in the ICF signed by concerned trial participants, at Novartis' expense.

(vii) Ensure the hospital records of Study Subjects are kept safely in a known and accessible location during the period defined here-above.

(viii) Make all Records available to Novartis or its nominee promptly upon request for monitoring and/or auditing purposes;

(ix) Be responsible for making any necessary applications for registration under the data protection legislation in connection with data obtained under this Agreement, as provided in Article 27.

(b) **Access and Inspection**

It is agreed that the authorized representatives of Novartis, and regulatory authorities to the extent required by law, shall be entitled to:

(i) Examine and inspect the Institution's facilities required for performance of the Study; and

(ii) Inspect and copy all data and work products relating to the Study (including, without limitation, access to records as necessary for study monitoring or to audit the conduct of the Study in accordance with Novartis standards). Sponsor will maintain the confidentiality of any subject-identifiable medical records.

(iii) If any governmental or regulatory authorities notifies Institution or the Principal Investigator that it will inspect Institution's records, facilities, equipment, or procedures, or otherwise take action related to the Study, Institution shall promptly notify Novartis or any designated person within 24 hours, allow Novartis to be present at the inspection/action or participate in any response to the inspection/action, and provide Novartis with copies of any reports or information issued by the authority and Institution's proposed and final response.

(iv) Grant access to Novartis or its representative to visit periodically, as frequently as required for the proper performance and oversight of the Study, the Study Site in order to proceed with any and all monitoring activities required for the Study.

(v) The Institution and the Principal Investigator will use their best efforts to facilitate the performance of any audit and inspection and shall give Novartis and any person designated by them access to all necessary facilities, data and documents.

(vi) The Institution and the Principal Investigator shall take appropriate measures required by Novartis to correct without delay all observations found during the audits or inspections.

(vii) It is expressly agreed between the Parties that Novartis will not compensate the Institution or the Principal Investigator for the audits and inspection.

The rights and obligations under this Article shall remain in effect for fifteen (15) years after the end of the Study.

6.7 **Reporting:** The Principal Investigator shall, either by himself/herself or his/her duly authorized representative, on reasonable notice

(a) Meet with a representative of Novartis to discuss the progress of the Study; and

(b) Make the hospital notes and Case Report Forms for each Study Subject available for source data verification or auditing purposes by representatives of Novartis representatives and the officers of any competent authority.

(c) On discovering any significant violations of the Protocol, the Principal Investigator shall notify Novartis immediately.

6.8 **Reporting of Safety Information:**

The Principal Investigator shall notify Novartis of each Serious Adverse Event encountered in the Clinical Trial within twenty-four (24) hours of becoming aware of it in accordance with the instructions set forth in the Protocol as well as local regulatory requirements. Each such notice shall be given by telefax or e-mail on a Novartis Serious Adverse Event Report form, whether or not notification was initially given by telephone. Section 6.6 shall apply to both the original copy of each Serious Adverse Event Report form and the telefax confirmation sheet or e-mail reflecting its transmission to Novartis.

The Principal Investigator shall also ensure that any person involved in the conduct of the study shall:

(a) Immediately report to Novartis according to the procedure set out in the Protocol, any new safety findings on the Study Drug, including Serious Adverse Event or Serious Adverse Reaction affecting or which could have an impact on the safety of the Study Subject or which could result in a re-assessment of the risk-benefit ratio of the Study Drug. The Principal Investigator shall follow up such immediate reports and provide the additional information in a detailed, written manner to Novartis in accordance with the Protocol and local regulatory requirements;

(b) Report to Novartis all Adverse Events (refer definition of adverse event as per ICH E6 guidelines for Good Clinical Practice and/or as mentioned in the protocol) in accordance with the study Protocol, applicable study procedures for safety data reporting;

(c) Cooperate with and supply any further information required by Novartis and/or any relevant ethics committee or Regulatory Authority with jurisdiction over the Study.-

These reporting obligations shall survive expiration or earlier termination of the Agreement.

Novartis shall further report the adverse events to the competent Regulatory Authorities, in accordance with the current Applicable Laws. Novartis will furthermore provide the Principal Investigator with safety-related information from other investigational sites in order to inform the ethics committees IRB/IEC, as required.

After completion of the Study and evaluation of the results, Novartis will inform the Principal Investigator about relevant safety-related findings in accordance with the guidelines and Study procedures.

6.9 **Items supplied by Novartis**

Novartis shall provide directly or indirectly the Principal Investigator and/or the Institution with all necessary information, documents and materials, including but not limited to:

(a) the Investigator Brochure (IB)

(b) the Protocol,

(c) the CRF/e-CRF

(d) he Study Drug

(e) the study related equipments on returnable basis listed in Annexure 1

6.10 The Principal Investigator, or coordinating investigator for multicentre studies, shall sign the clinical Study reports, which form part of the marketing authorization submission.

7. LIABILITY-INDEMNIFICATION

7.1 In the case of any injury occurring to a clinical trial subject or in the event of clinical trial related death of the subject, Novartis assumes responsibility to the extent and in the manner under the applicable laws

7.2 The Institution and Principal Investigator ("**Indemnifying Party**") will indemnify and hold harmless Novartis from and against any and all liabilities, claims, damages, losses, settlements, penalties, fines, costs and expenses, including attorneys' fees, (collectively, "**Damages**") of whatever kind or nature (but not including taxes) arising from any third party demand, investigation, claim, action or suit in the based on (i) the gross negligence, bad faith or willful or intentional misconduct of the Indemnifying Party (ii) a material breach by the Indemnifying Party of any term of this Agreement, or (iii) a violation of any relevant law, rule or regulation by the Indemnifying Party in the performance of its duties under this Agreement.

8. INSURANCE

The Institution warrants that it has appropriate and adequate professional indemnity insurance to cover claims or damages including those arising out of negligence of the Principal Investigator for which it shall be liable under this Agreement. The Institution shall provide evidence of its insurance upon request by Novartis.

Novartis warrants that it has insurance for the Study Subjects included in the Study in place at Study start.

9. COMPENSATION

9.1 In consideration for the satisfactory performance of the Study according to this Agreement and the Protocol, The Principal Investigator agrees to Payment Schedule attached hereto as Annex 1.

9.2 Novartis reserves the right to terminate the Agreement immediately if no subjects have been recruited at the Study Site by 29 Jan 2021.

9.3 Subjects not completing the Study will be paid for on a prorated basis according to the number of completed visits. All payment will be made for subject visits according to the above Payment Schedule attached as Annex 1. No payment will be made for any Study Subject excluded from analysis because of Protocol violations that were within the Institution or Principal Investigator's control. Reimbursement for expenses related to screening failures, patient travel, and local lab test will be made according to the Payment Schedule in Annex 1.

9.4 The Principal Investigator shall send the invoices to:

Novartis Healthcare Private Limited
GDO Trial Monitoring, India
Nisha Mahajan/ Isha Khopkar
6 & 7 floor , Inspire BKC
G Block, BKC Main Road
Bandra Kurla Complex
Bandra (East), Mumbai – 400051
Maharashtra, India

9.5 Each invoice shall specify the Study Code. Novartis shall make payments into the account indicated by the Institution and Principal Investigator within 60 (sixty) days of receipt of an invoice from the Institution.

10. EQUIPMENT

10.1 If necessary and based upon Novartis' assessment of Institution existing equipment, Novartis may provide equipment (the "**Equipment**") to the Institution and/or Investigator strictly on a returnable basis as detailed in Annex 1 The Equipment shall remain the sole and exclusive property of Novartis. It shall be used exclusively by the Institution and/or the Investigator: The Equipment shall only be used for the conduct of the Study in accordance with the Protocol, Novartis instructions and until the Study is completed or discontinued.

10.2 If Novartis, or its designee, provides the Institution and/or Investigator with Equipment for the purpose of this Study, the Institution and Investigator agree that the Equipment shall remain in the same condition during the Study, with the exception of ordinary depreciation.

10.3 During the term of the Study, Institution and/or Investigator shall be responsible for immediately notifying Novartis of any malfunctioning Equipment.

10.4 Following completion of the Study or upon discontinuation of the Study for any reason, the Institution and/or Investigator, as the case may be, shall return the Equipment to Novartis or alternatively, in the event the Equipment remains with the Institution and/or Investigator, the cost of such Equipment will be deducted from the last payment(s) to be made to either the Institution or Investigator, as the case may be.

11. TERMINATION

11.1 Either party may terminate this Agreement for any safety and/or efficacy concerns or other ethical grounds by giving written notice to the other party with immediate effect. In case of early termination the ***Father Muller Medical College Hospital/Dr Ramesh Bhat*** shall notify the relevant Ethics Committee of the early termination, and Novartis shall notify the regulatory authorities and any other competent authorities as relevant and appropriate within specified timelines

11.2 Novartis may terminate this Agreement for convenience by giving written notice to the Institution with immediate effect.

11.3 If Novartis terminates this Agreement, Novartis shall have no obligations under this Agreement except to reimburse the Institution for such reasonable costs and non-cancellable obligations

which has been approved by Novartis incurred in the performance of the Study prior to receiving notice of termination.

11.4 The termination or expiry of this Agreement shall not affect the rights and obligations of the parties which accrue prior to the date of termination. In particular, the Institution/Principal Investigator shall provide all outstanding Case Report Forms to Novartis and return to Novartis all documents and Equipment provided by Novartis under this Agreement.

12. INTELLECTUAL PROPERTY

12.1 All data, information and documents provided to the Institution by or on behalf of Novartis, whether in paper, oral, electronic or other form, shall remain the sole property of Novartis.

12.2 All data, information, documents, inventions and discoveries, resulting from or developed in the performance of the Study or this Agreement shall be the sole property of Novartis and may be used and/or transferred by Novartis in its sole discretion with no further payment or other obligation to the Institution. The Institution shall have no rights whatsoever therein.

12.3 The Institution agrees to, and to cause its employees and collaborators and the Principal Investigator to, execute promptly all documents and take all such other action as may reasonably be requested by Novartis to enable Novartis to obtain the benefit of its rights under this Agreement. This includes without limitation taking all necessary steps for the transfer of ownership of all data, information, documents, inventions and discoveries to Novartis in accordance with this Agreement, and assisting Novartis in the preparation and prosecution of patent applications. Furthermore, Institution and Investigator shall execute, or procure the execution of, and enforce all documents and deeds and do, or procure the doing of, all things as Novartis including but not limited to assignment of any and all rights, title and interest in resulting intellectual property in Novartis.

12.4 The Institution shall ensure that the Principal Investigator and the Institution's employees and collaborators involved in the Study will comply with its obligations under this Agreement.

13. TAXES AND SOCIAL SECURITY CONTRIBUTIONS

It shall be the Institution's responsibility to comply with all obligations in respect of taxes and social security contributions, if applicable, which relate to the subject matter of this Agreement, including without limitation those which relate to the Principal Investigator, the Institution and its employees and/or collaborators.

14. PUBLICATION

14.1 Novartis recognizes the Institution's interest in making publications and presentations relating to the Study in journals, at meetings or otherwise, and may therefore permit such publications and presentations, provided however that the Institution shall provide to Novartis any proposed presentation at least 15 (fifteen) working days prior to being disclosed and any other proposed publication at least 45 (forty-five) working days prior to being disclosed, and provided that Novartis shall have the right to require amendments to any such proposed presentation or publication on reasonable grounds including without limitation:

(a) to ensure the accuracy of the presentation or publication;

(b) to ensure that proprietary information is not inadvertently divulged;

(c) to enable intellectual property rights to be secured;

(d) to enable relevant supplementary information to be provided.

14.2 Authorship of any publications relating to the Study shall be determined by mutual agreement.

14.3 Novartis may require any proposed publication or presentation to be delayed for up to 4 (four) months to enable a patent application to be prepared and filed. The 4 (four) month period shall commence on the date of receipt of the proposed publication or presentation, or from the date when all relevant data from the Study are made available to Novartis, whichever is later.

14.4 If the Study is a multi-centre study, the first publication of data shall be based on consolidated data from all centres analysed according to the Protocol, unless otherwise agreed in writing by all the Principal Investigators involved in the Study and Novartis.

14.5 Except as otherwise required by law or regulation, neither Party shall release or distribute any materials or information containing the name of the other Party or any of its officers, agents or

employees without the prior written consent by an authorised representative of the non-releasing Party.

15. CONFIDENTIALITY

15.1 All information and data, trade secrets, privileged records and other confidential or proprietary information (including but not limited to the Protocol, CRFs and information on password-protected Novartis websites) disclosed to or collected or developed by the Institution, the Principal Investigator and/or the Institution's employees and/or collaborators in connection with this Agreement or the Study (collectively "**Information**") shall be treated as confidential. The Institution and/or the Principal Investigator agree not to disclose to any third parties or to use any Information for any purpose other than the performance of the Study. The Institution and/or the Principal Investigator shall ensure that the Institution's employees and collaborators are bound by confidentiality obligations not less strict than those set out herein prior to receiving any Information.

15.2 Upon termination or expiry of this Agreement, the Institution and / or Principal Investigator shall safely destroy (as set in the Data Privacy and Protection annexure to this Agreement) or return to Novartis, as per Novartis' request, all documents, samples and material containing or relating to Information, except for one copy of Information which is to be retained in the confidential files of the Institution for record purposes only. If requested by Novartis, such safe destruction shall be promptly confirmed in writing by the Institution to Novartis.

15.3 The confidentiality obligations set out above shall not apply to:

(a) Information which is, at the time of disclosure, in the public domain or thereafter becomes part of the public domain otherwise than by the act or omission of the Institution, the Principal Investigator, or the Institution's employees and/or collaborators;

(b) Information that the Institution can demonstrate by written evidence was in its possession prior to its disclosure by Novartis or that said information, its collection or creation did not occur during or in connection with the Study;

(c) Information which the Institution received from any third party not engaged in the activities which are the subject of this Agreement, where such information is not subject to an obligation of confidentiality in favour of Novartis or any of its affiliates.

16. NOTICES

Any notice given in connection with this Agreement shall, unless otherwise provided herein, be in writing and shall be delivered personally, or sent by registered mail or facsimile to the address given in this Agreement

Mr Murugananthan, K
GDO Trial Monitoring, India
Novartis Healthcare Private Limited
6 & 7 floor , Inspire BKC
G Block, BKC Main Road
Bandra Kurla Complex
Bandra (East), Mumbai - 400051
Maharashtra, India
Telephone: 02250243544
Fax: 022- 50243005

or to such other address as may have notified to the other party in writing.

17. ASSIGNMENT

Neither Party may assign its rights and obligations under this Agreement without the other Party's prior written consent, except that Novartis may (a) assign its rights and obligations under this Agreement or any part hereof to one or more of its Affiliates; or (b) assign this Agreement in its entirety to a successor to all or substantially all of its business or assets to which this Agreement relates. Any permitted assignee will assume all obligations of its assignor under this Agreement (or related to the assigned portion in case of a partial assignment). Any attempted assignment in contravention of the foregoing will be void. Subject to the terms of this Agreement, this Agreement will be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

18. SUBCONTRACTING

The Institution and /or Principal Investigator shall not retain any subcontractor to perform any of its obligations under this Agreement without the prior written consent of Novartis. Any such consent shall not relieve the Institution and/or Principal Investigator of its obligations hereunder.

19. SEVERABILITY

The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision hereof.

20. WAIVER

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

21. ENTIRE AGREEMENT

This Agreement (including the Protocol) represents the entire understanding between the parties with respect to the subject matter hereof. No amendment to this Agreement will be effective or binding unless it is in writing signed by both parties and refers to this Agreement.

22. DEBARMENT

Neither the Principal Investigator nor the Institution, nor any person employed thereby nor any collaborator who is involved in the performance of the Study has been debarred under the law including but not limited to provisions of the Indian Medical Council Act, 1956 as amended, Drug and Cosmetics Act, 1940 and no debarred person will in the future be employed or engaged by the Institution in connection with any work to be performed for or on behalf of Novartis. If at any time after the execution of this Agreement, the Institution becomes aware that the Principal Investigator or the Institution or any person employed or engaged thereby is debarred, or is in the process of being debarred, the Institution hereby certifies that the Institution will so notify Novartis at once.

23. CONFLICT OF INTEREST, FINANCIAL DISCLOSURE

The Institution and the Principal Investigator confirm that there is no conflict of interests between the Parties that would inhibit or affect their performance of the work specified in this Agreement. The Institution and the Principal Investigator further certify that they will promptly inform Novartis in the event any conflict of interests arises during the performance of this Agreement and certify that their performance hereunder does not violate any other agreement they may have with any other third party.

24. TRANSPARENCY/DISCLOSURE

24.1 In all materials relating to Services intended for an external audience, Principal Investigator shall disclose:

(a) that Novartis has retained Principal Investigator for professional services in relation to the conduct of the Study; and

(b) any other relationships that Novartis has with Principal Investigator which a reasonable and ethical person would expect to be disclosed.

24.2 Both parties agree to make all other disclosures and/or notifications as may be required in connection with entering into, performing, or receiving compensation under this Agreement, and Principal Investigator shall follow all Applicable Laws in this respect, including those relating to Principal Investigator's professional relationships with decision-making authorities or bodies (if any), such as, for instance, recusal from any votes, discussions or recommendations regarding investigational or marketed products of Novartis, regardless of whether such are subject to the Services.

24.3 The Institution and Principal Investigator understand and agree that Novartis may be required to disclose certain information to governmental agencies in different jurisdictions in order to comply with local laws regulating clinical trials. The Institution and Principal Investigator consent to the disclosure of certain information that otherwise may constitute personal data in order to comply with laws regulating clinical trials, including but not limited to the Institution's and/or Principal Investigator's name, clinical trial Study Site contact information, name of the clinical trial, sponsor,

copy of the Agreement, and costs and fees relating to Study Site's activities performed under the Agreement. Novartis will provide upon written request a list of any such disclosure made regarding the Institution and/or the Principal Investigator.

25. JURISDICTION AND APPLICABLE LAW

This Agreement shall be governed by and construed in accordance with the laws of India. The parties hereby submit to the exclusive jurisdiction of the competent courts of Mumbai, India without restricting any right of appeal.

26. DATA PROTECTION

A form regarding the disclosure of the Principal Investigator's personal data **together with the general provisions** regarding any personal information processed by the Institution under this Agreement is attached as Annex 2.

27. COUNTERPARTS

This Agreement may be executed in two or more counterparts each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

28. PRECEDENCE

To the extent that there may be any inconsistency between this Agreement and the Protocol, the Protocol shall take precedence in ONLY in relation with trial procedures while in all other instances the agreement shall prevail.

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

NOVARTIS HEALTHCARE PRIVATE LIMITED

By: _____

Name: Sachin Patil

Title: Clinical Study Manager

Date: 15th/Feb/2019

[Father Muller Medical College Hospital]

By: _____

Name: Rev. Fr Richard Aloysius Coelho

Title: Director, Father Muller Charitable Institutions

Date: 04 Feb 2019

Mar

[Principal Investigator]

By: _____

Name: Dr Ramesh Bhat M

Title: Principle Investigator

Date: 04/Feb/2019

Mar

FATHER MULLER CHARITABLE INSTITUTIONS
KANKANADY
MANGALORE
575 002

ANNEX 1: PAYMENT SCHEDULE

STUDY NUMBER: AIN457M2301

STUDY NAME: **A randomized, double-blind, multicenter study assessing short (16 weeks) and long-term efficacy (up to 1 year), safety, and tolerability of 2 subcutaneous secukinumab dose regimens in adult patients with moderate to severe hidradenitis suppurativa (SUNSHINE)**

Investigator's Name: Dr Ramesh Bhat M

Institute Name: Father Muller Medical College Hospital

Payee Name: Father Muller Research Centre

Pan Card Number: AAATF0345D

GSTIN: 29AAATF0345D1Z4

Committed Number of Study Subjects: 3

List of Equipments provided to Institution / Principal Investigator:

- ePRO Tablets
- Refrigerator for storage of study medications
- Thermohygrometer

Payment Schedule:

	Screening		***Treatment Period 1***							
Visit number	***Scr 1***	***Scr 2***	***baseline***	***wk 1***	***wk 2***	***wk 3***	***wk 4***	***wk 8***	***wk 12***	***wk 16/EOT1***
Day	(-28 to -14)	(-13 to -1)	1	8	15	22	29	57	85	113
Hospital Expenditures	*1500*	*1500*	*1500*	*1500*	*1500*	*1500*	*1500*	*1500*	*1500*	*1500*
Protocol Assessment Fess for PI	*10000*	*7500*	*10500*	*5500*	*6500*	*5500*	*6500*	*5500*	*5500*	*8500*
Co-I Fees	*1000*	*1000*	*1000*	*1000*	*1000*	*1000*	*1000*	*1000*	*1000*	*1000*
Institutional Overhead (20%)	*2500*	*2000*	*2600*	*1600*	*1800*	*1600*	*1800*	*1600*	*1600*	*2200*
TOTAL	***15000***	***12000***	***15600***	***9600***	***10800***	***9600***	***10800***	***9600***	***9600***	***13200***

Visit number	wk 17	wk 18	wk 19	wk 20	wk 24	wk 28	wk 32	wk 36	wk 40	wk 44	wk 48	wk 52/EOT2	wk 60/F8	Total
Day	120	127	134	141	169	197	225	253	281	309	337	365	421	
Hospital Expenditures	*1500*	*1500*	*1500*	*1500*	*1500*	*1500*	*1500*	*1500*	*1500*	*1500*	*1500*	*1500*	*1500*	34500
Protocol Assessment Fess for PI	*5500*	*5500*	*5500*	*5500*	*5500*	6500	6500	5500	5000	5500	5000	7500	7500	148000
Co-I Fees	*1000*	*1000*	*1000*	*1000*	*1000*	*1000*	*1000*	*1000*	*1000*	*1000*	*1000*	*1000*	*1000*	*23000*
Institutional overhead (20%)	*1600*	*1600*	*1600*	*1600*	*1600*	*1800*	*1800*	*1600*	*1500*	*1600*	*1500*	*2000*	*1500*	*40600*
TOTAL	**9600**	**9600**	**9600**	**9600**	**9600**	**10800**	**10800**	**9600**	**9000**	**9600**	**9000**	**12000**	**11500**	**246100**

Payment Terms:

- The amount of payment due to the Institution/Investigator will be calculated in respect of each patient visit according to the attached budget schedule.
- The budget includes Investigator, Sub investigator fee and protocol procedure charges which include all assessments to be performed at individual patient visit including study drug administration, vitals & all other assessments as per protocol visit assessment schedule
- Screen failure cost is inclusive of the above budget, and no separate screen failure cost will be provided by sponsor.
- Any other third parties designated by the Institution/Investigator that would receive remuneration, will be managed by & paid by the Institution/Investigator.
- Sponsor shall reimburse patient's travel cost per protocol visit as per actuals for which institution/PI shall provide original invoice along with the supporting bills.
- Ethics Committee fees will be paid as per actuals and subject to TDS deduction
- All payments are based on actual patient visits.
- All values are in INR. All budget schedule payments are subject to TDS (subject to Government of India, Tax regulations) and GST as applicable. GST will be paid on providing valid tax invoice with relevant details mentioning GST registration number on it.
- Rescue medication & antiseptic cost shall be reimbursed separately.

ANNEX 2: PRINCIPAL INVESTIGATOR – PERSONAL DATA DISCLOSURE FORM

Novartis wants to ask your permission to include certain elements of your personal data in a database maintained by a third party. The Grant Plan database, which is maintained and provided to pharmaceutical research sponsors by a company called TTC in the United States, is intended to assist research sponsors with transparency relating to clinical trial expenses. The database is used to support country specific forecasts for clinical trial costs and to provide benchmarking information in order to achieve transparency and fairness in setting costs for performing clinical trials.

The information is entered into the database in such a way that it is not possible for anybody except the personnel of TTC to view your name or link your site to a particular clinical trial or sponsor company.

In that regard, Novartis is asking for your permission to submit your name, clinical trial site contact information, name of the clinical trial, sponsor, copy of the clinical trial agreement, and costs and fees relating to your site's retention, to a third party administrator of this database. This information will be maintained in that database for five years. If you are conducting research for Novartis in countries other than the United States, such as those in Europe, you should note that the United States does not offer the same standards of privacy protection as those offered in Europe. You are not required to give consent to this disclosure in order to proceed with this clinical study. However, by doing so, you are helping to collect information on fair costs in clinical trials.

- ☐ Yes, I hereby agree that Novartis may disclose my personal data in connection with the Grant Plan database.
- ☐ No, I do not give my permission to disclose my personal data in connection with the Grant Plan database.

Place and Date: 04/Mar/2019
Mangalore.

Name: Dr Ramesh Bhat

Principal Investigator

Data Privacy and Protection

Provisions regarding any Personal Information Processed by Institution under this Agreement:

Defined Terms. For the purposes of this Section, the following terms shall have the meanings given below:

"**Personal Information or Data**" means any information that relates to an identified or identifiable person including without limitation electronic data and paper based files that include such information such as: (a) name or initials; (b) home or other physical address; (c) work, cell or home telephone number; (d) work or home email address or online identifier associated with the individual; (e) identification code; (f) credit card number; and (e) employment information, that is Processed directly or indirectly, by Institution on behalf of Novartis in connection with this Agreement.

"**Sensitive Personal Information or Data**" – constitutes a subset of Personal Information and relates to of an individual's (a) physical, physiological or mental characteristics, (b) economic status, (c) racial or ethnic origin, (d) political, ideological, religious opinions or philosophical beliefs, (e) trade union membership, (f) health or medical information including information related to payment for health services, (g) sex life or sexual preference, (h) genetic material or information, (i) human biological samples or cells, (j) unique biometric data, (k) Personality Profiles or (ii) an individual's name in combination with the individual's (a) Social Security number, (b) alien registration number, (c) driver's license number, (d) passport number, visa number or other government identifier, (e) credit card, debit card, or other financial account numbers, with or without any associated code or password that would permit access to such account, or (f) mother's maiden name; and as applicable under local laws.

"**Data Subject**" – and identified or identifiable person who's Agreement Personal Data are processed, accessed, received, transmitted, or maintained by the Supplier. An identifiable perosn is one sho can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological ,mental, economic, cultural or social identity.

"**Processing**" means any operation or set of operations which is performed upon personal information, whether or not by automatic means, such as collection, recording, organisation, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction or any other operation or set of operations otherwise defined in applicable Data Privacy Laws. This also includes the processing of personal information in structured manual files.

"**Institution Third Parties**" – any third party that assists Institution in performing its obligations under the Agreement, including an affiliate or direct or indirect subcontractor of Supplier.

General Obligations of Institution:

a. Compliance with Applicable Laws and Permitting Processing. Institution will, and will cause all Institution Third Parties to, hold Personal Information in confidence, use Process such data only for the benefit of Novartis and its Affiliates and Process such information in compliance with (i) all Applicable Data Protection Laws, (ii) the Agreement, (iii) any consent, authorization of a Data Subject or other authorized participant, such as subject's legal representative, (iv) industry standards, and (v) this Data Privacy and Protection Exhibit; provided, however, that Institution (or Institution's Third Party) may Process Personal Information only under the written instructions of an authorized signatory of Novartis.

To the extent that the Agreement involves the processing of personal information owned by or licensed to Institution prior to or separately from the Services, Institution represents and warrants that such data has been obtained in compliance with applicable laws and regulations, including Applicable Data Protection Laws and all necessary consents and authorizations, including those of any patient, if applicable. Institution further represents and warrants that Institution and/or Novartis is authorized to use such data as contemplated by this Agreement.

b. Obligations with respect to the Data Subjects participating in trials:
Institution shall take reasonable steps to ensure that each individual whose Personal Information were, or are, in its possession is able to assert his or her rights under local law, including but not limited to right of access to view and correct his or her Personal Data, right to withdraw consent and file complaint or grievance if any, with the Institution.

c. Obligations with Respect to Institution's Third Parties.

Within seven (7) business days of Novartis' written request, Institution will produce clear and accurate information stating who is holding and processing Agreement Personal Data, and in what country they

are located. In all such arrangements, Supplier will enter into agreements with Supplier Third Party(ies) that are substantially similar to this Data Privacy Exhibit. Supplier shall provide copies of such agreements to Novartis within seven (7) business days following a written request from Novartis therefor.

Data Safeguards. The parties agree to comply with the following:

(a) Without limitation of any provision of this Agreement, the parties agree to comply with all applicable Laws governing the privacy and security of Personal Information that Institution shall create, acquire, access or receive as a result of this Agreement, to the extent that such Laws apply to either party.

(b) Institution agrees to implement administrative, technical and physical security measures to protect Personal Information, from (i) unauthorised or accidental destruction, (ii) theft, forgery or loss, (iii) technical faults, (iv) forgery, theft or unlawful use (v) unauthorised alteration, copying access; or (vi) any other unauthorised processing.

(c) Security measures implemented by Institution must take into account (i) the purpose of the data processing, (ii) nature and extent of the processing, (iii) assessment of possible risks to the data subject; and (iv)current industry best practices and state of the art technologies, including but not limited to encryption of information at rest and in transit. Security measures shall be reviewed on a periodic basis and updated as required.

(d) All email communication with Novartis, especially those involving trial related information should happen via secure 'Institutional email Ids'. Exceptions (i.e. use of non-institutional email Ids), if any must be discussed with Novartis and a secure communication solution, as mutually agreed and in line with Novartis' security standards, is implemented.

(e) Institution shall not sub-contract any of its rights or obligations without the prior written notification to Novartis. In the event that any Institution Subcontractor shall have access to Personal Information, such access shall be permitted under a need-to-know basis and only to the extent required for the due performance of Institution's obligations. Institution shall enter into Agreements with its' subcontractors that contain privacy and security provisions that are equivalent to the provisions under this Agreement.

(f) Institution shall ensure that personnel who will be undertaking the Processing of Novartis Personal Information, including that by Institution's Third Party (if any) have appropriate skills and privacy and security training to handle Sensitive Personal Information.

(g) If Institution disposes of any paper, electronic or other record containing Agreement Personal Data, Supplier shall do so by taking all reasonable steps to destroy the information by (a) shredding; (b) permanently erasing and deleting; (c) degaussing; or (d) otherwise modifying the Agreement Personal Data in such records to make it unreadable, un-reconstructable and indecipherable.

(h) Institution shall maintain procedures to detect and respond to a Data Security Breach. Institution shall notify Novartis of any Data Security Breach within 24 hours of discovery of a data security breach. Institution shall promptly make available to Novartis details of the Data Security Breach and shall use commercially reasonable efforts to investigate and prevent the recurrence of such Data Security Breach. The parties shall reasonably cooperate to remediate a Data Security Breach and prevent any recurrence. Novartis, at its sole discretion, after consultation with Institution, shall determine whether and when to notify any individuals or persons (including Governmental Authorities) regarding any Data Security Breach affecting Novartis Personal Information. Institution, as determined in its sole discretion, shall comply with all applicable Laws to which it is subject with regard to the Data Security Breach.

ANNEX 3: NOVARTIS POLICIES & STUDY DOCUMENTS

I / We, the undersigned Institution and Principal Investigator for study number AIN457M2301 declare that I have received a copy of;

(a) Novartis global Antibribery Policy

(b) Professional Practices Policy

I / We, have read the policy (ies) understood its meaning and shall comply with the same.

[NAME OF INSTITUTION] _____	[PRINCIPAL INVESTIGATOR] _____
By: _____	By: _____
Name: REV. FR RICHARD ALOYSIUS COELHO	Name: DR. RAMESH BHAT M.
Title: DIRECTOR	Title: PI
Date: 04/Mar/2019	Date: 04/Mar/2019.

FATHER MULLER CHARITABLE INSTITUTIONS
KANKANADY
MANGALORE
575 002

NOVARTIS

Anti-Bribery Third Party Guideline

Novartis Global Guideline for engaging Third Parties

Effective: May 1, 2017

Version GIC 100.18.V3.EN

Group I&C

Contents

Glossary

Associate – Directors, officers, managers, and employees of Novartis AG and its affiliates.

Business Owner - The person from the business unit who requests or sponsors the engagement of a Third Party and who is responsible for the business impact of such engagement.

Compliance Confirmation – A Compliance Confirmation is an attestation requested from the Third Party to confirm their compliance with the law and to confirm the validity of the information collected as part of the due diligence. A template for the Compliance Confirmation is attached to Annex 5 of this Guideline.

Due Diligence Checklist – The Due Diligence Checklist is a document that is designed to help the Due Diligence Coordinator to conduct and document the efforts related to the due diligence. This checklist (issued by Group I&C) is not an exhaustive list but ensures that the main sources of information will be collected.

Due Diligence Coordinator – The person who receives the request to perform the risk-based Due Diligence on the prospective Third Party.

Executive Summary – The Executive Summary is a document that captures and summarizes the information collected during the due diligence process, the identified Red Flags, the proposed measures to address the risks identified with the proposed Third Party engagement, and the decision whether or not to engage the prospective Third Party.

Guideline – The term Guideline refers to this Anti-Bribery Third Party Guideline.

Material Change to the Structure of the Third Party – A material change to the structure of a Third Party covers the following two situations:

(a) **Change in ownership/control:** the Third Party or any person who Controls the Third Party has a change of Control. "Control" in this context means the direct or indirect ownership of more than 50% of the equity interest or voting rights in a corporation or business entity, or the ability in fact to control the management decisions of such corporation or business entity (e.g., by the appointment of a majority of the directors or management or otherwise); or

(b) **Change to membership of the executive body of the Third Party:** there is a change to the membership of the executive body of the Third Party. For example, a change to the **executive** management of the Third Party (e.g., CEO, N-1 to CEO).

Questionnaire for Third Parties – The Questionnaire is designed to assist the Due Diligence Coordinator to gather information from the Third Party amongst others about their business, their ownership and structure, government relations, compliance with laws and commercial references.

Red Flag – A Red Flag is information that indicates an increased risk of corruption or another potential issue with a Third Party, such as any undesirable characteristic that pertain to a company's ownership, business structure or relationships and/or compliance with laws.

Third Party – The term Third Party is defined in Section 2.8 of the Anti-Bribery Policy as any natural person or legal entity with whom Novartis interacts and who poses, due to the nature of their business, a particular level of bribery risk. Section 1.4 of this Guideline sets out the specific types of services that pose a bribery risk.

List of Acronyms

DDC – Due Diligence Coordinator

Group I&C – Group Integrity & Compliance

LCO – Local Compliance Officer

PEP – Politically Exposed Person

RCO – Regional Compliance Officer

1 Introduction

1.1 Purpose

Our continued commitment to ethical business conduct is central to earning and maintaining the trust and support of our key stakeholder groups and realizing our aspiration to be a trusted leader in changing the practice of medicine.

To achieve this aspiration, it is essential that Novartis only engages Third Parties that are suitable from an anti-bribery perspective. We expect Third Parties with whom we work to comply with bribery and corruption laws and to observe our requirements concerning anti-bribery.

This Guideline elaborates on section 2.8 of the Novartis Anti-Bribery Policy, and gives Associates instructions as to the requirements for the management of Third Parties from an Anti-Bribery perspective.

1.2 Scope and Applicability

This Guideline applies to all Associates.

It enters into force as of May 1, 2017 and replaces the previous version of the Novartis Third Party Guideline dated March 1, 2012.

This Guideline is not intended to override or supersede more restrictive laws relating to bribery. In addition to this Guideline, other Novartis principles and practices or equivalent documents may apply to the engagement of Third Parties (e.g. professional practices and procurement rules).

1.3 Roles and Responsibilities

The **Business Owner** has ultimate responsibility for managing and mitigating the bribery risks associated with Third Parties and must:

- confirm the legitimate need for the goods and/or service provided by the Third Party
- identify whether a Third Party falls within the scope of this Guideline
- ensure that the Due Diligence Coordinator (DDC) is provided with all necessary information to fulfill the requirements outlined in this Guideline
- validate the information captured in the Executive Summary and decide on the engagement of the Third Party
- ensure that the Agreement covers the content of the clauses listed in Section 2.2.1
- monitor the Third Party in adherence to the contract and in accordance with the measures identified in the Executive Summary
- define an audit plan, if necessary, for the Third Party in consultation with LCO and Legal

Procurement shall appoint DDCs in the relevant market, where possible cross-divisionally, and shall communicate the appointment.

The **DDC** is responsible for:

- Performing the due diligence or ensuring that it is performed for all new Third Parties or existing Third Parties who fall within the scope of this Guideline by virtue of the provision of a new service (see sections 2.1.1 and 2.1.2)

- Supporting the Business Owner in making an informed decision about the engagement of the Third Party (see section 2.1.3)
- Monitoring and performing any subsequent assessments after the Third Party has been engaged (see section 2.2.2)

If the Third Party is domiciled in a different country to the Novartis contracting entity, the DDC of the contracting entity may decide to request support from the DDC of the country in which the Third Party is domiciled. If such a request is made, the DDC in that country is obliged to provide support.

The **Local Compliance Officer** (LCO) is responsible for advising the Business Owner and the DDC. The LCO must approve any decision to pursue the engagement of any Third Party that is classified as medium or high risk.

Legal is responsible for supporting the Business Owner, as requested, when engaging the Third Party, including but not limited to the overall adequacy of the contract and inclusion of all necessary clauses.

The **Head Legal** of the local division or unit must approve any decision to pursue the engagement of any Third Party that is classified as high risk.

Group Integrity & Compliance (Group I&C) provides resources supporting the rollout of this Guideline (e.g., guidance, communication toolkits). They are responsible for keeping a central repository of these resources. A database of appointed DDCs is also maintained by Group I&C.

1.4 Third Parties Subject to this Guideline

A Third Party is subject to this Guideline if they engage in any of the activities specified below:

- Sell or resell or assist in selling or reselling Novartis products, through demand generation and/or active promotion of a Novartis product
- Act on behalf of Novartis or assist Novartis in dealing with government agencies to obtain permits, licenses, visas, regulatory approvals, pricing, reimbursement, participation in tenders, etc.
- Act on behalf of Novartis or assist Novartis in dealing or interacting with health care professionals
- Conduct clinical trials on behalf of Novartis

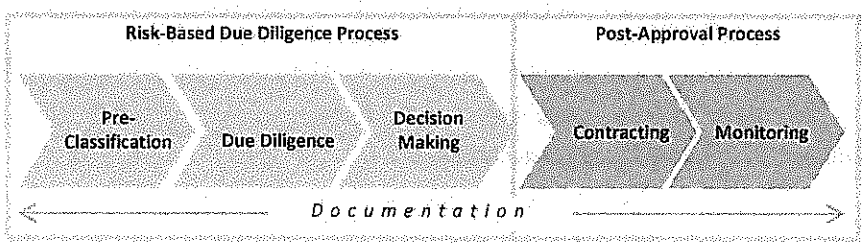
Further guidance to support the identification of Third Parties that fall within the scope of this Guideline can be found in Annex 6.

Due diligence on Third Parties that are selected as mandatory global providers for one or more of the activities listed above must be undertaken at the global level. Local organizations engaging such mandatory global providers for the activities that are subject to global due diligence are not required to perform a separate due diligence.

2 Anti-Bribery Third Party Risk Management

The management of Third Parties requires the identification, assessment, mitigation and monitoring of the risk associated with the engagement of Third Parties.

The following risk based due diligence and post-approval processes must be implemented to ensure that the risk is adequately managed:



2.1 Risk Based Due Diligence Process

2.1.1 Pre-classification of Third Party

Before the commencement of the due diligence, the Third Party must be pre-classified as "low", "medium" or "high" risk using the Novartis Risk Classification Methodology as per the Responsible Procurement Risk Assessment Process. This provides an indication of the risk-adjusted efforts required for each step of the management of the Third Party (e.g., due diligence, decision making, contracting and monitoring). Risk pre-classification is based on risk-related factors such as the geography, the type of services provided and background of Third Party.

2.1.2 Due Diligence

The purpose of the due diligence is to:

- Confirm the pre-classification through the collection and verification of due diligence process relevant information relating to the Third Party
- Identify and assess specific areas of elevated risk and seek to mitigate those risks

For all Third Parties, information on the Third Parties' business, ownership & management, government relations, compliance with laws, licenses, registrations, and certifications (such as licenses to trade) and commercial references must be collected. An essential component of this exercise is the full and accurate completion of the Novartis Anti-Bribery "Questionnaire for Third Parties" (Questionnaire) by the Third Party.

Depending on the Third Party risk pre-classification, the following due diligence activities must be completed.

Risk Classification	Minimum Activities Required
Low	Basic Due Diligence: • Verification of Questionnaire responses • Global screening of Third Party (sanctions and watch lists, etc.) • Conduct adverse internet & media search of Third Party in local language(s) and/or English
Medium	Mid-Level Due Diligence: • All low-risk due diligence activities plus: • Screening of key individuals [sanctions and watch lists, Politically Exposed Person list (PEP), etc.] • Conduct adverse internet and media searches of key individuals in the local language(s) and/or English
High	Enhanced Due Diligence: • All low and medium-risk due diligence activities plus: • Local public database searches focusing on in-country public records including litigation, regulatory, criminal, bankruptcy and directorship role of the Third Party • Verification of references collected in Questionnaire

Group I&C identifies external vendors that will provide the activities listed above.

Where the outcome of the due diligence is unclear due to conflicting or inadequate information, the DDC must conduct further investigation. This may require communication with the Third Party to clarify and validate the information collected, or to gather additional information. The DDC should discuss and align with Legal and/or the Local Compliance Officer as to whether further investigation by Global Security is needed.

Where Red Flags have been identified, mitigating and monitoring measures (if available) must be proposed to address the associated risks.

To conclude the due diligence, the DDC must prepare an Executive Summary of the information collected and verified during the due diligence; the Executive Summary must include:

- a final risk classification (i.e., low, medium or high risk)
- any Red Flags identified
- any proposed mitigating measures and monitoring activities

In order to support an informed decision, the DDC must send the Executive Summary to the Business Owner. In cases where the Third Party is classified as medium or high risk the Executive Summary shall also be sent to the LCO (for medium and high risk) and the Head Legal (for high risk only) of the local division or unit.

2.1.3 Decision Making

The Business Owner is responsible for deciding whether or not to engage the Third Party based on the results of the concluded due Diligence. For Third Parties that are classified as medium risk, the LCO has to approve the engagement. For Third Parties that are classified as high risk, the LCO and the Head Legal of the local division or unit have to approve the engagement.

Depending on the risk classification of a Third Party, the following functions and roles must be involved:

Risk Classification	**Decision**	**Consultation**	**Escalation in case of disagreement about**	
			Risk Classification, Mitigation and/or Monitoring	**Third Party Engagement**
Low Risk	Business Owner	DDC	LCO	-
Medium Risk	Business Owner & LCO	DDC	*Regional Compliance Officer (RCO) & next level manager of the Business Owner*	-
High Risk	Business Owner, LCO & Head Legal of the local division or unit	DDC	*Regional Compliance Officer (RCO) & Divisional Country Head*	

Legal, Finance, Integrity & Compliance, and other functions should be consulted by the Business Owner as appropriate.

The decision concerning the engagement of a Third Party must be documented in the Executive Summary. The concluded Executive Summary must be signed by the representatives of the functions involved.

Where Red Flags have been identified during the due diligence that could not be fully resolved (e.g. due to incomplete information), the Business Owner can only proceed if the other functions involved in decision making approve the engagement, and specific monitoring measures are documented in the Executive Summary.

Any due diligence that has been concluded may later be used by other Business Owners (from the same or another Novartis division or unit), provided that (i) the nature of the service remains the same (ii) the due diligence is not older than 3 years, and (iii) there is no Material Change to the Structure of the Third Party and there are no grounds to believe that the risk classification of the Third Party has increased.

A new due diligence may be conducted for any Third Party that failed to be approved after a prior Novartis due diligence if there are reasonable grounds to believe that the risk associated with the Third Party has decreased.

2.2 Post Approval Process

2.2.1 Contracting

Before a Third Party can be engaged by Novartis, or receive any payment from Novartis, a written contract or another written document with a similar legally binding effect (hereinafter referred to as "Agreement") must be concluded and must have come into effect. The Agreement must clearly describe the subject matter (e.g. goods and/ or services to be performed), and the terms of remuneration.

Clauses that address the following concepts must be included in each Agreement with a Third Party:

- An unequivocal statement that they will not promise, offer, pay, cause to pay, accept payment or induce payment or take any action that could be considered a bribe, and any such action will be grounds for immediate termination
- An unequivocal statement, agreeing to comply with the law, including those related to bribery and corruption such as the US Foreign Corrupt Practices Act, UK Bribery Act
- No sub-contracting of the services without Novartis prior written consent
- No assignment of the Agreement without Novartis prior written consent
- Obligation to inform Novartis of any Material Change in the Structure of the Third Party
- The right to terminate the Agreement upon occurrence of any of the following events (to the extent permitted under local law):
    - If the Third Party breaches the "Compliance with Law" clause
    - In the event of any material omission or misrepresentation of information provided by the Third Party in the due diligence
    - In the event of a material delay (at least thirty days) or failure to provide a Compliance Confirmation (where applicable)

  The termination right should be immediate where permitted under local law.

For Third Parties that pose a medium or high risk, the following additional concepts should be included in the Agreement:

- Right to audit the Third Party
- Refusal by the Third Party to be audited may result (subject to local law) in immediate termination of the Agreement by Novartis
- Responsibility to deliver during the term of the Agreement a Compliance Confirmation for each calendar year. The Compliance Confirmation shall be delivered during the first quarter of the year following the end of the calendar year to which the Compliance Confirmation relates
- Responsibility to provide training to the personnel of the Third Party or assign responsibility for such training to Third Party personnel according to the *Compliance Training Guideline for Externals Part 2: Companies and External Service Providers*

Examples of clauses that capture the aforementioned concepts are included in Annex 4 of this Guideline. Legal counsel shall have the authority to draft their preferred contract language which still adequately addresses the above concepts. Furthermore, some of these concepts may be covered by appropriate language in the Novartis Supplier Code if the Novartis Supplier Code is referenced in the Agreement with the Third Party.

2.2.2 Monitoring

The Third Party must be monitored on an on-going basis by the Business Owner and the respective DDC. The monitoring must be appropriate to the risk classification.

(a.) Event Triggered Monitoring Activities:
In instances where there is a change in circumstances (e.g., a Material Change to the Structure of a Third Party or newly identified Red Flags), the impact on the decision to continue to engage the Third Party and any possible mitigating and monitoring measures must be assessed. The Executive Summary must be updated accordingly.

This requires that the DDC and Business Owner work closely to inform each other of any relevant information that they become aware of that may have a negative impact on the risk classification of the Third Party.

(b.) Renewal of the Due Diligence:
The due diligence process must be renewed in line with the Novartis contract life and in any case at least every three years.

(c.) Pre-Defined Monitoring Activities:
An annual "Compliance Confirmation" shall be provided to Novartis by all Third Parties classified as medium and high risk. An example of such confirmation is included in Annex 5 of this Guideline.

The Business Owner in consultation with the LCO and Legal must define, if necessary, an appropriate audit plan for the Third Party.

3 Sub-Contracting and Assignment of Rights and Obligations

Any subcontracting of the services contracted by Novartis is subject to prior written approval in line with the Decision Making process defined in section 2.1.3. The risk classification of the Third Party applies to its sub-contractor.

Clauses that are materially equivalent to those that have been inserted into the Agreement with the Third Party as a result of applying section 2.2.1 should be included in the contract between the Third Party and its sub-contractor.

The requirements relating to sub-contracting also apply to any assignment of rights or obligations by the Third Party.

4 Record Keeping

Documentation related to the engagement of the Third Party must be retained to demonstrate that Novartis has taken reasonable precautions to avoid involvement in corrupt activities or with corrupt actors by providing evidence of credible due diligence, decision making, contracting and monitoring. The relevant documents should at a minimum include:

Due Diligence Process Documentation:

- Completed "Questionnaire for Third Parties" including any documentation provided by the Third Party
- Results of the Basic, Mid-Level or Enhanced Due Diligence
- Results of investigations performed by Global Security, if requested
- Completed "Due Diligence Checklist"
- Executive Summary of due Diligence
- Decision by the Business Owner, by the LCO (for medium or high risk Third Parties), and by Head Legal of the local division or unit (for high risk Third Parties); this should be shared across business units / divisions through the DDC

Contract Related Documentation:

- Agreement (e.g., Contract, Purchase Order, and evidence of relevant documentation required by Procurement)
- Documentation to support the conclusion that services and goods are priced at no more than market value (e.g., a fair market value analysis or the results of a procurement bidding process)
- Evidence of the transfer of value and/or proof the services or products were delivered (e.g. invoices)

Monitoring Related Documentation (as applicable based on Guideline):

- Documentation of training as defined by the Compliance Training Guideline for Externals Part 2: Companies and External Service Providers
- Evidence of an annual "Compliance Confirmation" by any medium or high risk Third Party
- Evidence of the results of any Third Party Audit, where performed
- Evidence of any additional local monitoring, where performed

All relevant documents should be made available at country level.

5 Implementation

5.1 Training

Associates must familiarize themselves with this Guideline. They must be trained in line with the Novartis-wide compliance training curriculum and the *Integrity & Compliance Training for Novartis Internal Associates Framework Guideline*. Additional training requirements may be defined in local company procedures.

Group I&C and/or divisional I&C provide the respective training tools.

The local compliance organization performs training about this Guideline. Procurement provides training about the systems and tools used to execute this Guideline.

5.2 Breach of this Guideline

Breaches of this Guideline will not be tolerated and can lead to disciplinary and other actions up to and including termination of employment.

5.3 Responsibilities with regard to the implementation of this Guideline

Subject to local adaption, every Novartis manager must implement this Guideline within his or her area of functional responsibility, lead by example, and provide guidance to the Associates reporting to him or her.

All Associates are responsible for adhering to the principles and rules set out in this Guideline.

The owner of this Anti-Bribery Third Party Guideline is Group I&C. They will prepare a high-level plan for the rollout of this Guideline which shall also define roles and responsibilities.

Any questions should be addressed to a representative from Integrity & Compliance or Legal.

Annexes

1. Questionnaire for Third Parties
2. Due Diligence Checklist
3. Executive Summary
4. Sample Clauses
5. Sample Compliance Confirmation
6. Guidance to support the identification of Third Parties that fall within the scope of the Anti-Bribery Third Party Guideline

NOVARTIS

Novartis Global Policy

Professional Practices Policy (P3)

Novartis Global Policy

March 1st, 2018

Version GIC 102V1.EN

NOVARTIS

Contents

1 Introduction

Purpose

Novartis' vision is to be a trusted leader in changing the practice of medicine. Consistent with this vision, Novartis is committed to the same high standard of ethical business conduct wherever it does business. Novartis has therefore adopted a single set of ethical principles that should be applied in daily decision-making by all Novartis Associates in any customer interaction and professional practice-related activity, including those not specifically covered by this Policy or related documents.

Scope and applicability

This Policy applies to all Novartis Associates as well as all professional practice-related activities conducted by third parties on behalf of Novartis. All such activities must be conducted in accordance with local laws, regulations and industry codes, which may be more stringent than the requirements outlined in this Policy.

This Policy serves as the foundation for P3 Guidelines ("Guidelines") and local standard operating procedures ("SOPs") all of which provide additional requirements for expected behaviors. As a result, this Policy should be read and applied in conjunction with the Guidelines and other references included in Section 5 of this document.

This Policy is effective as of March 1, 2018 and must be implemented by all Novartis affiliates. It replaces the existing versions of the divisional Professional Practices Policies.

The owner of this Professional Practices Policy (P3) is Group Integrity & Compliance

2 Principles

Put patients first

All interactions with our customers must ultimately benefit patients by enhancing the standard of care, raising awareness about diseases and their treatment options, or otherwise contributing to the ethical delivery of healthcare.

We will treat patient information with respect, protect confidentiality, where required obtain informed consent, and be transparent with patients at all times.

We must protect patient safety. If an Associate becomes aware of a product-related risk or complaint (e.g., adverse event, manufacturing defect or product failure) related to Novartis products (approved or investigated) it must be reported in a timely manner.

Fund responsibly

External funding, including grants, donations and sponsorships, must only be given to legitimate organizations and provided in a way that protects our reputation, aligns with society's expectations, and is consistent with the Novartis Mission to discover new ways to improve and extend people's lives.

The same rules apply for external in kind support.

Act with clear intent

As trusted partners in healthcare, all of our activities must have clear and transparent objectives that are accurate, truthful, not misleading, and appropriate for their intended context.

Novartis may conduct promotional and non-promotional activities throughout the product lifecycle. These activities ensure that products are developed to meet the needs of patients, to advance scientific understanding of disease, including disease management and treatment outcomes, and to discuss the appropriate use of products.

Non-promotional activities should never be conducted in a way that are intended or perceived to be promotional.

Engage appropriately

Associates must not offer, approve, or provide anything of value with the intent or consequence of inappropriately influencing or rewarding our customers for the use of Novartis products.

Novartis may choose to engage healthcare professionals or other customers to provide necessary and legitimate services to help us research, develop, and/or promote our products. Any compensation must be for a bona fide service, consistent with fair market value, properly documented and accounted for, and disclosed where required.

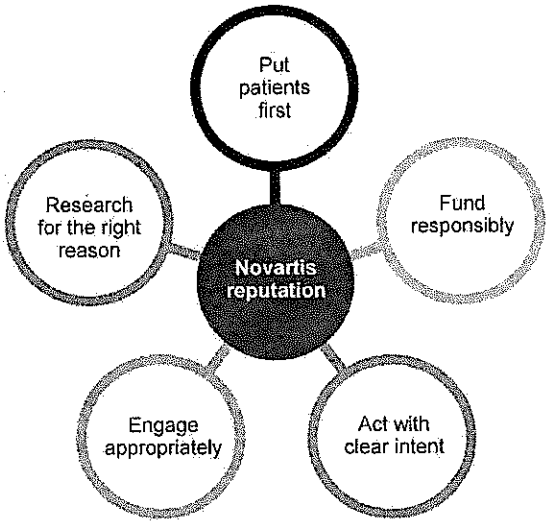
Allowable items of value, when provided to customers, must be modest, reasonable, infrequent, free from actual and perceived conflicts of interest, and disclosed where required.

Research for the right reason

Research and development must only be conducted to address valid medical or scientific questions aimed at enhancing patient care. We must always respect and protect the rights, safety and well-being of patients and animals and safeguard the integrity and validity of the data obtained.

Research and development activities must follow established ethical and scientific standards and be conducted by qualified investigators.

Research and development activities must never be promotional in nature.



3 Policy

3.1 Clinical Research

Novartis must conduct clinical **research for the right reasons**. Research must be conducted only if it is scientifically valid and designed to answer relevant medical, scientific, or health economic questions. It must follow the *Novartis Position on Clinical Study Transparency* and the *Novartis Quality Manual*.

Novartis Associates must always **put patients first** and protect their safety; if an Associate becomes aware of an adverse event related to any study or product, he/she must report it according to *Novartis Global Adverse Event Reporting Standard*.

Novartis supports the publication of study results in a timely manner and must not withhold or suppress data. We must protect confidential and/or patentable information, and personal information. Where required by local laws, regulations and/or industry codes, Novartis must disclose and report any payments or transfer of value made to HCPs and/or their institutions for research studies and third party medical writing support for publications. All publications must follow *Novartis Guidelines for the Publication of Results from Novartis-Sponsored Research*.

3.2 Pricing and Market Access

Novartis may interact with individuals, including HCPs, involved in recommending or deciding product reimbursement or purchase of Novartis products. However, these **interactions must not interfere with their independent judgment** or be perceived as improperly influencing them. Interactions may include proactive discussions to understand the needs of governments, payers and public health organizations (e.g., budgetary impact of new therapies) or responding to specific request for information (e.g., providing economic data or pipeline information that is in the public domain). All such discussions must be truthful and accurate. If these interactions are with public officials they may be subject to additional laws, regulations and industry codes. Engagement of HCPs for professional services who are formulary committee members must be disclosed according to local laws, regulations and industry codes. Discounts, rebates and other payments must be accurately and appropriately recorded in our books and records.

3.3 Pre-Approval Communication and Scientific Exchange

Products must only be **promoted consistent with approved labeling**.

Novartis supports the right of the scientific community and the public to be informed concerning scientific and medical progress. Therefore, where allowed by local laws, regulations and industry codes, Novartis may exchange scientific information. This may include communications at scientific events, public disclosure of information to investors/ shareholders, governments, reimbursement agencies or their agents and public health organizations.

Novartis may receive unsolicited requests for information on unapproved drugs and indications (off-label) from HCPs, patient organizations, and other stakeholders. Only the Medical function may provide such information in response to these requests. Novartis Associates who receive unsolicited requests for off-label information must forward such requests to the Medical function. The response provided by the Medical function, including any materials, must be accurate, not misleading, not promotional in nature, related solely to the subject matter of the request, and in compliance with local laws, regulations and industry codes. The Medical function should maintain written documentation of unsolicited requests and responses.

Novartis Medical Scientific Liaisons (MSLs) may interact with HCPs throughout the lifecycle of a product for the purpose of exchanging scientific information. Interactions must not be promotional in any way, and must have **clear intent and transparent objectives**.

3.4 Promotional Interactions

Upon receipt of marketing authorization, Novartis may interact with customers, either directly or via a third party, to promote Novartis products, related features, and benefits. All interactions must have **clear intent, transparent objectives,** and must not interfere with the independence of customers.

Products must only be promoted consistent with approved labeling, as approved by the local regulatory authorities. Anyone promoting a Novartis product must be trained and have sufficient knowledge of the product to provide full and accurate product information.

Any materials used for purposes of the interaction must be approved in accordance with the *P3 Guideline on Promotional and Non-Promotional Materials* and local laws, regulations and industry codes.

3.5 Promotional Content

Novartis may produce and disseminate content (printed, electronically, and orally) to inform, educate, or promote its products. All content **must be accurate, fair, balanced, truthful and not misleading**, based on adequate substantiation and consistent with the scope of the relevant product's marketing authorization. Content must be reviewed, approved and updated, as required in accordance with the *P3 Guideline on Promotional and Non-Promotional Materials* and local laws, regulations and industry codes.

3.6 Items of Medical Utility and Cultural Acknowledgements

Novartis must **engage appropriately with all customers**. Where permitted by local laws, regulations, and industry codes, items of medical utility and cultural acknowledgements may be offered or provided to HCPs if such items are modest, reasonable in value, offered on an occasional basis and according to the *P3 Guideline on Items of Medical Utility and Cultural Acknowledgements*.

Gifts (including personal gifts) or promotional aids, whether branded or unbranded, must not be provided to HCPs or their family members. This includes payments in cash or cash equivalents (such as gift certificates). Items made available to HCPs for use during Novartis meetings (such as pens and note pads) must not include any Novartis product or company branding.

Novartis Associates must not use their own personal funds to provide gifts to HCPs.

3.7 Samples, Demonstration and Evaluation Devices

Where permitted by local laws, regulations, and industry codes, free samples of Novartis pharmaceutical products may be provided to HCPs authorized to prescribe that product in order **to enhance patient care** or provide experience with the product. Pharmaceutical samples must be permanently labeled as samples, and managed with systems of control and accountability. They must never be resold or otherwise misused.

Over the counter (OTC) product samples may be distributed directly to customers where permitted by local laws, regulations, and industry codes.

Demonstration and evaluation devices may be provided free of charge to an HCP or HCO for a limited and agreed-upon duration. Devices provided must be labeled appropriately and must not be provided prior to receipt of marketing authorization for their intended use in that market. Title to the device must remain with Novartis for the entire duration of the evaluation and devices must not be stored at any HCP or HCO facility when not under evaluation.

3.8 Events

Novartis may organize events or fund events organized by third parties throughout the product lifecycle with the objective to provide scientific information or educate customers about our products or applicable disease areas. All events must have clear objectives, be **funded responsibly** and aligned with Novartis' mission, in a way that meets societal expectations.

Events must have **clear purpose and be transparently conducted.** If the purpose of the event is non-promotional we must not use materials with brand colors and logos or any promotional content, and avoid any perceptions of disguised promotion.

Common types of events organized or funded by Novartis are:

- Promotional **speaker programs** to educate HCPs on Novartis products or applicable disease areas.
- **Scientific meetings** to facilitate legitimate scientific debate, gain or provide scientific or medical educational information
- **Disease awareness programs** to increase knowledge and education about diseases and their management.
- **Investigator meetings** to initiate, update, or close-out Novartis sponsored or supported studies. Such meetings must be managed in accordance with the requirements of the relevant investigator study.
- Novartis **site visits** for customers or regulatory authorities. Such visits must be coordinated with the local site management.
- **Third party congress or symposia** to provide medical education.

Novartis Associates should organize events in accordance with the *P3 Guideline on Events and Professional Meetings.*

3.9 Venue, Travel, and Hospitality

All events, meetings, or activities must be held in a venue appropriate for scientific or educational exchange and in accordance with local laws, regulations, and industry codes. Novartis must avoid venues that may be perceived as extravagant or applying inappropriate influence. For Novartis-organized events, refreshments and/or meals incidental to the main purpose of the event may be provided, however no entertainment or other leisure/social activities should be provided or paid for by Novartis. Interactions with public officials may be subject to additional laws, regulations and industry codes.

Where permitted locally, Novartis may fund HCPs to attend events in their country of practice (or home country). However, Novartis does not fund HCPs to attend international events with the exception of HCPs who are providing a service to Novartis. International travel may be funded only under certain circumstances where HCPs are engaged by Novartis to provide professional services. In all instances, we must ensure that event funding does not interfere with HCP independence.

3.10 Fees for Service

Novartis may engage with HCPs and HCOs for professional services, either directly or via a third party. Such services may include the engagement of HCPs as **speakers for promotional speaking programs, scientific standalones, or other events, consulting engagements**, **advisory boards** and/or **market research**. Irrespective of direct engagement or via a third party, Novartis is responsible for **engaging appropriately** and without the intent, perception or consequence of inappropriately influencing HCPs or HCOs for the use of our products.

All engagements must be based on a legitimate need for the service. Any HCP or HCO engaged by Novartis must have the necessary experience and/or capabilities to provide the services. The engagement must be confirmed in a written agreement signed by both parties before commencing any services. Compensation for services must be reasonable and at fair market value in relation to the services rendered. Engagement of HCPs who are public officials may be subject to additional laws, regulations and industry codes.

Cross-country engagements of HCPs must be approved by qualified Novartis Associates from the HCP's practicing country for compliance with local laws, regulations and industry codes. Compensation for services must be paid into the HCP's practicing country.

Novartis Associates must follow the *P3 Guideline on HCP and HCO Engagement.*

3.11 Interactions with Patients and Patient Organizations

Novartis may interact with patients, caregivers, and patient organizations to understand their perspective and provide knowledge regarding diseases, treatments, and its care. All interactions must be ethical, transparent, non-promotional, and consistent with Novartis' mission and **maintain the independence of the patient and patient organizations**.

Novartis must treat **patient information with respect and protect confidentiality**. We must not accept any patient or caregiver information from third parties unless the patient or caregiver has provided explicit consent for the provision of the information to Novartis.

In most markets, interactions with patients are non-promotional activities and must not be used for, or mixed with, promotional purposes. Promotion of prescription-only products to patients (direct-to-consumer promotion, "DTC") is not allowed in most countries. Where such promotion is allowed, it must strictly follow the applicable local laws, regulations and industry codes. Advertisements for patient recruitment in public media, where permitted, must not be misused for promotion of a product.

Novartis may engage with patients or patient organization for services, such as participation in **patient advisory boards**. All engagements must be based on a legitimate need for the service and confirmed in a written agreement signed by both parties before commencing any services. Compensation for services must be reasonable in relation to the services rendered.
Novartis may also provide financial and other support to patients and patient organizations. Such support may be in the form of **Patient Support Programs** ("PSPs"), **Patient Assistance Programs** (PAPs), funding to support/establish patient organizations, etc.

Novartis Associates must follow the *P3 Guideline on Interactions with Patients and Patient Organizations*.

3.12 External Funding

Novartis may provide funding or other support to external organizations. This includes **grants, donations**, funding for medical education such as **preceptorship programs,** and **sponsorships.** We must **fund responsibly,** in a manner that maintains our reputation, aligns with our mission to discover new ways to improve and extend people's lives, advance medical or scientific knowledge, and supports communities where Novartis Associates live and work.

External funding or support must only be given to legitimate organizations, never to individuals, and in accordance with the *P3 Guideline on External Funding*. It must have a clear and defined purpose. Funding must be reasonable and legitimate in light of the activity being funded and properly tracked, documented, reported, and accounted for, as required by local laws, regulations and industry codes. Where applicable, funding must follow the *Novartis Anti-Bribery Policy*.

4 Definitions

Adverse Event

An adverse event is any unfavorable medical occurrence or unintended sign (including an abnormal laboratory finding), symptom, disease or injury temporally associated with the use of a medical device, medicinal or investigational product, in patients, users, or other persons, whether or not it is considered to be related to or due to the product.

Customer

Defined broadly as:

- Patients and patient organizations
- Healthcare partners, including but not limited to, healthcare professionals, healthcare organizations, payers, third party distributors/wholesalers, suppliers, intermediaries
- Non-HCP Retailers.

Caregiver

Someone who participates in or makes medical decisions for a patient. Examples of caregivers include parents or legal guardians, spouses or partners, adult children, relatives, or other friends.

Disease Awareness Programs

A program intended to provide information, awareness, or education regarding health and diseases and their management to the general public, potential patients, or HCPs.

Over the Counter (OTC) Product

A product marketed for use by consumer without the intervention of a HCP in order to obtain the product.

Cultural Acknowledgements

An inexpensive item, not related to the practice of medicine (also referred to as 'Courtesy Gift'), involving the HCP or their immediate family members to acknowledge significant national, cultural or religious holidays or events.

Donation

Benefit granted by Novartis to legitimate organizations for an altruistic and specified purpose, where Novartis does not expect to receive any benefit, consideration or service in return.

Event

A conference, congress, symposium, or any other meeting of a scientific, educational, or professional nature organized or funded partially or fully by Novartis or a third party to disseminate knowledge enhancing information, increase knowledge of Novartis products, provide scientific, educational and/or professional information.

Gifts

Benefits of any kind given to someone as a sign of appreciation or friendship without expectation of receiving anything in return.

Grant

Independently requested contribution conveyed to a legitimate organization for a specified purpose without agreement or intent to receive any tangible benefit (a measurable or quantifiable and objective benefit).

Healthcare Organizations (HCOs)

Any legal entity (such as a company, partnership, or healthcare institution), whether public or private, that offer/provide Medical Services to patients and may prescribe, order, dispense, recommend, purchase, supply, administer, lease, and use Novartis products, and all members of their office staff, and medical associations or organizations.

Examples of HCOs include: physician practices, hospitals (including university hospitals), ambulatory surgical centers, pharmacies, clinics, nursing facilities, managed care entities, group purchasing organizations (GPOs), specialty pharmacies, medical societies, and businesses owned by an individual or group of HCPs.

Healthcare Professional (HCP)

Any member, student, or researcher of the medical, dental, optometry, opticianry, pharmacy, or nursing profession or any other person, social workers, clinical psychologists, formulary committee members, and pharmacy & therapeutics (P&T) committee members who in the course of his or her professional activities provides medical services and may prescribe, order, dispense, recommend, purchase, supply, administer, lease, or use pharmaceutical products and/or medical technologies, and all members of their office staff.

Items of Medical Utility

Items given to HCPs that (1) are intended for the direct education of HCPs or patients, or are for use by patients to assist them in the administration of their treatment or management of their conditions, and (2) do not have value to HCPs outside of the scope of their practice and educational need.

Medical Services

Performing or ordering any examination, test, or procedure to diagnose or treat any medical or health-related issue, or filling a prescription for a pharmaceutical or device product that is eligible for payment by someone (whether payor is public or private) other than a patient/consumer.

Patient

Any person who may receive a prescription for, and/or are treated with a pharmaceutical product and/or medical technology for his or her individual needs.

Patient Organization

Independent organization which has the goal of providing direct support to people affected by an illness or advocating for, among other things, patients' rights, disease awareness and patient information in one or more therapeutic areas. Such organizations are often established by patients, their family members and caregivers but may also include Health Care Professionals (HCPs), volunteers and policy makers among their membership or leadership.

Patient Support Program

A program that involves direct or indirect interactions with a patient or patient's caregiver implemented by Novartis or a third-party on behalf of Novartis. Examples include helping patients manage medication administration and adherence, provide disease management support or provide or arrange for financial assistance for patients who cannot afford medications.

Pharmaceutical Samples

Free pharmaceutical products supplied to HCPs authorized to prescribe that product in order to enable HCPs and their patients to gain experience in dealing with the product.

Promotional Aid

Non-monetary items that are branded or include minimal information intended to promote Novartis or its products. Examples of Promotional Aids include pens, mousepads, and microfiber cloths.

Public Official

- Any elected or appointed officer or employee of a government or government department, government agency, or of a company owned or partially owned by a government. Medical and scientific personnel qualify as public officials when they work at a hospital, clinic, university or other similar facility owned or partially owned by a government.
- Any elected or appointed officers or employees of public international organizations, such as the United Nations

Received

- Any person acting in an official capacity for or on behalf of a government or a government department, government agency, or of a public international organization
- Politicians and candidates for a political office
- Any other person who is considered to be a public official according to applicable laws, regulations and industry codes

Research and development activities

Activities conducted to obtain scientific and clinical knowledge in order to address unmet medical needs. These activities include clinical and non-clinical studies, exploratory early stage research, investigator meetings, studies in human subjects or involving human/patient data, and animals or biological materials.

Scientific Exchange

Collection, publication, distribution and communication of scientific knowledge (knowledge related to, derived from or used in science for sharing), which may include information concerning a Novartis product.

Sponsorship

Agreement by which Novartis, for the mutual benefit of Novartis and the sponsored party, provides funding to establish an association between the Novartis' image, brands, or services and a sponsored event, activity, or organization.

5 References

- P3 Guideline on Items of Medical Utility and Cultural Acknowledgements
- P3 Guideline on Market Research
- P3 Guideline on Interactions with Patients and Patient Organizations
- P3 Guideline on External Funding
- P3 Guideline on Events and Professional Meetings
- P3 Guideline on HCP and HCO Engagements
- P3 Guideline on Promotional and Non-Promotional Materials
- Novartis Anti-Bribery Policy
- Novartis Position on Clinical Study Transparency
- Novartis Guideline for the Publication of Results from Novartis-Sponsored Research
- Novartis Quality Manual
- Novartis Global Adverse Event Reporting Standard
- Novartis Third Party Guideline

6 Implementation

Training

Associates must familiarize themselves with this Policy and the relevant Guidelines referred to in this Policy. Associates must be trained in line with the Novartis-wide compliance training curriculum. Additional training requirements for Associates and third parties conducting business on behalf of Novartis may be defined in local SOPs.

Third parties

Third parties involved in conducting activites covered by this Policy and on behalf of Novartis are expected to comply with this Policy, applicable laws and to adhere to ethical business practices. Novartis Associates contracting third parties are ultimately responsible for how third parties conduct these activities on behalf of Novartis.

Breach of this policy

Failure to comply with this Policy may lead to disciplinary and other actions, up to and including termination of employment.

Reporting potential misconduct/non-retaliation

Any Associate with knowledge of suspected misconduct must report his or her suspicion promptly in accordance with the Business Practices Office (BPO) process. Associates who report potential misconduct in good faith or who provide information or otherwise assist in any inquiry or investigation of potential misconduct will be protected against retaliatory action.

Exceptions

No exceptions can be granted from compliance with applicable laws, regulations and industry codes. The Compliance Leadership Team (CLT) will review exceptions related to this Policy.

Responsibilities

It is the responsibility of every Novartis Manager to adhere to this Policy within his or her area of functional responsibility, lead by example, and provide guidance to the Associates reporting to him or her. All Associates are responsible for adhering to this Policy.

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,

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