Funded Project List

RTI International (2-3t2-02t4712-s22191)
I.C.M.R. New Delhi (54/4/ger/Indo-Sweden/17-NCD-II dated 04.09.2017)
I.C.M.R. New Delhi (5/7/1233/2014-RCH)
Endocrine Society
I.C.M.R. New Delhi
I.C.M.R. New Delhi (5/4/1-6/12-NCD-II dated 13.11.2013)
IISC Bangalore (IMPR/MAE/RDP/011)
Indian Academy of Science (SEP/LW/APRIL 2017)
Govt. of Karnataka
Rajiv Gandhi University of Health Sciences, Bangalore (RGU: R&D:Res.Proposal-M-55:2015-16)
Rajiv Gandhi University of Health Sciences, Bangalore (RGU: R&D:Res.Proposal-M-55:2015-16)
United Nations Industrial Development Organsiation (3000040233)
George Institute for Global Health
I.C.M.R. New Delhi (NTF/2017/HSR/01/01)
Rajiv Gandhi University of Health Sciences, Bangalore
Endocrine Society
Rajiv Gandhi University of Health Sciences, Bangalore
Rajiv Gandhi University of Health Sciences, Bangalore
Rajiv Gandhi University of Health Sciences, Bangalore
Amgen Technology Pvt Ltd
IQVIA RDS India pvt ltd
Lambda Therapeutics pvt ltd
Eli Lilly India Pvt Ltd
PPD Pharmaceuticals pvt ltd
Icon Clinical Research India pvt ltd
Eli lilly India Pvt Ltd
Novo Nordisk India pvt ltd
Lupin ltd
Novartis Health Care Pvt Ltd
PPD Pharmaceutical pvt ltd
Klinera Corporation ltd
Eli lilly India Pvt Ltd
Novo Nordisk India pvt ltd
Eli lilly India Pvt Ltd
Glenmark pharmaceuticals pvt ltd

IQVIA RDS India pvt ltd
Lambda Therapeutics pvt ltd
Novo Nordisk India pvt ltd
Novartis Health Care Pvt Ltd
UCB scienes Gmbh
Meril Life Sciences
Quintiles Research India Pvt Ltd
Navitas Life sciences
Navitas Life sciences
Novo Nordisk India pvt ltd
Lambda Therapeutics pvt ltd
Siro Clinopharm pvt Ltd
Eli Lilly India Pvt Ltd
PPD Pharmaceuticals pvt ltd
INC Research UK Ltd
Boehringer Ingelheim Pvt Ltd
Klinera Corporation ltd
IPCA Laboratories Ltd
Novartis Health Care Pvt Ltd
Eli Lilly India Pvt Ltd

Ph.26588980,26588707
Fax: 011-26588381

web-site :www.icmr.nic.in
e.mail :icmrhqds@sansad.nic.in

Sheet 1 of 2

भारतीय आयुर्विज्ञान अनुसंधान परिषद
INDIAN COUNCIL OF MEDICAL RESEARCH

अन्सारी नगर, पोस्ट बॉक्स 4911, नई दिल्ली - 110 029
ANSARI NAGAR, POST BOX 4911, NEW DELHI - 110 029

File No. 5/4-5/13/ADR/2015-NCD-I

Dated: 19/05/15

To

Dr. Chandrakiran C
Prof. & HOD, ENT,
M S Ramaiah Medical College,
Bangalore-560054.

Sub: Conceptual model for infant screening of hearing impairment through otoacoustic emission device in rual areas"

Sir/Madam

Reference the above mentioned proposal submitted by you for financial assistance by this Council.

I am directed to inform you that the above mentioned scheme has been technically approved by the Council with the following comments:

Recommended with staff of Audiologist, SRF (Medical), contingency for workshops Rs. 50,000/=, contingency for printing of modules and information booklets Rs. 1,50,000/=. questionnaires/screening instruments Rs. 10,50,000/= computer, UPS printer not agreed.

Staff	I st year	IInd Year	IIIrd Year	Total
Audiologist @ Rs. 28,773/- p.m. 12	3,45,276	6 1,72,638 (six months)	-	5,17,914
SRF @ Rs. 28,000/- p.m. + HRA 30% (8400) = 36,400/- 12	4,36,800	6 2,18,400	-	6,55,200
Total	7,82,076	3,91,038		11,73,114
.ntingency				
i)Workshops	50,000	-	-	50,000
ii)Printing of modules and information booklets	75,000	75,000		1,50,000
Total II	9,07,076	4,66,038		13,73,114
Overhead charges 3%	27212	13981		41193
Total I& II	9,34,288	4,80,019		14,14,307
Non recurring				
Equipment				
Field based screening instruments and hearing testing devices -3 sets otoacoustic emission device. (Headlight with light source , Lack's Tongue Depressors Thudicum's Nasal speculum, Aural Probe, IDL Mirrores, Nasal Packing Forceps , Nasal/ Aural Suction Cannula, Suction Apparatus, Aural Syringe, Nasal and Ear Foreign Body Removal Probe / Hook	3,50,000	3,50,000	3,50,000	10,50,000
Grand Total	12,84,288	8,30,019	3,50,000	24,64,307

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

It is requested that the following information may also be sent to this office immediately

1. Whether having more than 3 projects with ICMR.
2. Whether project has been submitted to other agency for financial assistance.
3. Undertaking duly signed by Head of Institute .
4. Copy of the (Deptt. of Science & Industrial Research (DSIR) Certificate
5. Approval of the Ethical Clearance Report of the above mentioned project.
6 Non-availability certificate of equipments as per enclosed format.
8. Mandate form along with Cancelled Cheque in original.
9. Name and address of the statutory audit authority of the host Institute duly signed by the head of the Institute.

Further action will be taken on the receipt of the same.

Yours faithfully,

(S.S. Behl)
Administrative Officer
For Director-General

Encl: As above.

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

22/16
11/1

भारतीय आयुर्विज्ञान अनुसंधान परिषद
INDIAN COUNCIL OF MEDICAL RESEARCH

अन्सारी नगर, पोस्ट बॉक्स 4911, नई दिल्ली - 110 029
ANSARI NAGAR, POST BOX 4911, NEW DELHI - 110 029

No. 5/4-5/13/ADR/2015-NCD-I

Dated : 07.01.2016

Subject: Payment of 1st installment of the 1st year of grant-in-aid for the Ad-hoc Project entitled "Conceptual Model for infant screening of hearing impairment through OTO- Acoustic emission device in rural areas" under Dr. Chandrakiran C, Ms Ramaiah Medical College and Hospital, Bangalore.

MEMORANDUM

The Director-General, ICMR sanction the payment of Rs. 15,22,299/- (Rupees fifteen lakhs twenty two thousand two hundred ninety nine only) as the 1st installment of 1st year grant for incurring expenditure in connection with the above mentioned research scheme. The amount of Rs. 15,22,299/- may be debited in the provision of Rs. 19,94,597/- made for the above mentioned research scheme for the current financial year.

A formal bill for Rs. 15,22,299/- is sent herewith for payment by cheque/demand Draft to the Principal & Dean, M.S. Ramaiah Medical College & Teaching Hospital, MSR Nagar, MSRIT Post Bangalore – 560054, Karnataka.

M S RAMAIAH MEDICAL COLLEGE BANGALORE-54
11 JAN 2016
RECEIVED

(Sushila Kargaonkar)
Sr. Administrative Officer
For Director-General

Accounts Section V, (RFC No-(P-66)/ NCD/TSP/4/2015-16/dt.3/11/2015.

Copy to:-

1. The Principal & Dean, M.S. Ramaiah Medical College & Teaching Hospital, MSR Nagar, MSRIT Post, Bangalore – 560054, Karnataka
2. Dr. Chandrakiran C, Professor & HOD, ENT, M.S. Ramaiah Medical College and Hospitals, MSR Nagar, MSRIT Post, Bangalore – 560054
3. IRIS Section (2014 – 1279)
4. Sr. A.O
5. Dr. Geeta Menon, Scientist – "D"

For Director-General

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

Ad-hoc

Sub: Conceptual Model for infant screening of hearing impairment through OTO- Acoustic emission device in rural areas" under Dr. Chandrakiran C, MS Ramaiah Medical College and Hospitals, Bangalore.

Budget

15.1.2016 to 14.1.2017

(I) Staff	1st year
Audiologist @ Rs. 29,607/- p.m. (fixed) 12 months	3,55,284/-
SRF @ Rs. 28,000/- p.m. + HRA 30% (8400) = 36,400/- 12 months	4,36,800/-
Total of I	**7,92,084/-**
(II) Contingency	
i)Workshops	50,000/-
ii)Printing of modules and information booklets	75,000/-
Total II	**1,25,000**
Total I& II	**9,17,084/-**
Overhead charges 3%	27,513/-
Non recurring	
Equipment Field based screening instruments and hearing testing devices -3 sets otoacoustic emission device. (Headlight with light source , Lack's Tongue Depressors Thudicum's Nasal speculum, Aural Probe, IDL Mirrores, Nasal Packing Forceps , Nasal/ Aural Suction Cannula, Suction Apparatus, Aural Syringe, Nasal and Ear Foreign Body Removal Probe / Hook	10,50,000/-
Grand Total	**19,94,597/-**

(Rupees nineteen lakhs ninety four thousand five hundred ninety seven only)

File No. 5/4-5/13/ADR/2015-NCD-1

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

23/16
23/11/16

Ph.26588980,26588707
Fax: 011-26588381

web-site :www.icmr.nic.in
e.mail:icmrhqds@sansad.nic.in

भारतीय आयुर्विज्ञान अनुसंधान परिषद
INDIAN COUNCIL OF MEDICAL RESEARCH
अन्सारी नगर, पोस्ट बॉक्स 4911, नई दिल्ली - 110 029
ANSARI NAGAR, POST BOX 4911, NEW DELHI - 110 029

No. 5/4-5/13/ADR/2015-NCD-I

Dated: 07.07.2016

To

The Principal & Dean
M.S. Ramaiah Medical College & Teaching Hospital
MSR Nagar , MSRIT Post
Bangalore – 560054
Karnataka

Sub: Project entitled "Conceptual Model for infant screening of hearing impairment through OTO- Acoustic emission device in rural areas" under Dr. Chandrakiran C, MS Ramaiah Medical College and Hospitals, Bangalore.

Dear Sir,

The Director-General of the Council sanctions the above mentioned research scheme for a period of One Year from 15.1.2016 to 14.1.2017 subject to extension upto the total duration specified in para 3(3) below.

The Director-General of the Council also sanctions the budget allotment of Rs. 19,94,597/- (Rupees nineteen lakhs ninety four thousand five hundred ninety seven only) as detailed in the attached statement for the period 2015-2016.

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

1. The payment of the grant will be made in lump-sum to the head of the Institution. The first installment of the grant will be paid generally as soon as a report regarding the commencement of the project and appointment of the staff is received by the Council. The demand for payment of the subsequent installment of the grant should be placed with the Council in the prescribed Performa attached.
2. The staff appointed on the project should be paid as indicated in the budget statement attached.
3. The approved duration of the scheme is (3 years) Three years . The annual extension will be given after review of the work done on the scheme during the previous year.
4. A report on the progress made will be submitted to the Council as and when called for.
5. The Institute will maintain a separate account of the receipts and the expenditure incurred on the scheme and will furnish a utilization certificate and an audited statement of account pertaining to the grant.
6. The other terms and conditions are indicated in Annexure-I.

The receipt of this letter may please be acknowledged.

Yours faithfully,

(Sushila Kargaonkar)
Sr. Administrative Officer
For Director-General

Accounts Section V. (RFC No-(P-66)/ NCD/TSP/4/2015-16/dt.3/11/2015.

Copy to:-

1. Dr. Chandrakiran C, Professor & HOD, ENT, M.S. Ramaiah Medical College and Hospitals, MSR Nagar, MSRIT Post , Bangalore – 560054
2. IRIS Section (2014 – 1279)
3. Sr. A.O
4. Dr. Geetha Menon, Scientist – "D"

M S RAMAIAH MEDICAL COLLEGE BANGALORE-54
RECEIVED

For Director-General

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

भारतीय आयुर्विज्ञान अनुसंधान परिषद
INDIAN COUNCIL OF MEDICAL RESEARCH

अन्सारी नगर, पोस्ट बॉक्स 4911, नई दिल्ली - 110 029
ANSARI NAGAR, POST BOX 4911, NEW DELHI - 110 029

No. 5/4-5/13/ADR/2015-NCD-I

Dated : 9/08/16

Subject: Payment of 2nd installment of the 1st year of grant-in-aid for the Ad-hoc Project entitled "Conceptual Model for infant screening of hearing impairment through OTO- Acoustic emission device in rural areas" under Dr. Chandrakiran C, Ms Ramaiah Medical College and Hospital, Bangalore.

MEMORANDUM

The Director-General, ICMR sanction the payment of Rs. 4,72,298/- (Rupees four lakhs seventy two thousand two hundred ninety eight only) as the 2nd installment of 1st year grant for incurring expenditure in connection with the above mentioned research scheme. The amount of Rs. 4,72,298/- may be debited in the provision of Rs. 19,94,597/- made for the above mentioned research scheme for the current financial year.

A formal bill for Rs. 4,72,298/- is sent herewith for payment by RTGS to the Principal & Dean, M.S. Ramaiah Medical College & Teaching Hospital, MSR Nagar, MSRIT Post Bangalore – 560054, Karnataka.

Rec'd on 18/8/16

Sushila

(Sushila Kargaonkar)
Sr. Administrative Officer
For Director-General

Accounts Section V, (RFC No-(P-66)/ NCD/TSP/4/2015-16/dt.3/11/2015.

Copy to:-

1. The Principal & Dean, M.S. Ramaiah Medical College & Teaching Hospital, MSR Nagar, MSRIT Post, Bangalore – 560054, Karnataka
2. Dr. Chandrakiran C, Professor & HOD, ENT, M.S. Ramaiah Medical College and Hospitals, MSR Nagar, MSRIT Post , Bangalore – 560054
3. IRIS Section (2014 – 1279)
4. Sr. A.O
5. Dr. Geetha Menon, Scientist – "D"

Dr Chandrakiran
- Dr B.S Nandakumar
Act-1
17/8/16

M S RAMAIAH MEDICAL COLLEGE, BANGALORE-54
17 AUG 2016
RECEIVED

For Director-General

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

भारतीय आयुर्विज्ञान अनुसंधान परिषद
INDIAN COUNCIL OF MEDICAL RESEARCH
अन्सारी नगर, पोस्ट बॉक्स 4911, नई दिल्ली - 110 029
ANSARI NAGAR, POST BOX 4911, NEW DELHI - 110 029

No. 5/4-5/13/ADR/2015-NCD-I

Dated : 4/08/16

Subject: Payment of 2nd installment of the 1st year of grant-in-aid for the Ad-hoc Project entitled "Conceptual Model for infant screening of hearing impairment through OTO- Acoustic emission device in rural areas" under Dr. Chandrakiran C, Ms Ramaiah Medical College and Hospital, Bangalore.

MEMORANDUM

The Director-General, ICMR sanction the payment of Rs. 4,72,298/- (Rupees four lakhs seventy two thousand two hundred ninety eight only) as the 2nd installment of 1st year grant for incurring expenditure in connection with the above mentioned research scheme. The amount of Rs. 4,72,298/- may be debited in the provision of Rs. 19,94,597/- made for the above mentioned research scheme for the current financial year.

A formal bill for Rs. 4,72,298/- is sent herewith for payment by RTGS to the Principal & Dean, M.S. Ramaiah Medical College & Teaching Hospital, MSR Nagar, MSRIT Post Bangalore – 560054, Karnataka.

(Sushila Kargaonkar)
Sr. Administrative Officer
For Director-General

Accounts Section V, (RFC No-(P-66)/ NCD/TSP/4/2015-16/dt.3/11/2015.

Copy to:-

1. The Principal & Dean, M.S. Ramaiah Medical College & Teaching Hospital, MSR Nagar, MSRIT Post, Bangalore – 560054, Karnataka
2. Dr. Chandrakiran C, Professor & HOD, ENT, M.S. Ramaiah Medical College and Hospitals, MSR Nagar, MSRIT Post , Bangalore – 560054
3. IRIS Section (2014 – 1279)
4. Sr. A.O
5. Dr. Geetha Menon, Scientist – "D"

For Director-General

Dr Chandrakiran
Dr B.S. Nandakumar
Act-1
17/8/16

M S RAMAIAH MEDICAL COLLEGE, BANGALORE-54
17 AUG 2016
RECEIVED

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

Dr Vani Form RAGAS ON ELECTROPHYSIOLOGY & STRESS (RGUHS)

RGUHS

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-83: 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. 5,10,000-00 (Rupees Five lakhs ten thousand only) towards research proposal "ASSESSMENT OF THE EFFECT OF

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054

VARIOUS RAGAS OF INDIAN MUSIC ON ELECTROPHYSIOLOGICAL PARAMETERS AND SALIVARY STRESS MARKERS - A RANDOMIZED CONTROL TRIAL" furnished by Dr. Kirthana Kunikullaya U, Assistant Professor, Department of Physiology, M. S. Ramaiah Medical College, MSR Nagar, MSRIT Post, Bangalore, Karnataka, India – 560054 for the year 2015-16. The Grant-in-aid will be released in the name of Director of M. S. Ramaiah Medical College, Bangalore 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. 5,10,000-00
2.	First Installment (50%)	Rs. 2.55,000-00
3.	Second Installment (25%)	Rs. 1,27,000-00
4.	Third Installment (15%)	Rs. 77,000-00
5.	Fourth Installment (10%)	Rs. 51,000-00

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.

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

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

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054

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. Director, M. S. Ramaiah Medical College, MSR Nagar, MSRIT Post, Bangalore, Karnataka, India – 560054.
2. Dr. KirthanaKunikullaya U, Assistant Professor, Department of Physiology, M. S. Ramaiah Medical College, MSR Nagar, MSRIT Post, Bangalore, Karnataka, India – 560054.

Copy to:

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

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

Title of project: ASSESSMENT OF THE EFFECT OF VARIOUS RAGAS OF INDIAN MUSIC ON ELECTROPHYSIOLOGICAL PARAMETERS AND SALIVARY STRESS MARKERS - A RANDOMIZED CONTROL TRIAL

Funded By RGUHS

Investigators: Dr. Kirthana Kunikullaya U, Dr.Vijayadas, Dr. Jaisri Goturu, Ms. Radhika Kunnavil, Dr. Prakash V S, Dr. N S Murthy

Total research grant requested. Give details of the break up along with justification for the grants requested.

STAFF:			**TOTAL COST**
Research assistant & Technician	Rs.700/CASE	140 SAMPLE SIZE * 700 (200 people recruited/screened)	Rs.1,40,000/-
RECURRING:			
PARAMETER	**COST PER UNIT**	**REQUIRED QUANTITY**	
ECG Electrodes	Rs.10/lead (500 leads/pack)	3 per person – 140*3= 420 Leads required	Rs.5,000/-
EEG Skin preparation gel (Nuprep)	$31.63/tube*64= Rs.2025*3= Rs.6073/- 1$=Rs.64/-	4 oz tubes * 3	Rs.6,073/-
EEG Conductive Paste (Ten20)	$45.12/jar*64= Rs.542*3=Rs.1625/-	8 oz jars * 3	Rs.1,625/-
Microtips	Rs.1000/pack (500 Tips/pack)	2 packs	Rs.2,000/-
Micro-Centrifuge tubes	Rs.2200/pack (500 Tips/pack)	2 packs	Rs.4,400/-
Swab Storage Tube (SST)	Rs.8175/pack (50/pack)	8 packs	Rs. 65,400/-
SalivaBio Oral Swab (SOS)	Rs.9185/pack (50/pack)	8 packs	Rs.73,480/-
Alpha-amylase Kinetic Reaction Kit	Rs.30,000/-	96 Wells/kit (available* – 6 kits	Rs.1,80,000/-
Compact Discs with pre-recorded music	Rs.100/CD	10 discs	Rs.1,000/-
STAI			Rs.15,000/-
Stationery			Rs.20,000/-
Presentation in National conference			Rs. 10,000/-
Publication of article			Rs.10,000/-
TOTAL BUDGET			Rs.4,98,978/-
OVERHEAD CHARGES:(5% of the total cost)			Rs.24,948.9/-
TOTAL BUDGET			Rs.5,23,926.9/-

*Conditions similar to ICMR apply; Sample size: 140 *considering wastage during analysis and standards and controls; * Pre-intervention, during music and post-intervention recordings = 3

533978
2669
5,60,67

486058 = Budget
24303
510361

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

Physio

36750

"Disability among Elderly"

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-55: 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. 6,00,000-00 (Rupees Six lakhs only) towards research proposal "Epidemiology of Disability among Elderly in an Urban

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

and Rural area for Development of Feasible Model of Care - An Exploratory study" furnished by Dr. Lalitha K. Associate Professor, Community Medicine, M.S.Ramaiah Medical College, Bangalore for the year 2015-16. The Grant-in-aid will be released in the name of Director of M.S.Ramaiah Medical College, Bangalore 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. 6,00,000-00
2.	First Installment (50%)	Rs. 3,00,000-00
3.	Second Installment (25%)	Rs. 1,50,000-00
4.	Third Installment (15%)	Rs. 90,000-00
5.	Fourth Installment (10%)	Rs. 60,000-00

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

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital

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

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital

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. Director, M.S.Ramaiah Medical College, Bangalore
2. Dr. Lalitha K. Associate Professor, Community Medicine, M.S.Ramaiah Medical College, Bangalore

Copy to:

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

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

13. Facilities in terms of equipment, etc, available at the institution for carrying out the proposed research project. Give details of the equipments available in the institution for carrying out the research project.

The institution runs a separate geriatric clinic and provides geriatric services at concessional rates. The centre has facility for providing cataract surgery at free of cost which will improve the visual disability of the elderly. The institution has hearing aid facilities, physiotherapy, laboratory facilities at concessional rates for elderly.

14. Total research grant requested. Give details of the break up along with justification for the grants requested.

Sl.No	Expense Head		Unit cost* No. of unit	Subtotals
1.	**Honorarium**			
	Honorarium for Medico-social worker – 2 one for urban and one for rural area Medico-social worker		2 *15,000* 6 months	1,80,000
2.	**Investigations- Nil**			
3.	**Presentation in National conference**			
	Presentation in National conference (Registration fees, TA /DA, etc., only for the PI or Co-PI)		80,000	80,000
4.	**Publication of article**			
	Publication of article in national/international indexed journals/RGUHS journal		20,000	20,000
5.	**Contingencies (like stationary, photocopying, local conveyance, etc.)**			
5a.	Stationeries and printing charges			85,000
5b.	FGD meetings @ Rs 5,000 =4 in each area			40,000
5c.	Data management, printing of reports			80,000
5d.	Travel conveyance	Travel expense for monitoring @ Rs. 500@ weekly once visit (4 visits per month) for 6 months for Urban area	500*4* 6 = 12,000	84,000

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

		Travel expense for monitoring @ Rs. 2,000 @ weekly once visit (4 visits per month) for 6 months for rural area	2000*4* 6 = 48,000	
		Travel allowance for medico social workers @ Rs.2,000 pm for 2 MSW	2,000*2*6 = 24,000	
	Subtotals			5,69,000
	Institutional administrative and overhead charges @ 5% of total budget			28,450
	Grand total			**5,97,450**
	Five lakhs ninety seven thousand four hundred and fifty rupees only			

15. Possibility of Industrial applicability and technology transfer, wherever applicable.
NO

16. Utility of the project for healthcare system.

The National programme for health care of the elderly The NPHCE is an articulation of the International and national commitments of the Government. But the programme is still in initial stages. The findings of this study will help in strengthening the health care for geriatrics in general and disability in specific. This will throw light on how the health care system can gear up to provide need based relevant geriatric services.

17. Potential of the project for filing Intellectual Property Rights, wherever applicable. If Yes, guidelines of RGUHS with regard to IPR will be applicable. -
NA

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION

VIENNA INTERNATIONAL CENTRE
PO BOX 300, A-1400, VIENNA, AUSTRIA
TELEPHONE: (+43 1) 26026-4837 FAX: (+43 1) 26026-6815 http://www.unido.org E-mail: unido@unido.org

Ref: CMO/OSS/PRO/AB

Date: 20 July 2020

Subject: **Amendment No. 3 to UNIDO Contract No. 3000040233**
Provision of additional services for the training component of project "Environmentally Sound Management of Medical Wastes"

Dear Madam/Sir,

I have pleasure in forwarding herewith by DHL two (2) originals of the UNIDO Amendment no. 3 to the Contract No. 3000040233 of the above-mentioned project.

I would be grateful if you could sign, date and return one original and retain the other for your own records.

Please print the name of the person who signs each set of the Contract Amendment.

I am looking forward to receiving the above mentioned document at your earliest convenience.

Yours sincerely,

Alessandra Bravin
Associate Procurement Officer
Procurement Services Division
Department of Operational Support Services
Directorate of Corporate Management and Operations

GOKULA EDUCATION FOUNDATION
(RAMAIAH MEDICAL COLLEGE & HOSPITALS)
Attn.: Medha Y. Rao
MSR Nagar Rd Extension, M S R Nagar,
Mathikere, Bengaluru,
Karnataka 560054,
India
Tel.: +91-80-23605190 / 23601742 /23601743 / 23605408

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

AMENDMENT NO. 3

to

CONTRACT No. 3000040233

between

THE UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION (UNIDO)

and

GOKULA EDUCATION FOUNDATION (M.S. RAMAIAH MEDICAL COLLEGE)

for the provision of services relating to the

TRAINING COMPONENT OF THE PROJECT "ENVIRONMENTALLY SOUND MANAGEMENT OF MEDICAL WASTES IN INDIA"

This Amendment No. 3 to Contract No. 3000040233 and its Amendments No. 1 and No. 2 (collectively hereinafter referred to as "the Contract") is entered into between the UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION (hereinafter referred to as "UNIDO") and GOKULA EDUCATION FOUNDATION (M.S. RAMAIAH MEDICAL COLLEGE) (hereinafter referred to as the "Contractor"), jointly referred to as the "Parties" and individually as the "Party", for the following reasons:

- To increase the scope of the contracted services by expanding mainly Components No. 2, 3 and 5 with a specific focus on COVID-19 wastes;
- To supplement Annex C of the Contract (Terms of Reference dated 10 December 2016) and Annex A of Amendment No. 2 (Terms of Reference dated 24 May 2019) with the Terms of Reference dated 21 May 2020 (Annex A hereto), which shall form an integral part of this Amendment No. 3;
- To supplement the Contractor's Proposal for the Contract with the Contractor's follow-up proposal for Amendment No. 3 submitted via e-mail on 28 May 2020. The Contractor's said follow-up Proposal, although not attached hereto, is made a part hereof by way of reference;
- Consequently, to increase the Contract Price by United States Dollars one hundred eleven thousand eight hundred sixty-two (111,862.00 USD), therefore from United States Dollars one million forty-one thousand seven hundred ninety-seven (USD 1,041,797.00) to United States Dollars one million one hundred fifty-three thousand six hundred fifty-nine (1,153,659.00 USD).
- To extend the completion of the Contractor's Work until end of February 2021;

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

NOW, THEREFORE, the Parties hereto mutually agree to amend the Contract as follows:

Paragraph 1.01 of the Contract is hereby supplemented with the following provisions of *Paragraph 1.01 – Synopsis*:

1.01 Synopsis

The aim of this Contract Amendment No. 3 is to increase the scope of the contracted services, as detailed in the Terms of Reference, attached hereto as Annex A.

Paragraph 2.02 of the Contract is hereby supplemented with the following provisions of *Paragraph 2.02 – Contractor's Services*:

2.02 Contractor's Services

For the performance of its obligations under this Amendment No. 3, the Contractor shall make available sufficient work-months of personnel services in line with its follow-up Proposal for this Amendment.

Paragraph 2.04 of the Contract is hereby supplemented with the following version of *Paragraph 2.04 – Commencement and Completion of the Contractor's Work*

2.04 Commencement and Completion of the Contractor's Work

With regard to this Amendment No. 3, the Contractor's Team shall be in the Project Area and commence performance at the earliest possible date and shall complete all work no later than end of February 2021.

Paragraph 2.09 of the Contract is hereby supplemented with the following provisions of *Paragraph 2.09 – Reports*:

2.09 Reports

With regard to this Amendment No. 3, the following reports shall be submitted by the Contractor in English language in one hard copy and in electronic format compatible with MS Word and PDF to Ms. Erlinda GALVAN, Associate Industrial Development Officer and Project Manager, E.Galvan@unido.org; with a copy to Ms. Alessandra BRAVIN, Associate Procurement Officer, A.Bravin@unido.org.

a) **Progress Report No. 1 related to Amendment No. 3**
A Progress Report No. 1 related to Amendment No. 3, as detailed in paragraphs II and V of the Terms of Reference (attached hereto as Annex A), shall be submitted no later than end of September 2020.

b) **Progress Report No. 2 related to Amendment No. 3**
A Progress Report No. 2 related to Amendment No. 3, as detailed in paragraphs II and V of the Terms of Reference (attached hereto as Annex A), shall be submitted no later than end of November 2020.

c) **Final Report related to Amendment No. 3**
A Final Report related to Amendment No. 3, as detailed in paragraphs II and V of the Terms of Reference (attached hereto as Annex A), shall be submitted no later than end of February 2021.

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054

All above Reports shall include sufficient information for UNIDO to determine the extent of the work carried out at the Contractor's Home Office by the personnel referred to in paragraph 2.03 a) of the Contract. No invoice submitted for payment, pursuant to the stipulations of paragraphs 4.01 and 4.04 hereinafter shall be paid by UNIDO unless the relevant reports submitted by the Contractor and/or other information as may be available to UNIDO confirm that satisfactory progress has been achieved also in the performance of the work at the Contractor's Home Office.

Paragraph 4.01 of the Contract is hereby replaced in its entirety by the following version of *Paragraph 4.01 – Contract Price*:

4.01 Contract Price

UNIDO shall pay the Contractor for the full and proper performance of his obligations under the Contract, including this Amendment No. 3, the sum of United States Dollars one million one hundred fifty-three thousand six hundred fifty-nine (1,153,659.00 USD). Payment of this sum shall be made in the currency and in the pro-rated amounts hereinafter set forth. This sum shall cover all expenses incurred by the Contractor including, but not limited to: salaries, travels, subsistence allowance, indemnities, social charges, overheads, technical assistance and supervision costs.

Paragraph 4.02 of the Contract is hereby replaced in its entirety by the following version of *Paragraph 4.02 – Contract Ceiling*:

4.02 Contract Ceiling

The Contractor shall not do any work, provide any materials or equipment or perform any services which may result in any charges to UNIDO over and above the said sum of United States Dollars one million one hundred fifty-three thousand six hundred fifty-nine (1,153,659.00 USD) without the prior written consent of UNIDO and a formal amendment to this Contract.

Paragraph 4.03 of the Contract is hereby replaced in its entirety by the following version of *Paragraph 4.03 – Currency of Payment*:

4.03 Currency of Payment

The total Contract Price inclusive of this Amendment No. 3, of United States Dollars one million one hundred fifty-three thousand six hundred fifty-nine (1,153,659.00 USD) shall be paid in this currency.

Paragraph 4.04 of the Contract is hereby replaced in its entirety by the following version of *Paragraph 4.04 – Progress Payments*:

4.04 Progress Payments

Progress payments on account of the Contract Price, inclusive of this Amendment No. 2, set forth in paragraph 4.01 shall be made against the Contractor's invoices rendered as follows:

a) upon UNIDO's receipt of the Contract duly countersigned the sum of..... 87,077.50 **[ALREADY PAID]**

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

b) upon UNIDO's receipt and acceptance of the Contractor's First set of Progress Reports referred to in sub-paragraph 2.09 a) of the Contract, the sum of..... 217,693.75 **[ALREADY PAID]**

c) upon UNIDO's receipt and acceptance of the Contractor's Second set of Progress Reports referred to in sub-paragraph 2.09 b) of the Contract, the sum of..... 174,155.00 **[ALREADY PAID]**

d) upon UNIDO's receipt and acceptance of the Contractor's Third set of Progress Reports referred to in sub-paragraph 2.09 c) of the Contract, the sum of..... 174,155.00 **[ALREADY PAID]**

e) upon UNIDO's receipt and acceptance of the Contractor's Final Report and Audit Reports referred to in sub-paragraph 2.09 d) of the Contract, the sum of 217,693.75

f) upon UNIDO's receipt of the Contract Amendment No. 2 duly countersigned, and upon UNIDO's receipt and acceptance of the Contractor's First set of Progress Reports related to Amendment No. 2 referred to in sub-paragraph 2.09 a) of Amendment No. 2, the sum of ..... 59,857.70 **[ALREADY PAID]**

g) upon UNIDO's receipt and acceptance of the Contractor's Second set of Progress Reports related to Amendment No. 2 referred to in sub-paragraph 2.09 b) of Amendment No. 2, the sum of ..... 68,408.80 **[ALREADY PAID]**

h) upon UNIDO's receipt and acceptance of the Contractor's Final set of Progress Reports related to Amendment No. 2 referred to in sub-paragraph 2.09 c) of Amendment No. 2, the sum of 42,755.50

i) upon UNIDO's receipt of the Contract Amendment No. 3 duly countersigned, and upon UNIDO's receipt and acceptance of the Contractor's Progress Report No. 1 related to Amendment No. 3 referred to in sub-paragraph 2.09 a) hereinabove, the sum of 39,151.70

l) upon UNIDO's receipt and acceptance of the Contractor's Progress Report No. 2 related to Amendment No. 3 referred to in sub-paragraph 2.09 b) hereinabove, the sum of 44,744.80

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054

m) upon UNIDO's receipt and acceptance of the Contractor's Final Report related to Amendment No. 3 referred to in sub-paragraph 2.09 c) hereinabove, the sum of 27,965.50

Grand Total: **USD 1,153,659.00**

The making of any payment hereunder by UNIDO shall not be construed as an unconditional acceptance by UNIDO of the work accomplished by the Contractor up to the time of such payment.

This Contract Amendment No. 3, inclusive of Annex A, shall be deemed to be effective from the date of its signature by both Parties.

All other terms and conditions of the Contract shall remain unchanged and in full force and effect.

IN WITNESS WHEREOF, the Parties hereto have executed this Amendment No. 3 to the Contract.

GOKULA EDUCATION FOUNDATION (M.S. RAMAIAH MEDICAL COLLEGE)

By.....

(print name) Dr. Medha Y Rao
Principal & Dean,
M. S. Ramaiah Medical College,

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054

MSR Nagar Rd Extension, M S R Nagar,
Mathikere, Bengaluru,
Karnataka 560054
INDIA

Date:.....

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION

By.....

Ms. Fatou Haidara
Managing Director
Directorate of Corporate Management and Operations and Director ad interim
Department of Operational Support Services

UNIDO
P.O. Box 300
A-1400 Vienna
AUSTRIA

Date: 23/07/2020

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054

Annex A
Ref.: Amendment No. 3 to
Contract No. 3000040233

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION

TERMS OF REFERENCE

AMENDMENT 3 of Contract 3000040233

For provision of additional services for the training component of project

"Environmentally Sound Management of Medical Wastes"

SAP ID 104160, Grant 200000252

The Project

The Terms of Reference (TOR) is established to further those activities to be undertaken by the contractor for the GEF project "Environmentally Sound Management of Medical Wastes in India".

I. THE SCOPE OF THE PROPOSED CONTRACTED SERVICES

The Terms of Reference (TOR) sets out the responsibilities of the contractor (Gokula Education Foundation/M.S. Ramaiah Medical College, India) to undertake project activities in addition to Contract 3000040233 and its Amendment 2 signed in 2016 and 2019 respectively covering training needs assessment (*Component 1*), development of training documents, guidance manuals and awareness campaign materials on medical waste management and develop medical curriculum and training modules on medical waste management (*Component 2*); implementation of training programmes on medical waste management (*Component 3*); assessment on the influence and effectiveness of the training model systems (*Component 4*); community awareness generation programme in model districts (*Component 5*) and training on usage of microwave systems, assessment on collection/segregation efficiency and operationalization of the BAT/BEP interventions (*Component 6*).

The sudden outbreak of COVID-19 pandemic has engulfed the whole world and India as the second populous country in the world is no exception. There have been nearly 4.9 million confirmed COVID-19 infected cases in 216 countries, areas and territories across the globe. In India alone has a confirmed COVID-19 case of 101,139 and deaths of 3,163 as of 19th May 2020. The COVID-19 crisis has led to a significant increase in infections thus also increase in medical wastes generation. According to information gathered in the 5 participating States, there is already an increase of 12% in generated medical waste due to COVID-19. To contribute in the emergency plan of India, preparation of guidelines, protocols and training materials for safe management of COVID-19 waste as well as continuous training and awareness raising to include COVID-19 is of importance. Due to this emergency and based on the significant impact of the training programme that the contractor has created with the beneficiaries and stakeholders in the application of training and training materials provided under the project, it is recommended that additional training related activities should be undertaken by the contractor as follows:

a) In line with Activities 1, 5 and 8 of Component 2 of the initial contract, the Contractor will produce soft copies of Kannada translated version of Standard Operating Procedures (SOPs), training guidance manuals for integrated medical waste management and training materials as well as their distribution to

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

all HCFs (project and non-project HCFs including public, private, railways and defense, others) in the model district of Karnataka. Master copy of the translated materials in other vernacular languages will be shared accordingly to other 4 participating States for their local production and distribution.

The Contractor will also compile (in pen drives) all SOPs, training guidance manuals, training materials and video on biomedical waste management including COVID-19. Each participating States will receive e-copies of the above materials in English, Hindi and vernacular languages for mass distribution to HCFs and other relevant stakeholders.

b) In line with Activity 3 of Component 3 of the initial contract and Component 5 of Amendment 2, all HFCs including the non-project HCFs from public, private, railways, defense, others in the model district of the 5 participating States will be trained by the Contractor where outcome of the Master Trainers' training undertaken in other HCFs will be presented in a participatory manner. This will create sound biomedical waste management systems in the model districts.

c) Training manual including COVID-19 will be developed and training conducted for project Common Biomedical Waste Treatment Facility (CBWTF) in 5 participating States in accordance with Biomedical Waste Management (BMWM) Rules 2016 and its amendments.

d) Inclusion of a chapter covering the environmentally sound management of COVID-19 wastes in SOPs, guidance manuals and training materials.

The scope of work will include, but not limited, to the following activities:

	Activities	Timeframe
1.	Prepare a chapter for inclusion in guidance manual covering the best environmental practices and best available techniques (BAT/BEP) in the management of COVID-19 wastes in English as well as an exclusive handbook on SOPs and distributed across project States	Months 1-6
2.	Prepare training materials (pamphlets, posters and booklets) with illustrations explaining the best environmental practices for the management of COVID-19 wastes	
3.	Produce soft copies of Kannada translated version of SOPs and training materials on COVID-19 and distribute to all HFCs (project and non-project including public, private, railways and defense, others) in the model district of Karnataka.	
4.	Prepare e-copies (in pen drives) of all SOPs, guidance manual and training materials including COVID-19 in English for distribution to participating States	
5.	Conduct the training programme including topics on COVID-19 for all the HCFs (project and non-project) including public, private, railways, defense, others in the model district of participating States in order to establish model systems on integrated biomedical waste management	
6.	Collaborate with national/international technical experts in the development of guidance manual on integrated biomedical waste management for CBWTFs in accordance with the BMWM Rules of 2016 and its amendments	
7.	Conduct training workshop for CBWTFs' personnel in the model district of participating States	

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

II. GENERAL TIME SCHEDULE

The subcontract will start upon signature of UNIDO and the Contractor for a period of 6 months. The total costs of the subcontract will be paid in a series of payments against set milestones. These milestones will be represented by (a) signature of the subcontract; and (b) delivery of formal reports on set milestones, including – as annexes, the activity progress reports of the contractor, its national experts and subcontractors.

A total of **three (3) payments** will be made by UNIDO. The amounts to be transferred at each payment have been assessed according to the phasing of project activities as set out in the table below:

Description	Amount in US$	Time Schedule
1st payment upon delivery and acceptance by UNIDO of Progress Report 1 required for Activities 1-4	35%	Month 2
2nd payment: upon delivery and acceptance by UNIDO of Progress Report 2 required for Activities 5-7	40%	Month 4
Final payment: Upon delivery and acceptance by UNIDO of the: - Final Report comprising of: - Summary of activities undertaken under the subcontract - Final Financial Audited Report	25%	Month 7

The Contractor shall submit to UNIDO audited financial statements with respect to the GEF resources received from UNIDO under this ToR, indicating expenses incurred and their compliance with the ToR budget, and enclosing supporting documentation.

III. PERSONNEL IN THE FIELD

The Contractor shall provide personnel including technical and support staff exclusively for this project. The key personnel to be engaged in this contract must have the following qualifications /experience:

- Post graduate degree in Medicine /Environmental Sciences/ Environmental Engineering/Microbiology/ Life Sciences/ Public Health / Hospital Administration or any other interdisciplinary subject
- Minimum 3 years of experience in implementation of Bio Medical Waste Management and Handling Rules
- Experience in implementation of training programmes for the stakeholders of Biomedical Waste Management
- Experience in Communication and dessimination of Information, Information Technology.

IV. LANGUAGE REQUIREMENTS

The working and reporting language of the contract is English.

V. DELIVERABLES

Reports for submission to UNIDO should be prepared in English and be made available in both hardcopy and electronic formats. The contractor will be responsible for compiling the reports of the national experts and

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

subcontractors it engages to undertake any of the activities set out above. The following are the deliverables:

Activities	Deliverables	Payment
Progress Report 1: ***Inclusion of COVID-19 in SOPs, guidance manual and training materials***	- Chapter on management of COVID-19 wastes - Training materials on COVID-19 - Soft copies of SOPs, and training materials in Kannada version - E-copies of SOPs, guidance manual, training materials including COVID-19 in English for distribution to participating States	1st payment
Progress Report 2: ***Training programme including COVID-19 to HCFs in model districts of participating States***	- Workshop proceedings - List of trained HCFs (project and non-project) including public, private, railways, defense, etc.	2nd payment
Development of guidance manual for CBMWTFs and training of personnel	- Training reports - Guidance manual for CBMWTFs	2nd payment
Final report - Summary of activities undertaken under the subcontract - Audited financial statement	- Summary of activities undertaken including annexes - final financial audit statement	Final payment

VI. EQUIPMENT COMPONENT

The contract does not include supply of equipment.

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

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-PT-362:2015-16 DATE:07-01-2016

Pursuant to the approval of the Syndicate, sanction is hereby accorded for release of grant-in-aid amounting to Rs. 50,000-00 (Rupees Fifty thousand only) towards research proposal "Should physical activity questionnaires includes

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

information on stair climbing?-A mixed methods study" furnished by Dr. V. Sundar Kumar, Assistant Professor, M S Ramaiah medical College, Bangalore for the year 2015-16. The Grant-in-aid will be released in the name of Principal of M S Ramaiah Physiotherapy College, Bangalore 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. 50,000-00
2.	First Installment (50%)	Rs. 25,000-00
3.	Second Installment (25%)	Rs. 13,000-00
4.	Third Installment (15%)	Rs. 7,000-00
5.	Fourth Installment (10%)	Rs. 5,000-00

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

PRINCIPAL AND DEAN
M.S. Ramaiah Medical C...
& Teaching Hospital
Bangalore - 560 054.

PS

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

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054

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. The Principal, M S Ramaiah Physiotherapy College, Bangalore
2. Dr. V. Sundar Kumar, Assistant Professor, M S Ramaiah Medical College, Bangalore

Copy to:

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

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

PS

5. Amount of grant-in-aid asked for (details are to be furnished in Section B)

	1st year	2nd year	Total	
i. Honorarium for Staff (Upto 30% of the total project cost)	30,000	Nil	30,000	15,0
ii. Cost per test done outside (in case if the concerned tests are not done in the institutions)	Nil	Nil	Nil	Nil
iii. Presentation in National conference (Registration fees, TA /DA, etc., only for the PI or Co-PI)	25,000	Nil	25,000	15,00
iv. Publication of article in national/international indexed journals/RGUHS journal	50,000	Nil	50,000	Nil
v. Contingencies (like stationary, photocopying, local conveyance, etc.)	15,000	Nil	15,000	20,00
Total	1,20,000		1,20,000	50,00

6. Institution responsible for the research project

Name of the Principal/Director	Dr. A.C.Ashok
Postal address	M.S. Ramaiah Medical College & Teaching Hospitals MSRIT Post, MSR Nagar, Bangalore - 560054
Telephone	Tel: 080-2360 5190 / 1742 / 1743 Mobile No.9341238027 FAX No.080 23605190
	E-mail: msrmedical@gmail.com; msr_medical@dataone.in

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

CLINICAL TRIAL AGREEMENT
Protocol # MYL-Her 3001

This Clinical Trial Agreement ("Agreement") between

INC Research UK Limited with registered offices located in the United Kingdom at Riverview, The Meadows Business Park, Station Approach, Blackwater, Camberley, Surrey GU17 9AB, UK, including its affiliates, subsidiaries, and specifically its parent company INC Research, LLC (hereinafter "INC Research")

and

M S Ramaiah Medical College and Hospitals, with a place of business at MSRIT Post, new Bel Road, Bangalore-560054, India ("Institution")

and

Dr.Vinayak V Maka with a place of business at M S Ramaiah Medical College and Hospitals, with a place of business at MSRIT Post, new Bel Road, Bangalore-560054, India ("Principal Investigator")

When signed by all parties, is effective as of date of last signature.

By separate agreement, MYLAN GmbH with a principal place of business at Thurgauerstrasse 40, CH-8050 Zurich, Switzerland ("Sponsor") has engaged INC RESEARCH, LLC, a contract research organization, with a principal place of business in the United States at 3201 Beechleaf Court, Suite 600, Raleigh, NC 27604-1547 USA acting as an independent contractor, to act on behalf of Sponsor for the purposes of transferring certain obligations in connection to this Agreement, said obligations including negotiations and execution of the Agreement and payment administration of grant amounts described hereunder.

Sponsor wishes to support a clinical trial entitled "A MULTICENTER, DOUBLE-BLIND, RANDOMIZED, PARALLEL-GROUP, PHASE III STUDY OF THE EFFICACY AND SAFETY OF HERCULES PLUS TAXANE VERSUS HERCEPTIN® PLUS TAXANE AS FIRST LINE THERAPY IN PATIENTS WITH HER2-POSITIVE METASTATIC BREAST CANCER" ("Protocol") to be conducted at Institution and to involve Trial Subjects ("Trial").

The parties agree as follows:

1. Investigators and Research Staff.

1.1 Principal Investigator. The Principal Investigator will be responsible for the direction of the Trial in accordance with applicable Institution policies.

1.2 Subinvestigators and Research Staff. Institution and Principal Investigator will ensure that only individuals who are appropriately trained and qualified assist in the conduct of the Trial as subinvestigators or research staff.

1.3 Obligations of Institution and Principal Investigator. Institution and Principal Investigator are responsible to Sponsor for compliance by all Trial personnel with the terms of this Agreement. Institution and Principal Investigator will ensure that any personnel who assist in the conduct of the Trial are informed of and agree to abide by all terms of this Agreement applicable to the activities they perform. Institution will determine which of the obligations in this Agreement it will delegate to Principal

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

In the event that the parties execute this Agreement by exchange of electronically signed copies or facsimile signed copies, the parties agree that, upon being signed by both parties, this Agreement will become effective and binding and that facsimile copies and/or electronic signatures will constitute evidence a binding Agreement with the expectation that original documents may later be exchanged in good faith.

Agreed to and Accepted:

INSTITUTION

By: _____
Signature

Dr.D.C.Sundaresh
Printed Name

PRESIDENT – MSRCRC
Title

1.12.2014
Date

INC RESEARCH UK LIMITED

By: _____
Signature

Kirit Sacnden
Printed Name

Manager, Site Contracts
Title

27 NOV 2014
Date

PRINCIPAL INVESTIGATOR

By: _____
Signature

Dr. Vinayak V Maka
Printed Name

Associate prof. Medical Oncology
Title

29. NOV. 2014
Date

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

2016-22

CLINICAL TRIAL AGREEMENT

("Agreement")

between

Boehringer Ingelheim India Private Limited
1102, Hallmark Business Plaza,
Gurunanak Hospital Road,
Bandra (East), Mumbai- 400051
VAT-ID-No. 27310359308V.. Taxpayer Ident. No.: MUMB12332F
("Sponsor)

Authorised Signatory
Bandra (E) Branch

And

M.S. Ramaiah Medical College & Hospitals,
MSRIT Post, New BEL Road
Bangalore-560054, Karnataka, India
("Institution")

And

Dr. Uma Maheshwari
Department of Respiratory Medicine,
M.S. Ramaiah Medical College & Hospitals,
MSRIT Post, New BEL Road
Bangalore-560054, Karnataka, India
("Investigator")

RECITALS

WHEREAS, Sponsor, a research-driven pharmaceutical company, is sponsoring and conducting a clinical trial of **[Tiotropium + olodaterol fixed dose combination inhalation solution-RESPIMAT®]** ("Investigational Product") according to the Clinical Trial Protocol for BI Trial No. **[BI 1237.19]** including all documents attached thereto and referenced therein ("Protocol") entitled "**[A randomised, double-blind, active-controlled parallel group study to evaluate the effect of 52 weeks of once daily treatment of orally inhaled tiotropium + olodaterol fixed dose combination compared with tiotropium on Chronic Obstructive Pulmonary Disease (COPD) exacerbation in patients with severe to very severe COPD. [DYNAGITO]]**" as amended **(BI 1237.19)**, incorporated herein by reference and provided to Institution and/or Investigator by the Sponsor under separate cover in the regulatory document package; and

WHEREAS, Sponsor seeks to engage the services of Institution and Investigator to carry out the Trial in accordance with the Protocol; and

WHEREAS, Institution operates a facility engaged in research activities and services including the creation, implementation and documentation of clinical research, testing and trials and desires to participate as a site for the conduct of the Trial, as contemplated by this Agreement; and

WHEREAS, Investigator is engaged in medical research on behalf of Institution and desires to participate in and serve as the principal Investigator on behalf of Institution and to conduct clinical investigations as part of the Trial, as contemplated by this Agreement.

NOW, THEREFORE, Parties hereto agree as follows:

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

SS WHEREOF, the Parties have executed this Agreement in three [3] originals by their thorized representatives

Boehringer Ingelheim India Pvt Ltd

By: _____

Name: **Dr. Viraj Suvarna**
Title: **Medical Director**

Date: 28/11/14

By: _____

Name: **Thomas Wilmesmeier**
Title: **Finance Director**

Date: 11/12/14 **Stamp:**

BOEHRINGER INGELHEIM INDIA PVT. LTD. Mumbai 400 051.

INSTITUTION

By: _____

Name: Dr. D.C. SUNDARESH
President
M.S. Ramaiah Clinical Research Centre

Title: President, M. S. Ramaiah Clinical research Centre

Date: 10/Dec/2014 **Stamp:**

INVESTIGATOR:

By: _____

Name: **Dr Uma Maheshwari K**

Date: 10 DEC '14 **Stamp:**

10 Dec 2014
Dr. Uma Maheshwari K.
KMC Reg. No. 40811
Respiratory Medicine

Dr. Uma Maheshwari K.
KMC Reg. No. 40811
Respiratory Medicine

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

2016 - 18.

CLINICAL TRIAL AGREEMENT

THIS AGREEMENT is made and entered into effective as of 4-DEC-09, (hereinafter "Effective Date") by and between **BRISTOL-MYERS SQUIBB INDIA PRIVATE LIMITED,** a company incorporated under the Companies Act, 1956 having its registered office at 1st floor, "A" Block, Shiv Sagar Estate, Dr. Annie Besant Road, Worli, Mumbai - 400 018 (hereinafter "SPONSOR"),

Gokula Metropolis Clinical Research Centre,
M.S. Ramaiah Memorial Hospital, New BEL Road, MSRIT Post, Bangalore-560054

a profit corporation in **KARNATAKA** of **Gokula Metropolis Clinical Research Centre, M.S. Ramaiah Memorial Hospital, New BEL Road, MSRIT Post, Bangalore-560054,** India (hereinafter "INSTITUTION ").

And

Dr. B.S Satyaprakash
Prof. & Head, Dept. of gastroenterology,
M.S. Ramaiah Memorial Hospital, New BEL Road, MSRIT Post, Bangalore-560054
[Herein referred to as "Principal Investigator"]

RECITALS

WHEREAS, SPONSOR conducts business in the research, development, manufacture and sale of pharmaceutical, nutritional and healthcare products, and

WHEREAS, SPONSOR desires INSTITUTION and Principal Investigator to conduct a clinical trial and INSTITUTION and Principal Investigator desires to conduct same, said trial being entitled:

Study Title: Randomized, Observational Study of Entecavir to Assess Long-term Outcomes Associated with Nucleoside/Nucleotide Monotherapy for Patients with Chronic HBV Infection: The REALM Study

Protocol Number: AI463-080

(said study, as it may be amended or supplemented from time to time in accordance with this agreement, hereinafter referred to as the "Study") and

WHEREAS, SPONSOR has contracted with **PPD PHARMACEUTICAL DEVELOPMENT INDIA PRIVATE LIMITED** (hereinafter "CRO") to coordinate and/or perform certain activities required for the conduct of the Study.

NOW, THEREFORE, subject to the terms, conditions and covenants hereinafter set forth, INSTITUTION, Principal Investigator and SPONSOR agree as follows:

The Greater Bombay Co-operative Bank Ltd. Unit No G-1, Wing B Silver Astra Apt., J.B. Nagar, Andheri (E), Mumbai-400059.
D-5/STP(V)/CR/ 024/03/05/212-215
INDIA STAMP DUTY MAHARASHTRA Rs. 0017971-PB5283

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

(f) Principal Investigator and INSTITUTION may not use the Technology for any purpose other than performance of the obligations required by the Protocol, as set forth in this Agreement and the Protocol. Principal Investigator and INSTITUTION shall allow only those people directly involved in the conduct of the Study access to the Technology. SPONSOR agrees to provide Principal Investigator with maintenance and repair service for the Technology during the Study. At no time shall Principal Investigator and INSTITUTION attempt to repair, fix or correct any errors or technical problems related to the Technology.

IN WITNESS WHEREOF, Principal Investigator, INSTITUTION and SPONSOR have caused this Agreement to be executed in multiple counterparts by their duly authorized representatives.

BRISTOL-MYERS SQUIBB INDIA PRIVATE LIMITED

By: **Mr. Alok Sonig**

Title: M.D. BMS INDIA

Date: 4-DEC-09

GOKULA METROPOLIS CLINICAL RESEARCH CENTRE, M.S.RAMAIAH MEMORIAL HOSPITAL, BANGALORE

By: _____

Title: Head of Operations

Date: 18 Nov 09

Permanent Account Number: **AACCP1414E**

I HAVE READ AND UNDERSTAND THE ABOVE AGREEMENT AND AGREE TO ABIDE BY THE TERMS THEREOF:

Dr. B.S Satyaprakash
PRINCIPAL INVESTIGATOR

18/11/09
Date

ACKNOWLEDGED BY PPD PHARMACEUTICAL DEVELOPMENT INDIA PRIVATE LIMITED

Name: _____

Virendra Alate
Head of Clinical Management, Central India
PPD Pharmaceutical Development India Pvt. Ltd.
01-Dynasty B-Wing (Kanakia Spaces), Andheri-Kurla Rd.
Mumbai-400059, India

Title: _____

Date: 23 Nov 2009

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 0..

2017-19 (1)

CLINICAL STUDY AGREEMENT

This Clinical Study Agreement (hereinafter 'Agreement') is made,

BETWEEN

Roche Products (India) Private Limited, an Indian Company, having it's registered office at "The Capital", 15th Floor, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, INDIA, (hereinafter called as **"RPIPL",** which expression unless repugnant to the context shall mean and include its successors-in-interest and permitted assigns) of the FIRST PART;

AND

M.S.Ramaiah Medical College and Hospitals (hereinafter referred to as **"Institution"**, which expression unless repugnant to the context shall mean and include its successors-in-interest and permitted assigns) of the SECOND PART;

AND

Dr.Nalini Kilara working as Senior Prof.And Head, having his place of business at, **M S Ramaiah Medical College and Hospital, New BEL Road, (Gokula extension) MSR Nagar, Bangalore 560094** (hereinafter called as **"Principal Investigator or P.I."**, which expression unless repugnant to the context shall mean and include his legal heirs, representatives, successors and permitted assigns) of the THIRD PART;

(each a "Party" and collectively "Parties)

WHEREAS, Roche Group has the Intellectual Property Rights in respect of the product - **Perjeta RO4368451**) (hereinafter called as "Product")

WHEREAS, RPIPL wishes to engage the P.I., to carry out the research in respect of clinical study titled **"A Phase IV, Multicenter, Open-Label, Single-Arm Study Of Pertuzumab (In Combination With Trastuzumab And Docetaxel) In First Line Treatment Of Indian Patients With Her2-Positive Advanced (Metastatic Or Locally Recurrent) Breast Cancer"** (hereinafter "The Study") as defined in the Protocol No. "ML29282" {'Protocol'};

WHEREAS, the PI and Institution are willing to conduct the Study on the terms and conditions set forth in this Agreement. The P.I. shall conduct the Study at Institution. ("PI and Institution collectively called as Site");
NOW THEREFORE, the Parties hereto have agreed as follows.

EFFECTIVE DATE: This Agreement will become effective on the date of approval of the Study by Drugs Controller General of India or on the date of approval of the Study by the Ethics Committee or on the date on which this Agreement is last signed by the parties, whichever date is later, and shall continue until completion of study or until terminated in accordance with the provision in Clause 14

1. PROTOCOL AND INVESTIGATOR BROCHURE

The scope and nature of the clinical study to be performed under the responsibility of the P.I. and Institution will be in accordance with Protocol number **"ML29282"**.

THE KAPOL CO-OP. BANK LTD. FORT BRANCH AUTHORISED SIGNATORY

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

IN WITNESS WHEREOF, Parties through their authorized representatives have signed this Agreement.

I. **Signed on behalf of Roche Products (India) Pvt. Ltd.**

11 Aug 2015

Dr. Aditi P. Parekh
Associate Director – Clinical Operations

Date

11 August 2015

Mr. Sachin Bobhate
Senior Manager – Legal and Admin.

Date

II. **I hereby agree to the above conditions:**

Principal Investigator (P.I.)
Dr.Nalini Kilara
M.S.Ramaiah Medical College and Hospitals
New BEL Road , MSRIT Post
Bangalore -560054

Date

III. **Signed on behalf of M.S.Ramaiah Medical College and Hospitals**

18/8/15

Date

Authorized signatory from Institution

Name: Dr.D.C.Sundaresh

Designation: President- MSRCRC

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

2017-14

Reliance Life Sciences Pvt. Ltd.
R-282, TTC Area of MIDC, Thane - Belapur Road,
Rabale, Navi Mumbai - 400 701, Maharashtra, INDIA.
Phone: +91-22-4067 8000 • Fax: +91-22-4067 8099

Reliance
Life Sciences

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (the Agreement) is entered on the 14th day of August 2014 between **Dr. K C Gurudev ("Investigator")** Senior Professor & HOD, Department of Nephrology at, M S Ramaiah Medical College and Hospitals, New BEL Road, MSRIT Post, Bangalore - 560054 Karnataka, India and **M S Ramaiah Medical College and Hospitals** ("**Institution**") having its address at New BEL Road, MSRIT Post, Bangalore - 560054 Karnataka, India and **Reliance Life Sciences Pvt. Ltd.**; through its **Clinical Research Business** ("**CRO/Reliance**"), with a registered office at Dhirubhai Ambani Life Sciences Centre, Plot no. R - 282, TTC Area of MIDC, Thane Belapur Road, Rabale, Navi Mumbai 400 701, India.

"Investigator", "Institution", and "Reliance" are hereinafter collectively referred to as 'Parties" and individually as a 'Party".

PROTOCOL NUMBER:	**RLS/TP/2012/03**
PROTOCOL TITLE:	**Prospective, multi-centre, randomized, open-label, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of *R-TPR-026/* Aranesp® when given subcutaneously in patients for correction of anemia due to Chronic Kidney Disease (CKD).**
STUDY PRODUCT:	**R-TPR-026**
SPONSOR:	**Reliance Life Sciences Pvt Ltd**
INVESTIGATOR	**Dr. K C Gurudev**
INSTITUTION/SITE:	**Department of Nephrology, M S Ramaiah Medical College and Hospitals, New BEL Road, MSRIT Post, Bangalore - 560054 Karnataka, India**

WHEREAS, Clinical Research Business of Reliance Life Sciences is a Contract Research Organization ("CRO") that is engaged in providing clinical trials management and related clinical development services on a contract basis to the pharmaceutical and biotechnological industries;

WHEREAS, Reliance wishes to engage the Investigator to carry out the clinical study set out and described in protocol **RLS/TP/2012/03** and the Investigator is able and willing to conduct a clinical trial (the "Study"), in accordance with the above-referenced Protocol (the "Protocol" and any subsequent amendments thereto) on the terms and conditions set forth in this Agreement. CRO wishes to contract with the Investigator for conducting the Study at the Institution.

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore-560 054.

provision shall not be affected thereby and shall be given full effect without regard to the invalidity or unenforceability of the remainder of this Agreement. Notwithstanding anything herein seemingly to the contrary, any party may seek injunctive relief from a court of competent jurisdiction to prevent or limit damage to that party's intellectual property.

17.10 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which shall constitute the same instrument. This Agreement shall be effective upon full execution by facsimile or original, and a facsimile signature shall be deemed to be and shall be as effective as an original signature.

ACKNOWLEDGED AND AGREED BY
RELIANCE LIFE SCIENCES PVT. LTD:

By: V. Ras Sett
fa
Name: Ramaprasad J
Title: Head – Finance and Accounts
Date: 14.08.2014

ACKNOWLEDGED AND AGREED BY INVESTIGATOR:

By: _____
Name: Dr. K C Gurudev
Title: Senior Professor &HOD, Department of Nephrology,
Date: 23/8/14

ACKNOWLEDGED AND AGREED BY THE INSTITUTION:

By: _____
Name: Dr D C Sundaresh
Title: President- M S Ramaiah Clinical Research Centre
Date: 26.08.2014

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

தமிழ்நாடு तमिलनाडु TAMILNADU

AS 136262

R. T. KRIPAKARAN
L.No.18 / CH (S) 2008 Dt: 03-12-2008
VELACHERY, CHENNAI - 600 042.

ICON CLINICAL RESEARCH INDIA (P) LTD

35073
17/12/13

CLINICAL STUDY AGREEMENT
between
ICON Clinical Research India Pvt Ltd
and
M. S. Ramaiah Medical College and Hospitals
and
Dr. Arun Narayan

Pfizer Protocol # B1851140

This Clinical Study Agreement ("Agreement") between

ICON Clinical Research India Pvt Ltd, Campus 3A - 2nd Floor, RMZ Millennia Business Park, #143, Dr. M. G. R. Road, Kandanchavady, Chennai – 600096, Tamil Nadu, India ("CRO")

and

M. S. Ramaiah Medical College and Hospitals, with a place of business at **New BEL Road, MSRIT Post, Bangalore – 560054, Karnataka, India** ("Institution"),

and

Dr. Arun Narayan, with a place of business at **Department of Medicine, M. S. Ramaiah Medical College and Hospitals, New BEL Road, MSRIT Post, Bangalore – 560054, Karnataka, India** ("Investigator"),

when signed by all parties, is effective as of **24 Jan 2014**.

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

(d) if the Institution, its employees or agents shall have made any admission in respect of such claim or proceeding or taken any action relating to such claim or proceeding prejudicial to the defence of it without the written consent of Wyeth Ltd, such consent not to be unreasonably withheld provided that this condition shall not be treated as breached by any statement properly made by the Institution, its employees or agents in connection with the operation of the Institution's internal complaint procedures, accident reporting procedures or disciplinary procedures or where such statement is required by law.

5. Wyeth Ltd. shall keep the Institution and its legal advisers fully informed of the progress of any such claim or proceeding, will consult fully with the Institution on the nature of any defence to be advanced and will not settle any such claim or proceeding without the written approval of the Institution (such approval not to be unreasonably withheld).

6. Without prejudice to the provisions of paragraph 4(c) above, the Institution will use its reasonable endeavours to inform Wyeth Ltd. promptly of any circumstances reasonably thought likely to give rise to any such claim or proceeding of which it is directly aware and shall keep Wyeth Ltd. reasonably informed of developments in relation to any such claim or proceeding even where the Institution decides not to make a claim under this indemnity. Likewise, Wyeth Ltd. shall use its reasonable endeavours to inform the Institution of any such circumstances and shall keep the Institution reasonably informed of developments in relation to any such claim or proceeding made or brought against Wyeth Ltd. alone.

7. The Institution and Wyeth Ltd. will each give to the other such help as may reasonably be required for the efficient conduct and prompt handling of any claim or proceeding by or on behalf of Subjects (or their dependants).

8. For the purpose of this indemnity, the expression "agents" shall be deemed to include without limitation any nurse or other health professional providing services to the Institution under a contract for services or otherwise and any person carrying out work for the Institution under such a contract connected with such of the Institution's facilities and equipment as are made available for the Study under paragraph 2 above.

SIGNED for and on behalf of the **M. S. Ramaiah Medical College and Hospitals**

Signed: ..... Printed: Dr. D. C. Sundaresh

Title: **President – M. S. Ramaiah Clinical Reseach Centre** Dated: 12 Feb 2014.

SIGNED by **Dr. Arun Narayan (Investigator)**

Signed: ..... Dated: 04/02/2014

Title: **Sr. Prof., Dept. of Medicine, M. S. Ramaiah Medical College and Hospitals**

SIGNED for and on behalf of **Wyeth Ltd. (Subsidiary of Pfizer Inc.)**

Signed: ..... Printed: **Denzil Benjamin**

Title: **Sr. Dir. Clinical Trial Mgmt, ICON Clinical Research** Dated: 27/JAN/2014

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

CLINICAL TRIAL AGREEMENT

THIS AGREEMENT IS MADE AND ENTERED INTO BY AND BETWEEN:

- SHANTHA BIOTECHNICS LIMITED
  a company organized and existing under the laws of India, having its registered office at 3rd and 4th Floors, Vasantha Chambers, H. No. 5-10-173, Fateh Maidan Road, Basheerbagh, Hyderabad – 500 004, Telangana - India;

  (Hereinafter referred to as the "**Sponsor**")

AND:

- **M. S. Ramaiah Medical College and Hospitals**
  An institution incorporated under the laws of India, having its registered head office at New BEL Road, MSRIT Post, Bangalore – 560054.

  (Hereinafter referred to as the "**Institution**")

- and –

- Dr. Somashekar
  Practicing at Department of Pediatrics as a Professor

  (hereinafter referred to as the "**Principal Investigator**")

With each of the parties collectively or individually referred to as "Party" or "Parties"

THIS AGREEMENT RELATES TO THE FOLLOWING CLINICAL TRIAL:

A Phase III Bridging study to evaluate Immunogenicity and Safety of a Pentavalent vaccine (DTwP-HepB-Hib) Shan5 (with Shantha pertussis) as compared to the licensed vaccine, Shan5 (with imported pertussis) when administered as three dose primary series at 6-8, 10-12 and 14-16 Weeks of Age in Healthy Indian Infants.
Code: SH505

Initial here

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the date written above in Section 13.

The SPONSOR

Signature: _____
Name: : N. Rajasekar
Title: CFO & Secretary
Date: 15/10/2014

The INSTITUTION

Signature: _____
Name: Dr. D.C. Sundaresh
Title: President, MSRCRC
Date: 13/10/14

The SPONSOR

Signature: _____
Name: Dr. Mandeep Singh Dhingra,
Title: Chief Clinical, PV & CQA Officer.
Date: 15 Oct 2014.

The PRINCIPAL INVESTIGATOR

Signature: _____
Name: Dr. Somashekar A. R.
Title: Professor
Date: 11/10/2014

The CO-INVESTIGATOR

Signature: _____
Name: Dr. Mallikarjuna H. B.
Title: Professor
Date: 13/10/2014

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

DHR Anuradha

INDIAN COUNCIL OF MEDICAL RESEARCH
V. Ramalingaswami Bhawan, Ansari Nagar, New Delhi – 110 029
Phone : 26588980, 26588707, 26589336, 26589745, 26589873,
FAX: 011-26588662, 26589791, GRAM : SCIENTIFIC,
Web-site: www.icmr.nic.in, e-mail: icmrhqds@sansad.nin.in

No.GIA/44/2014-DHR

Dated: 04/12/

Subject: Grant-in-aid Scheme of the Department of Health Research for "Metabolic risks associated with Antipsychotic Drugs:A Cross Sectional Study"under Dr. Anuradha HV

OFFICE MEMORANDUM

Reference 'this office letter of even No.DHR dated 04/12/2014

The Secretary DHR and Director-General, ICMR sanctions the payment of **Rs.3,83,670/- (Rupees Three lakh eighty three thousand six hundred seventy only)** for the above stated project. The amount of **Rs. 3,83,670/-** may be debited in the provision of **Rs. 7,67,340/-** made for the above mentioned research scheme as 1st Installment of 1st year grant for incurring expenditure in connection with above mentioned research scheme.

A formal bill for **Rs. 3,83,670/-** is sent herewith for payment by **RTGS/Electronic Transfer**/cheque/demand draft to The Principal and Dean, M.S. Ramaiah Medical College, And hospital, MSR Nagar, MSRIT Post, Bangalore – 560 054 (Mandate form enclosed)

(Arti Chawla)
Administrative Officer
for Director General

Accounts Section-V : -

1. Copy to :.The Principal and Dean, M.S. Ramaiah Medical College, And hospital, MSR Nagar, MSRIT Post, Bangalore – 560 054. The amount of Rs. **3,83,670/-** as 1st installment of 1st year will be sent to you by Electronic Transfer in due course. The grant has been sanctioned on the conditions laid down in our letter referred to above.
2. Dr. Anuradha H.V., Associate Professor G-II, Department of Pharmacology, M.S. Ramaiah Medical College and Hospitals, Bangalore – 560 054.
3. Finance Section. **RFC No. DHR/GIA/79/Inter-Sectoral Convergence/2014-15 dated 15.10.2014.**
4. Mr. R.K. Ahluwalia, Under Secretary to the Govt., Department of Health Research, 2nd Floor, Indian Red Cross Society Building, Red Cross Road, New Delhi – 110001.
5. Head, Division of BMS, Indian Council of Medical Research, Ansari Nagar, New Delhi

For Director-General

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

DHR

INDIAN COUNCIL OF MEDICAL RESEARCH
V. Ramalingaswami Bhawan, Ansari Nagar, New Delhi – 110 029
Phone : 26588980, 26588707, 26589336, 26589745, 26589873,
FAX: 011-26588662, 26589791, GRAM : SCIENTIFIC,
Web-site: www.icmr.nic.in, e-mail: icmrhqds@sansad.nin.in

No.GIA/44/2014-DHR

Dated: 04/12/2014

To

The Principal and Dean
M.S. Ramaiah Medical College,
And hospital,
MSR Nagar, MSRIT Post,
Bangalore 560 054

Subject: Grant-in-aid Scheme of the Department of Health Research for "Metabolic risks associated with Antipsychotic Drugs:A Cross Sectional Study" under Dr. Anuradha HV,

Dear Sir/Madam,

In pursuance of letter number of V.25011/226/2014-GIA/HR dated 24th September, 2014 from the Deptt. of Health Research (Ministry of Health & Family Welfare), approval of the Director-General of the Indian Council of Medical Research (ICMR) is hereby conveyed for the funding of the above mentioned research project, initially for a period of one year from **01.11.2014** subject to extension upto the total duration as specified in para 3 below.

2. The Director-General, ICMR also sanctions the budget allotment of **first year of Rs. 7,67,340/- (Rupees Seven lakh sixty seven thousand three hundred forty only)** as detailed in the attached statement **(Annexure-I).**

3. The component wise break - up of the total budget for whole duration as sanctioned is given in the enclosed statement **(Annexure-II).**

4. The approved total duration of the research scheme is **One Years.**

5. The project is covered under the component **"Research studies with emphasis on public health"** of the aforesaid Scheme.

6.The payment of grant-in-aid will be further subject to the Rule 206 to 215 of provisions of GFR-2005/DFPR-1978/Receipt and Payment Rules 1983 (as amended from time to time) and the following terms and conditions:

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

a. The project would deem to have become operative on the day the grant is received by the Investigator. This date would have to be communicated by the host Institute to the DHR/ICMR. It will in no case be later than one month after the receipt of the grant by the Institute. The grant of the project will be released in favour of " **The Principal and Dean, M.S. Ramaiah Medical College, And hospital, MSR Nagar, MSRIT Post, Bangalore – 560 054.**"

b. The funds will be released in installments biannually. The first installment of 1st Year budget as sanctioned is being released along with this approval letter. It would include the entire grant for purchase of equipment, and recurring grant for six months.

c. The Host Institute would be required to submit the periodical/annual progress report, the final completion report and the audited Utilization Certificate annually etc. as per provisions of the scheme guidelines.

d. The 2nd installment of the year would be released based on the submission of the Utilization Certificate (UC) along with the item-wise statement of expenditure, for at least 70% of the previously released grant, duly certified by the designated Accounts Officer of the Host Institute and the Principle Investigator.

e. Steps to procure the approved equipment should be initiated immediately (to avoid escalation of cost) following the prescribed norms of the host institution.

f. The salary of staff appointed on the project should be paid as indicated in the budget statement attached. An undertaking would be furnished by the host institution that the staff will be engaged for the project purely on contractual basis and would have no claim to a permanent employment with the DHR/ICMR. No alteration in the staff approved can be made by the institute/research Organization without the permission of DHR/ICMR.

g. The Institute shall not dispose of or encumber or utilize the assets acquired wholly or substantially out of the Government grant for purpose other than those for which the grant has been sanctioned without prior sanction of the Government.

h. The Institute shall maintain a separate account for funds received and expenditure incurred under the said scheme.

i. If the grant or any part thereof is not utilized for the purpose for which it is sanctioned, it shall be refunded to the Government of ICMR immediately.

j. The Institute should maintain a register in Form GFR-40 of the payment and semi-permanent assets acquired wholly or mainly out of Government grants and a copy there of furnished to ICMR.

k. The register of assets maintained by the Institute shall be made available for scrutiny by the Audit.

l. A utilization certificate in the proforma prescribed (GFR 19-A) and the audited statement of accounts should be furnished to the ICMR soon after the accounts of the Institute of the year 2014-15 are audited to enable the Government to satisfy themselves that the amount has been utilized for the purpose for which it was sanctioned. These documents should be sent to the ICMR immediately after the closure of the current financial year and in any case not later than the end of the third month of the next financial year. (format enclosed)

m. The accounts of the grantee institution shall be open to inspection by the sanctioning authority and audit both by the CAG of India under the provision of CAG(DPC) Act, 1971 and internal audit wing of the O/o CCA of the Ministry, whenever the institution of organization is called upon to do so.

n. Grantee/institution receiving the grant shall furnish Achievement-cum performance report (final) two months prior of the scheduled period of the project.

o. Utilization of Travel Grant, Contingency Grant, etc would be as per the Guidelines of the Scheme, which are available on the website of ICMR/DHR (www.icmr.nic.in / www.dhr.gov.in)

p. ICMR guidelines for the extramural projects as available on the ICMR website may also be followed.

q. Any change in sanctioned budget / salary component / staff or any component of the approved project will not be entertained.

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

Other Terms & Conditions of the Grant:

I. The payment of the grant-in-aid will be made by the Electronic transfer/Demand Draft/Cheque and the receipt of the same shall be duly acknowledged by the Institute.

II. After completion of the project/activity the ownership of the physical and intellectual assets created or acquired out of the funds granted shall vest with the Department of Health Research and decision on the assets acquired shall be taken by the Department.

III. Expenditure should on no account exceed the budget sanctioned for the project. Re-appropriation of savings to meet excess expenditure under various sub heads shall not be made without the approval of the DHR/ICMR. No expenditure shall be incurred on items not sanctioned under the scheme.

IV. Extension beyond the approved duration would not be entertained. If interesting/important leads emerge that need to be followed-up, a separate proposal may be submitted. Only in exceptional cases, where a valid justification exists, and recommended by the technical Evaluation Committee and Project Approval Committee an extension can be considered to complete the project.

V. The Host Institute would be required to submit an annual progress report and also give audited statement of expenditure by the Auditor of the research Organization/Institute etc. However, the first progress report should be submitted at least three months prior to the completion of the annual report.

VI. At the completion of the project, the final report should be sent in the prescribed format (10 Copies). The report should be submitted not later than three months from the date of completion of the project. Failure to submit the Annual/Final report in time may lead to termination of the project without any notice.

The receipt of the letter may kindly be acknowledged.

Yours faithfully,

(Arti Chawla)
Administrative Officer
for Director General

Copy together with a copy of the budget statement forwarded for information to:

1. Dr. Anuradha H.V., Associate Professor G-II, Department of Pharmacology, M.S. Ramaiah Medical College and Hospitals, Bangalore – 560 054.
2. Copy together with one copy of the budget statement forwarded to the Accounts Section-V information and necessary action.
3. Copy together with two copies of the budget forwarded to budget section (Fin.) ICMR for compilation of the Council's budget **RFC No.DHR/GIA/79/Inter-Sectoral Convergence/2014-15 dated 15.10.2014**
4. IRIS Cell No. 2013-18980
5. Mr. R.K. Ahluwalia, Under Secretary to the Govt., Department of Health Research, 2nd Floor, Indian Red Cross Society Building, Red Cross Road, New Delhi 110001
6. Head, Division of BMS, Indian Council of Medical Research, Ansari Nagar, New Delhi – 110029

For Director General

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

Annexure-I

File No.GIA/59/2014-DHR:
Date of Start: 01.11.2014
Duration : 1 years
IRIS No. 2013-18980

"Metabolic risks associated with Antipsychotic Drugs:A Cross Sectional Study"under Dr. Anuradha HV,

Budget Statement
01.11.2014 to 31.10.2015
2014-15

S.No	Item	Duration
1	**Staff**	**1st Year**
	One SRF of Rs.18000/- pm +HRA 30% 5400 pm	2,80,800/-
2.	Contingencies (Recurring)	4,50,000/-
3.	Overhead charges 5%	36540/-
	Total	**7,67,340/-**

RFC No. DHR/GIA/79/Inter-Sectoral Convergence/2014-15
Dated 15.10.2014

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

ಕರ್ನಾಟಕ ಸರ್ಕಾರ

ವಿಜ್ಞಾನ ಮತ್ತು ತಂತ್ರಜ್ಞಾನ ದಾರ್ಶನಿಕ ಸಮೂಹ

ಮಾಹಿತಿ ತಂತ್ರಜ್ಞಾನ, ಜೈವಿಕ ತಂತ್ರಜ್ಞಾನ ಹಾಗೂ ವಿಜ್ಞಾನ ಮತ್ತು ತಂತ್ರಜ್ಞಾನ ಇಲಾಖೆ

ಕರ್ನಾಟಕ ಸರ್ಕಾರದ ಸಚಿವಾಲಯ, 5ನೇ ಮಹಡಿ, 5ನೇ ಹಂತ, ಬಹುಮಹಡಿ ಕಟ್ಟಡ, ಡಾ॥ ಅಂಬೇಡ್ಕರ್ ವೀದಿ, ಬೆಂಗಳೂರು-560 001

ದೂರವಾಣಿ: 080-2203 2473, ಫ್ಯಾಕ್ಸ್: 080-2226 2450, ಮೊಬೈಲ್: 94480 86957 ಇ-ಮೇಲ್: visiongroup.st@gmail.com, ವೆಬ್‌ಸೈಟ್: www.vgst.in

ಡಾ॥ ಎಸ್. ಅನಂತ್ ರಾಜ್
ಸಮಾಲೋಚಕರು

No.VGST/K-FIST(2012-13)/GRD-146/2013-14 April 15, 2014

The Principal and Dean,
M.S. Ramaiah Medical College and Teaching Hospital,
Bangalore - 560 054

Dear Sir/Madam,

Greetings from Vision Group on Science and Technology (VGST)

Sub: Release of Second & Final Instalment of "VGST - K-FIST (Level-II) grant" for the FY 2013-14 - Reg.

****

As you are aware that Dr. K.N. Chidambara Murthy, Dept. of Central Research Laboratory was awarded K-FIST (Level - II) grant during FY 2012-13. In this context, VGST would like to inform you that VGST - Auditor have issued Audited Utilization Certificate (AUC) for the utilization of I instalment of K-FIST (Level -II) grant (2012-13).

Hence, the Second & Final instalment of K-FIST (Level-II) grant of Rs.20,00,000/- (Twenty lakhs only) is being released through - State Bank of Mysore, cheque No.984776 dated 29/03/2014. Kindly return the enclosed "**ACKNOWLEDGEMENT LETTER**" to VGST.

You are requested to make all the entries such as "Budget Estimate (Non Recurring and Recurring)", "Technical Specification of the equipment (TSE) - (Annexure - 2)", "Justification for the Purchase of Equipment (JPE) - (Annexure - 3)", "Purchase Committee (P.CMT) - (Annexure - 4)", "Declaration Form (DF) - {Annexure - 5(a)}, Programme Co-ordinator's Acceptance letter (PCAL) - {Annexure - 5(b)} the "PART - A" of GRD - Book" (enclosed) and submit the GRD - Book to VGST by 30/04/2014 for VGST's approval for the "Budget Estimate" (both Non Recurring and Recurring). Obtaining VGST's approval for PART - A of GRD is mandatory vide Sl.No.14 of GTC. The Programme Co-ordinator is not allowed to procure any Equipment/Item without the Approval of PART - A (Budget Estimate) by VGST.

...2/-

PRINCIPAL AND DEAN
M.S. Ramaiah Medical Coll...
& Teaching Hospital

Your co-operation for the speedy implementation of the VGST - K-FIST (Level-II) programme is most essential. Please refer to **VGST - Guidelines, Terms and Conditions (GTC)** - (Annexure -1 of GRD - Book) for further details.

IMPORTANT NOTE:

The period of implementation of VGST programme is only 8 months from the issue of VGST grant cheque date.

Sl. No.	Particulars	dates
1	Last date to obtain the Approval of PART - A of GRD (Budget Estimate) of both Non-Recurring and Recurring	30th April 2014
2	Last date the complete the Procurement process and submit PART - B (purchase documents) for Audit purpose	30th June 2014
3	Last date to submit PART - C (Annual Progress Report / Final Progress Report)	30th November 2014

Please submit PART - A of GRD for VGST's approval by 30th April 2014 without fail.

Thanking you.

Yours faithfully,

(Dr. S. Ananth Raj)

15.4.14

Copy to:

Dr. K.N. Chidambara Murthy, Dept. of Central Research Laboratory, M.S. Ramaiah Medical College And Teaching Hospital, Bangalore - 560 054

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

Tel. : 26588895, 26588980,
26589794, 26589336
Email: headquarters@icmr.org.in
icmrhqds@sansad.nic.in

GRAM :SCIENTIFIC
FAX :011-26588662

INDIAN COUNCIL OF MEDICAL RESEARCH

V. Ramalingawami Bhawan, Ansari Nagar, Post Box Bo. 4911
New Delhi – 110029

APPLICATION FOR GRANT-IN-AID OF AD-HOC RESEARCH PROJECT

Section A
GENERAL

1. **Title of the Research Project** : Histopathological evaluation of renal allograft biopsies with emphasis on the role of C4d immunohistochemistry in the diagnosis of humoral rejection.

2. **Name and Designation of**

i) **Principal Investigator & Email**

Clement Wilfred D, MD (Patho) DNB (Patho),
Associate Professor, Department of Pathology,
M.S Ramaiah Medical College and Hospitals,
MSRNagar, MSRIT Post, Bangalore- 560054
E-mail – clement.wilfred@yahoo.com

ii) **Co-Investigator & Email**

Vijaya Viswanath Mysorekar, MD (Patho),
Senior Professor and Head of the Department, Department of Pathology,
MS Ramaiah Medical College and Hospitals,
MSRNagar, MSRIT Post, Bangalore- 560054.
E-mail – vijayamysorekar@yahoo.com

3. Duration of Research Project

i) Period which may be needed for collecting the data	2 years
ii) Period that may be required for analyzing the data	1year 6months
	6months

4. Amount of grant-in-aid asked for (details are furnished in Section B)

	1st year	2nd year
i. Staff	1,50,000	1.50,000
ii. Contingencies		
Recurring	Rs. 4,48,000	Rs.4,57,000
Non recurring (equipment)	Rs. 1,03,000	NIL
Travel	NIL	Rs. 20,000
iii. Overhead charges	Rs.22,400	Rs. 22,850
TOTAL	Rs.7,23,400	Rs.6,49,850

5. Institution responsible for the research project

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

Path-1

Name
Postal address
Telephone
e-mail
Fax No.

Department of Pathology,
M.S.Ramaiah Medical College and
Hospitals,
MSR Nagar, MSRIT Post,
Bangalore- 560054
080-23601742, 23601743, 23605190
Fax: 080-23606213
e-mail: msr_medical@dataone.in
Web: http//www.msrmc.ac.in

6. Institutional ethical clearance and Project approval (Necessary documents indicating institutional ethical clearance must be enclosed for research involving human subjects as also animal experiments).

Yes

7. Is radio tagged material proposed to be used in the project either for clinical trials or experimental purposes? **No.**

8. No recombinant DNA/Genetic engineering work is involved in the study.

9. Approval of the institutional ethics committee (IEC) should be enclosed. Guidelines for IEC for animal experiments should follow CPCSEA requirements and for human studies should follow ICMR guidelines.

The institutional ethical clearance certificate is enclosed

10. The Institution where the study is being done should ensure that there is no financial conflict of interest by the investigators. **YES**

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

DECLARATION AND ATTESTATION

i. I/We agree to submit (online) all the raw data (along with descriptions) generated from the project to the ICMR Data Repository within one month from the date of completion /termination of the project.

Signature of the:

a) Principal Investigator: Clement Wilfred Devadass D. Clement Wilfred

PROF. OF PATHOLOGY
M. S. Ramaiah Medical Colle
BANGALORE-560

b) Co-Investigator: Vijaya Viswanath Mysorekar V. Mysorekar

PROF. & HOD.
DEPT. OF PATHOLOG
M.S. RAMAIAH MEDICAL COL
BANGALORE - 560 054

c) Head of the Department: Vijaya Viswanath Mysorekar V. Mysorekar

PROF. & HOD.
DEPT. OF PATHOLOGY
M.S. RAMAIAH MEDICAL COLL
BANGALORE - 560 054

Date: 3/6/2015

Signature of the Head of the Institution with seal

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

Section - B
DETAILS OF THE RESEARCH PROJECT

1. **Title of the project**: Histopathological evaluation of renal allograft biopsies with emphasis on the role of C4d immunohistochemistry in the diagnosis of humoral rejection.

2. **Objectives:** i) To evaluate the histopathologic lesions in renal allograft biopsies
   ii) To determine the causes of early (0-6 months) and late (> 6 months post transplantation) graft dysfunction
   iii)To determine the frequency of peritubular C4d positivity by immunohistochemistry and its correlation with microvascular inflammation in humoral rejection.

3. **Summary of the proposed research** indicating overall aims of the research and importance of the research proposal.

Renal allograft biopsy (RAB) is indispensible for the diagnosis of renal transplant rejection and clinical management of patients with graft dysfunction (GD).[1,2] A diverse histopathologic range of lesions, including immunological rejection, non-rejection injury [acute ischemic tubular injury (ATN), drug toxicity, infections, obstruction /reflux, renal artery stenosis and de novo glomerular disease], recurrent primary disease and auto/alloantibody mediated diseases are encountered in RAB, many of which pose a clinical diagnostic dilemma.[3] Meticulous RAB evaluation is required for accurate and timely identification and differentiation of rejection from nonrejection causes, which is crucial for therapeutic management.[1,2,3]

The causes of GD vary between studies and are determined by differences in kidney source (cadaver, living related, living nonrelated), donor and recipient age, race and genetic variability, HLA match, presensitization, type of immunosuppressive protocol, methods of case identification and timing of biopsy, variability of renal lesions. Further there is a scarcity of information on the histopathologic patterns of GD in the native South Indian population. Thus the aim of the proposed study is to evaluate the varied histopathologic lesions in RAB and determine the causes of early and late GD in a tertiary care hospital in South India.

Banff 2007 incorporated peritubular capillary C4d (PTC C4d) staining as one of the diagnostic criteria for humoral rejection i.e. antibody-mediated rejection (AMR) along with histopathological features of tissue injury and presence of donor-specific antibody.[4,5] However many recent studies have questioned the sensitivity and specificity of C4d staining and have supported the existence of C4d negative AMR.[6,7] Several studies have shown statistically significant correlation between PTC C4d deposition and microvascular inflammation.[8,9] Thus the other aim of the study is to determine the frequency of C4d peritubular capillary staining and its correlation with microvascular inflammation in our patient population.

4. **Present knowledge and relevant bibliography including full titles of articles relating to the project.**

A study on 119 renal allograft biopsies (RAB) conducted in North India, revealed the commonest cause of graft dysfunction (GD) as nonrejection changes (47.1%) followed by T cell- mediated rejection (31.9%), humoral rejection (28.6%), interstitial fibrosis and tubular atrophy (IFTA)(12.6%), borderline changes (7.6%) and normal findings (4.2%).[10] The authors concluded that nonrejection pathology forms a significant cause of renal dysfunction in patients with renal allograft transplantation.

PRINCIPAL AND DE
M.S. Ramaiah Medical Co.
& Teaching Hospital

Another study conducted in Nepal, evaluated the histopathology of 98 graft biopsies of which 24.7% were rejection, 14.3% were due to nonrejection causes, 50.1% were normal, 1% was due to IFTA and 9.2% were nondiagnostic.[1] In the early post-transplant period humoral rejection, acute ischemic injury and T cell-mediated rejection were the major causes for GD. In the late post transplant period, transplant glomerulopathy, chronic calcineurin inhibitor toxicity, viral infections and graft senescence including donor derived disease were the major causes of GD. The authors concluded that RAB remains the gold standard for diagnosis of GD.

As C4d is an indirect sign/ footprint of an antibody response, peritubular C4d deposition (PTC C4d) (detected by immunofluorescence/immunohistochemistry) became the cornerstone of humoral rejection diagnosis. However recent data has suggested that it is no longer a sensitive marker of humoral rejection. A study done in Japan by Takeda A et al found C4d positivity only in 46.9% of humoral rejection cases (62.5% positivity in acute humoral rejection and 31.3% in chronic humoral rejection). The authors concluded that peritubular C4d deposition is not a specific marker of humoral rejection.[5]

Corrêa RRM et al in their article aimed at "identification of the role of C4d in episodes of humoral rejection" concluded that C4d was a less sensitive marker than initially thought.[7]

Pichhadze RS conducted a systematic review of the literature to re-evaluate the role of C4d in the diagnosis of acute humoral rejection of kidney allografts. They found that PTC C4d exhibited slight to moderate agreement with microvascular inflammation (glomerulitis and peritubular capillaritis).[4]

Bibliography/References:

1. Aryal G, Shah DS. Histopathological evaluation of renal allograft biopsies in Nepal: interpretation and significance. Journal of Pathology of Nepal 2012;2:172- 179.
2. D' Agati VD, Jennette JC, Silva FG. In Pathology of renal transplantation in: Donald WK, ed. Non-neoplastic kidney diseases. Washington DC: American Registry of Pathology/Armed Force Institute of Pathology. 2005:pp667-709.
3. Nickeleit V, Mengel M, Colvin RB. Renal Transplant Pathology, Chapter 29. In: Hepinstall's Pathology of the Kidney,7th ed. Jennette JC, Olson JL, Silva FG, D' Agati VD, Eds. Lippincott Williams & Wilkins, Philadelphia. 2014;2:1321-1431.
4. Pichhadze RS, Curran SP, John R, Tricco AC, Uleryk E, Laupacis A, et al. A systematic review of the role of C4d in the diagnosis of acute antibody-mediated rejection. Kidney International. 2015;87:182–194.
5. Takeda A, Otsuka Y, Horike K, Inaguma D, Hiramitsu T, Yamamoto T, et al. Significance of C4d deposition in antibody-mediated rejection. Clin Transplant 2012:26:43–48.
6. Haas M, Sis B, L. Racusen LC, Solez K, Glotz D, Colvin R B, et al. Banff 2013 Meeting Report: Inclusion of C4d-Negative Antibody-Mediated Rejection and Antibody-Associated Arterial Lesions. Am J Transplant 2014;14: 272–283.
7. Corrêa RRM, Machado JR, Vinícius da Silva M, Helmo FR, Guimarães CSO, Rocha LP, et al. The Importance of C4d in Biopsies of Kidney Transplant Recipients. Clinical and Developmental Immunology 2013:8pages.678180.
8. Satoskar AA, Lehman AM, Nadasdy GM, Sedmak DD, Pesavento TE, Henry ML, et al. Peritubular capillary C4d staining in late acute renal allograft rejection--is it relevant? Clin Transplant. 2008;22:61-7.

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

9. Verghese P, Dunn T, Najafian B, Kim Y, Matas A. The impact of C4d and microvascular inflammation before we knew them. Clin Transplant. 2013;27:388-96.
10. Philip KJ, Calton N, Pawar B. Nonrejection pathology of renal allograft biopsies: 10 years experience from a tertiary care center in north India. Indian J Pathol Microbiol 2011;54:700-5.
11. Bhowmik DM, DindaAK, Mahanta P, Agarwal SK. The evolution of the Banff classification schema for diagnosing renal allograft rejection and its implications for clinicians. Indian Journal of Nephrology 2010;20:2-8.

5. Preliminary work already done by the Investigator on this problem.

A pilot study was done in the West Indian population- "Evaluation of renal allograft biopsies for graft dysfunction and relevance of C4d staining in antibody mediated rejection" by the principal investigator (Dr Clement Wilfred D) at Institute of Kidney Diseases and Research Centre & Dr. H.L Trivedi Institute of Transplantation Sciences, Ahmadabad (host institute). Based on the results obtained the investigator has proposed to undertake this study in the South Indian population at his parent institute (M.S.Ramaiah Medical College, Bangalore).

6. Links with other ICMR projects : NIL

7. List of important publications of last 5 years of the all the investigators in the relevant fields:

The list of publications of the principal and co investigators is provided in Section C (Biodata). The principal investigator has 18 publications and the co investigator has 42 publications.

8. Detailed research plan.

8.1 Source of data

The study is a prospective study that will be conducted on "clinically indicated" renal allograft biopsies from kidney transplant recipients received in the department of pathology, M. S. Ramaiah Medical College and Hospitals, Bangalore over a duration of 2 years.

8.2 Methods of Data collection:

Prospective period: All the biopsy specimens will be processed for light and immunofluorescence microscopy and C4d immunohistochemistry as per standard protocol. For light microscopy, 3 to 4 µm thick sections will be stained with Hematoxylin and Eosin. Gomori's trichrome, periodic acid Schiff and Jones silver methenamine staining will be performed when required. Direct immunofluorescence (IF) study will be done on 3 to 4 µm thick frozen sections using fluorescein isothiocyanate conjugated goat anti- human immunoglobulin (Ig)G, IgM, IgA, Kappa, Lambda, C1q and C3 antibodies (from BioGenex). The C4d immunohistochemistry (IHC) will be done on 4 µm thick paraffin sections using "Super Sensitive Link Label HRP detection system" with rabbit anti-human C4d polyclonal antibody (BioGenex).

The data regarding patient's age, gender, allograft age, HLA match, basic renal disease, and laboratory investigations like serum creatinine, 24-hour urinary protein will be collected from the patient's case file.

Histological categories will be classified as per Banff'13 modified update diagnostic categories for renal allograft biopsies into six categories; normal (category 1),

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

humoral rejection (AMR) (category-2), borderline T-cell mediated rejection (category-3), T-cell-mediated rejection (TCR) (category- 4), interstitial fibrosis and tubular atrophy (IFTA) (category-5) and others: changes not due to rejection/ non-rejection causes (category-6).[3,6] "Revised Banff,'13 criteria for classification of AMR which includes C4d-Negative AMR will be used for AMR diagnosis.[6] Special emphasis will be laid on the first 2 criteria i.e. 1. Histological evidence of tissue injury and 2. Evidence of recent antibody interaction with vascular endothelium (PTC C4d deposits or moderate microvascular inflammation) for AMR diagnosis. Donor specific antibodies will be performed and serum tcarolimus levels will be estimated. The Banff scoring system (scores ranging from 0-3) will be used for the grading of acute and chronic changes occurring in the interstitium, tubules, glomeruli, arteries and arterioles.[3] C4d staining of the PTC will be graded as C4d0- negative, C4d1- minimal: 1-10%, C4d2- focal: 10-50%, and C4d3- diffuse > 50% PTCs.[11] PTC C4d deposition will be considered positive if grade is >C4d0 and negative if C4d0.[6]

8.3 Inclusion Criteria:

i) Optimal biopsies, defined as a specimen with at least 10 non-sclerotic glomeruli and 2 arteries;
ii) Marginal biopsies, having 7 to 9 glomeruli and 1 artery;
iii) Minimally acceptable biopsies having 7 glomeruli and 1 artery.

8.4 Exclusion Criteria:

Non- diagnostic biopsies: Specimens with < 7 glomeruli or no arteries or with only medulla.

8.5 Sample size determination:

i) Philip KJ et al (2011) in their series have observed immunological rejection (T cell mediated rejection + humoral rejection + borderline changes) in 68.1% of the renal allograft biopsies.[10] In the present study, with a relative precision of 18% and desired confidence level of 95%, the estimated sample size will be 56 cases.

ii) Takeda etal (2012) in their series have observed that 46.9% of the humoral rejections were positive for PTC C4d deposition.[5] In the present study, with a relative precision of 30% and desired confidence level of 95%, the estimated sample size for the study will be 50 cases.

8.6 Statistical Analysis of Data:

Descriptive statistics of histopathological lesions will be analysed and presented in terms of proportion and its 95% confidence interval will be estimated. The frequency of each category of renal disease will be computed. All continuous parameters will be expressed as mean and standard deviation and all qualitative variables as proportion. Fisher Exact test will be used to compare C4d score with degree of microvascular inflammation. Data will be analyzed using Microsoft Excel. $P < 0.05$ will be considered as statistically significant. The sensitivity of C4d in detecting AMR will be calculated as a/a+b [a = true positive {No. of C4d positive AMR}, b = false negative {No. of C4d negative AMR}].

8.7 Does the study require any investigation or interventions to be carried on patients or other humans or animals?

Histopathological (light and immunofluorescence microscopy) examination will be performed on the renal allograft biopsies as a part of routine protocol for diagnosis. The C4d immunohistochemistry will be performed on the paraffin embedded blocks of the same renal biopsies. No other investigation or interventions will be done specially for the purpose of the study.

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital

9. Facilities in terms of equipment, etc, available at the sponsoring institution for the proposed investigation.

Equipments needed to carry out the research work – i) Automated microtome (LEICA RM 2255), Histokinette (automatic tissue processor, LEICA TP 1020) and reagents/chemicals for preparing Hematoxylin & Eosin stained tissue sections and special stains and ii) Cryostat (LEICA CM 15105), immunofluorescence microscope (OLYMPUS Cx41) and fluorescein isothiocyanate conjugated antibodies for IgG, IgA, IgM, and C3 (BioGenex) for direct immunofluorescence is already available in the institute

10. Budget requirements (with detailed break-up and full justification).

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

		1st year	2rd year
i.	Staff – Technical	1,50,000	1,50,000
ii.	Contingencies		
ii.a	Recurring		
	Primary Kit [primary (C4d) antibody]. 1 kit (for 30-35 cases) per year.	30,000 (1 kit)	30,000 (1 kit)
	BioGenex polymer Kit (secondary antibody). 1 kit (for 30-35 cases) per year.	20,000 (1 kit)	20,000 (1 kit)
	Miscellaneous chemicals/ consumable items for C4d immunohistochemistry (Deionized water, disposable 3ml Pasteur pipettes, yellow tips, frosted microslides, cover slips, DPX, xylene, alcohols, poly L lysine, labels, tissue paper rolls, swabs etc.)	20,000	20,000
	Fluorescein isothiocynate conjugated anti-human immunoglobulin for kappa light chain deposits. 1 kit (for 30-35 cases) per year.	30,000	30,000
	Fluorescein isothiocynate conjugated anti-human immunoglobulin for lambda light chain deposits. 1 kit (for 30-35 cases) per year.	30,000	30,000
	Fluorescein isothiocynate conjugated anti-human immunoglobulin for C1q deposits. 1 kit (for 30-35 cases) per year.	30,000	30,000
	Serum tacrolimus levels (HPLC) (3300 Rs/ case)	1,00,000 (for 30 cases)	1,00,000 (30 cases)
	Donor specific antibody levels (5000 Rs/ case)	1,50,000 (for 30 cases)	1,50,000
	Stationery	5000	5000
	Data entry, typing of research reports, Computer utilities	20,000	20,000
	Publication charges (30 copies)	-	9,000
	Books	10,000	10,000
	Statistical analysis (consultancy charges)	3,000	3,000
ii.b			
	pH meter (1 in quantity) (for C4d immunohistochemistry)	10000	-
	Adjustable micro volumetric pipettes 10- 100 µl (1 in quantity) (for C4d immunohistochemistry)	7000	-
	Adjustable micro volumetric pipettes 20- 200 µl (1 in quantity) (for C4d immunohistochemistry)	7000	-
	Microwave oven (for antigen retrieval) Solo170 (1 in quantity) (for C4d immunohistochemistry)	12,000	-
	Color laser printer (1 in quantity)	18,000	-

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

	Olympus mercury lamp (model U-RFL-T) (1 in quantity) (for immunofluorescence microscopy)	**45,000**	**-**
	Color Cartridges (5 in quantity)	**4,000**	**-**
ii.c	**Travel**	**-**	**20,000**
iii	**Overhead charges (excluding equipment cost)**	**18,000**	**19,000**
	Total	**7,23,400**	**6,49,850**

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

733237/2017/SCIENTIST(KR)

पी.ए.बी.एक्स./PABX : 26588980, 26588707, 26589336, 26589745, 26589873, 26589414
फैक्स/FAX : 011-26588662, 011-26589791, 011-26589258

तार/GRAM : विज्ञानी/SCIENTIFIC
Web-site : www.icmr.nic.in
E-mail : icmrhqds@sansad.nic.in

भारतीय आयुर्विज्ञान अनुसंधान परिषद
INDIAN COUNCIL OF MEDICAL RESEARCH

स्वास्थ्य अनुसंधान विभाग (स्वास्थ्य एवं परिवार कल्याण मंत्रालय)
वी. रामलिंगस्वामी भवन, अन्सारी नगर, नई दिल्ली-110 029
DEPARTMENT OF HEALTH RESEARCH (MINISTRY OF HEALTH & FAMILY WELFARE)
V. RAMALINGASWAMI BHAWAN, ANSARI NAGAR, NEW DELHI-110 029

FORMAL BILL

A Formal bill for **Rs. 723400/- (Rupees Seven Lakh Twenty Three Thousand Four Hundred only)** as the 1st year grant to meet expenditure in connection with the research scheme **"Histopathological evaluation of renal allograft biopsies with emphasis on the role of C4d immunohistochemistry in the diagnosis of humoral rejection" PI: Dr. Clement Wilfred** for payment to **"M.S. Ramaiah Medical College, MSR Nagar, MSRIT Post Bangalore - 560054".**

A Formal bill for **Rs. 723400/- (Rupees Seven Lakh Twenty Three Thousand Four Hundred only)** is sent herewith for payment by RTGS/Electronic Transfer/Cheque/Demand draft to **"M.S. Ramaiah Medical College, MSR Nagar, MSRIT Post Bangalore - 560054".** The amount is to be debited from the HRD grant of **Rs. 30815400/-** which has already been sanctioned to Indian Council of Medical Research, New Delhi on 30th March, 2017 for awarding Fellowship under the scheme "Human Resources Development for Health Research" during the financial year 2017-18.

Dr. V.P. Singh
Scientist-D
For Director General

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

Annexure-I

No.V.25011/541-HRD/2016-HR

HRD Scheme of the Department of Health Research for **"Start-up Grant"** – the project titled **"Histopathological evaluation of renal allograft biopsies with emphasis on the role of C4d immunohistochemistry in the diagnosis of humoral rejection"** PI: **Dr. Clement Wilfred.**

Budget breakup for entire project duration:

S. No.	Head	1st Year	2nd Year	Total
Non recurring				
1.	Equipments*	103000	0	103000
Recurring				
1.	Manpower	150000	150000	300000
2.	Contingency/Consumables	448000	457000	905000
3.	Travel	0	20000	20000
4.	Overhead charges	22400	22580	44980
	Total	**723400**	**649580**	**1372980**

Annexure-II

No.V.25011/541-HRD/2016-HR

HRD Scheme of the Department of Health Research for **"Start-up Grant"** – the project titled **"Histopathological evaluation of renal allograft biopsies with emphasis on the role of C4d immunohistochemistry in the diagnosis of humoral rejection"** PI: **Dr. Clement Wilfred.**

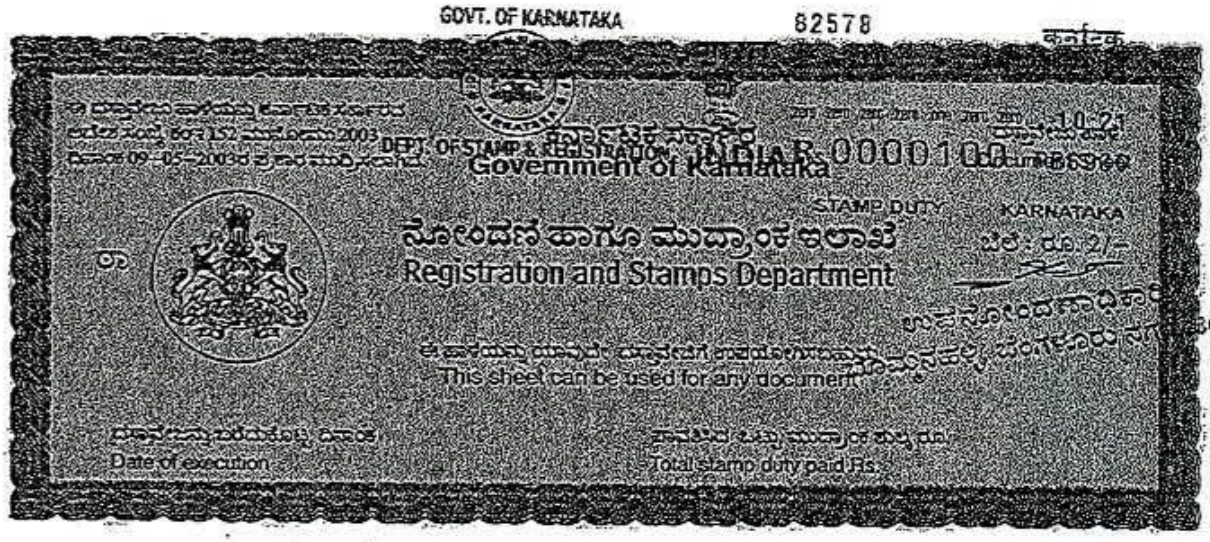
Budget breakup for 1st year release:

S. No.	Head	Amount for 1st year release
Non recurring		
1.	Equipments	103000
Recurring		
1.	Manpower	150000
2	Contingency/Consumables	448000
3.	Travel	0
4.	Overhead charges	22400
	Total	**723400**

(Rupees Seven Lakhs Twenty Three Thousand Four Hundred only)

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

Path-1



CLINICAL TRIAL AGREEMENT

This agreement is made on this 23rd Jan 2014 year(hereinafter 'Effective Date') by and between "NorwichClinical Services"having its principal place of business at Norwich Clinical Services, a company incorporated under Companies Act, 1956 and having its registered office at ACR mansion, No.147/F, 8th main, 3rd block, Koramangala, Bangalore-S600034, (hereinafter referred to as CRO),which expression unless repugnant to the context or meaning thereof shall include its successors and permitted assigns) being of the One Part;

AND

"Dr NaliniKilara"havingherprincipal place of businessat M S Ramaiah Curie Centre of oncology,M S Ramaiah Medical College and Hospitals ,MSRIT Post, New BEL road, Bangalore - 560054 (Hereinafter referred to as "Principal Investigator" or "P.I"),which expression unless repugnant to the context or meaning thereof shall include its successors and permitted assigns) being of the other Part;

And

M S Ramaiah Medical College and Hospitals, (hereinafter referred to as "Hospital/Institution")

MSRIT Post, New BEL road, Bangalore - 560054

1. BACK GROUND

1.1 WHEREAS the purpose of this agreement is for conducting clinical study having Study Title:

"An open label, multicentre, randomized, balanced, two-treatment, two-period, two-sequence,single dose, crossover, oral bioequivalence study of Melphalan Tablets 2 mg of Alvogen Pine Brook., USA compared with that of ALKERAN® (melphalan) Tablets 2 mg of GlaxoSmithKline, USA in adult patients under fasting conditions" in whichMelphalan Tablets 2

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

mg of Alvogen Pine Brook of Alvogen Pine Brook Inc.10 Bloomfield Avenue, Building B,Pine Brook, NJ 07058Tel.: +1 973 796 3400, Fax: +1 973 796 3439 is compared with that of ALKERAN® (melphalan) Tablets 2 mg of GlaxoSmithKline, USAin patients under fastingconditions,in accordance with Good Clinical Practices (GCP), Good Laboratory Practices (GLP) and ICMR Guideline 2000, on patients as stated in the protocol (hereinafter referred to as the subjects).

1.2 The SPONSOR (Alvogen Pine Brook Inc.)is a pharmaceutical Company engaged inter alia in the business of manufacturing and/or marketing of various active pharmaceutical ingredients and pharmaceuticals in finished dosage forms;

1.3 NORWICHCLINICAL SERVICES (hereinafter referred to as CRO) is a professional clinical research organization in India engaged in the business of undertaking biostudies, Clinical Trial Services and pharmacovigilance servicesin conformance to international standards.

1.4 The CROhas represented and warranted to sponsor that it has the necessary skill, experience, expertise and necessary facilities/infrastructure to provide the services contemplated under this agreement.

1.5 The CROhas also represented that all licenses, authorizations and permissions required under law for providing the services contemplated under this agreement will be obtained and that all such licenses, authorizations and permissions will be in full force and effect at the time of executing the services outlined in this agreement.

1.6 Whereas the CROdesires to enter into agreement with M S Ramaiah Medical College and Hospitals &Dr NaliniKilarato conduct the study in their hospital.

1.7 The CROhas agreed to engage Dr NaliniKilarawho is a Specialist in the therapeutic area required for the study, be a Principal Investigator for the study mentioned above.

1.8 The CROhas agreed to engage M S Ramaiah Medical College and Hospitals& the principal Investigator for providing the services contemplated under this agreement, subject to the terms and conditions contained herein.

1.9 Whereas during the term of this Agreement, the terms and conditions herein contained shall govern the services to be provided by the M S Ramaiah Medical College and Hospitals& Principal Investigator to CROunder any subsequent individual agreement for specific services to be rendered, referred to as a Specific Protocol

1.10 The Project shall be conducted as per the CRO's confidentiality requirements.

1.11 M S Ramaiah Medical College and Hospitals & the principal Investigator agree that the CRO shall have the right to enter their facility at reasonable times to inspect the facility, and the

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

Note:

- Hospital stay expenses during the study period will be paid at the end of each period.
- Lab investigation at the time of screening, before the study start and after study completion will be paid by the CRO at actuals only on production of original bills along with the investigator fee.
- Compassionate Medications to each patient will be provided as follows:
  Patient will be provided following medications as per the PI's prescription for each cycleupto a maximum of 6 cycles.
  a)Melphalan
  b)Thalidomide
  c)Prednisolone
  An indent form will be submitted by the site prior to each cycle indicating quantity of medication required for patients

- **Any adverse event experienced by the subject (whether related or unrelated) which necessitates medical treatment, the expenses will be borne by the sponsor.**

The following deductions will be made, if applicable:

- Tax deduction at source for all payments of fee unless a valid tax exemption certificate is provided by the investigator/ institution.

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

For Norwich Clinical Services Private Limited , Bangalore

Dr SaralThangam
Managing Director
Norwich Clinical Services Private Limited.

For Principal Investigator

Dr NaliniKilara
Professor & Head, Dept. of Oncology

Seal:

For Norwich Clinical Services Pvt. Ltd.

Dr.Saral Thangam
Managing Director

Seal Prof. NALINI KILARA, MD DM
HOD MEDICAL ONCOLOGY
M.S. Ramaiah Medical College & Hospital
KMC Reg No 15080

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

गुजरात गुजरात GUJARAT ... 30 JUL 2012 Y 580223

QUINTILES RESEARCH (INDIA) PVT. LTD.
B-101-106, Shapath IV,
Opp. Karnavati Club,
Sarkhej - Gandhinagar Road,
Ahmedabad - 380 051, India

PROTOCOL NUMBER:	RI-01-002
PROTOCOL TITLE:	A Randomised, Multi-centre, Double-blind, Parallel Group Study to Compare the Pharmacokinetics, Pharmacodynamics, Safety and Efficacy of Two Anti-CD20 Monoclonal Antibodies in Combination with CHOP in Patients with CD20-Positive Diffuse Large B-cell Lymphoma
PROTOCOL DATE:	16 Nov 2011
SPONSOR:	Dr. Reddy's Laboratories Ltd
PRINCIPAL INVESTIGATOR:	Dr. Nalini Kilara an employee of Institution
KEY ENROLLMENT DATE: (date by which site is to enroll at least one (1) subject)	**100 Calendar Days after Site Initiation Visit**

WHEREAS, the Investigator and Institution, (hereafter, jointly, the "Site") are willing to conduct a clinical trial (the "Study"), in accordance with the above-referenced protocol and any subsequent amendments thereto (the "Protocol") and Quintiles requests the Site to undertake such Study;

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

ii Inspect source documents, including but not limited to the hospital/ outpatient/ records, laboratory investigations relevant to the completion of the case report forms & other study related documents.

Investigator and/or Institution may hold and represent other clients, but such work should not conflict with Investigator's and Institution's Services for Quintiles, as mutually determined by Investigator, Institution and Quintiles. Investigator and Institution shall disclose to Quintiles in advance and in writing the specific nature of any potential conflict of interest or personal interest in any proposed services. Investigator and Institution represent and warrant that execution of this Agreement and performance of the services described in this Agreement do not and will not breach any other contractual and/or legal obligations or the applicable policies of any third party (including but not limited to an agreement in the nature of a confidentiality and/or non-disclosure and/or non-competition agreement) and do not require the consent of any other person, or that the proper consent has been obtained.

ACKNOWLEDGED AND AGREED BY QUINTILES RESEARCH (INDIA) PRIVATE LIMITED:

By: _____
Sucheta Srivatsa

Name: Director

Title: Head Integrated Site Services India

Date: 08 OCT 2012

ACKNOWLEDGED AND AGREED BY M. S. RAMAIAH MEDICAL COLLEGE AND HOSPITALS:

By: _____

Name: Dr D C Sundaresh

Title: President-Clinical Research

Date: 21/9/2012

ACKNOWLEDGED AND AGREED BY THE PRINCIPAL INVESTIGATOR:

By: _____

Name: Dr Nalini Kilara

Date: 20/Sep/2012

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

CLINICAL TRIAL AGREEMENT

This Agreement is made on 26th July 2010 between Biogen Idec Ltd of 70, Norden Road, Maidenhead, Berkshire, SL6 4AY, England, (Biogen Idec),and

Pharmaceutical Research Associates, India Pvt. Ltd. located at 402, B Wing, Business Square, Andheri – Kurla Road, Chakala, Andheri (E), Mumbai 400 093, India (***"PRA" or "CRO"***), and

Gokula Metropolis Clinical Research Centre, M S Ramaiah Medical College and Hospitals located at MSRIT Post, New BEL Road, Bangalore- 560054, India (the ***Institution***) and

Dr. R. Srinivasa located at Dept. of Neurology, M S Ramaiah Medical College and Hospitals, MSRIT Post, New BEL Road, Bangalore- 560054, India (the ***Investigator***).

WHEREAS, Biogen Idec is sponsoring a multi-centre clinical study involving patients on ***DAC-HYP (Daclizumab)*** (the ***Product***) to be entitled ***"Multicenter, Double-blind, Randomized, Parallel-group, Monotherapy, Active-control Study to Determine the Efficacy and Safety of Daclizumab High Yield Process (DAC HYP) versus Avonex® (Interferon β-1a) in Patients with Relapsing-Remitting Multiple Sclerosis", (protocol Lumber*** **205MS301** (the ***Study***);

WHEREAS, the Investigator is an employee of the Institution and wishes to participate as a clinical investigator in the conduct of a trial at the Institution to form part of the Study (the ***Trial***); and

WHEREAS, solely for the purpose of enabling the CRO to make payments on its behalf, the parties agree that CRO shall be a party to this agreement for the sole purpose of making such payments hereunder, and CRO shall have no other rights or obligations under this agreement.

IT IS THEREFORE AGREED AS FOLLOWS:

1. Subject matter of this Agreement

(a) Biogen Idec entrusts the Institution and the Investigator to conduct the Trial in accordance with the provisions as stipulated in the Study protocol governing the Trial (as may be amended from time to time, confirmed in writing by Biogen Idec and approved as per the procedure prescribed by the Applicable Laws and Regulations) (the ***Protocol***).

(b) The provisions as stipulated in the Protocol, the respective schedules and the information documents, including the informed consent of subjects participating in the Trial (the ***Subject(s)***), shall be binding on the parties and thus constitute an integral part of this Agreement. This shall apply accordingly to any amendments of the Protocol and the resulting new versions of the Protocol.

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

(g) **No waiver.** No failure or delay by a party in exercising any right or remedy provided by law or pursuant to this Agreement shall impair such right or remedy, be construed as a waiver, or preclude its exercise at any subsequent time. No single or partial exercise of any such right or remedy shall preclude any other or further exercise of it or the exercise of any other right or remedy.

IN WITNESS WHEREOF, Biogen Idec, the CRO, the Institution and the Investigator have executed this Agreement (in the case of Biogen Idec, the CRO and the Institution) through their duly authorised representatives on the date written below.

PHARMACEUTICAL RESEARCH ASSOCIATES INDIA PRIVATE LIMITED

By: _____
Authorised Signature

Name: Dr. Pramod Kabra

Title: Director of Clinical Operations

Date: 27-July-2010

BIOGEN IDEC LTD.

By: _____
Authorised Signature

Name: Amanda Precious
Senior Contracts & Outsourcing Manager

Title: _____

Date: 14 SEP 2010

INVESTIGATOR

By: _____

Name: Dr. R. Srinivasa

Title: Principal Investigator

Date: 04/Sep/10

BIOGEN IDEC LTD.

By: _____
Authorised Signature

Name: Maria Allen
Senior Contract Manager

Title: _____

Date: 14 SEP 2010

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

RAMAIAH
Medical College

To,

Date: 19.03.2018

Dr. Medha Y Rao,
Principal & Dean,
MSRMC, Bangalore

Dear Madam,

Sub: Sanction of budget allotment for ICMR project entitled: 'Descriptive epidemiology of unintentional childhood injuries in India: An ICMR Task Force Multisite study."

We are happy to inform you that the budget for the above mentioned childhood injuries project has been sanctioned by the ICMR for the period from 26th March 2018 for two years.

Please find the enclosed grant letter from ICMR budget statement for two years and terms and conditions of the grants.

Thanking you,

Yours Sincerely,

19/3/18

Dr. Shalini C. Nooyi
Professor (Principal Investigator),
Dept. of Community Medicine,
Ramaiah Medical College

Kind Info:-
Principal & Dean
ACP
22/3/18

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

/PABX : 26588980, 26588707, 26589336, 26589745, 26589873, 26589414
FAX : 011-26588662, 011-26589791, 011-26589258

तार / GRAM : चिकित्सा / SCIENTIFIC
Web-site : www.icmr.nic.in
E-mail : icmrhqds@sansad.nic.in

1.11

भारतीय आयुर्विज्ञान अनुसंधान परिषद्
INDIAN COUNCIL OF MEDICAL RESEARCH

वी.रामलिंगस्वामी भवन, अन्सारी नगर, पोस्ट बॉक्स 4911, नई दिल्ली -110 029
V.RAMALINGASWAMI BHAWAN, ANSARI NAGAR, POST BOX 4911, NEW DELHI - 110 029

To,

Principal and Dean
M.S Ramaiah Medical College & Teaching Block,
Bangalore – 560 054.

No. 5/7/1233/2014-RCH
Dated: 12.03.2018

Subject : Sanction of Budget Allotment for the ICMR 'NTF' project entitled: "Descriptive Epidemiology of unintentional childhood injuries in India: An ICMR Task Force Multisite Study" under Dr. Shalini C. Nooyi (Coordinating Unit), M.S Ramaiah Medical College, Bangalore.

Dear Sir/Madam,

The Director General of the Council sanctions the above mentioned research scheme with total budget allotment of Rs. 59,13,170/- (Rs. Fifty Nine Lakhs Thirteen Thousand One Hundred Seventy only) for duration of 2 years. (Annexure-I).

The details of the first year budget allotment of Rs. 34,04,240/- (Rs. Thirty Four Lakhs Four Thousand Two Hundred Fouty only) as detailed in the attached statement (Annx. II) for the period from 26th March 2018 to 25th March 2019.

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

1. The payment of the grant will be made lump sum to the Head of the institute. The installment of the grant will be paid generally as soon as the Council receives report regarding the commencement of the subsequent installment of the grant should be placed with the council in prescribed Performa attached.
2. The staff appointed on the project should be paid as indicated in the budget statement attached.
3. The approval duration of the research scheme is 2 years annual extension will be give after review of the work done on the research scheme during the previous year.
4. Ten copies of the annual progress report of work done be submitted to the Council every year after completion of 10 months of the project. Failure to submit the report in-time may lead to termination of the project.
5. The institute will maintain a separate account of the receipts and the expenditure incurred on the research scheme and will furnish a utilization certificate and an audited statement of the account pertaining to the ground.
6. The other terms and conditions are indicated in Annexure-III.

Yours faithfully,

(Harjeet Kaur Bajaj)
Administrative Officer
For Director General

Copy to:

1. Dr. Shalini C. Nooyi (CCU Unit), Professor, Dept. of Community Medicine, M.S Ramaiah Medical College, Bangalore – 560 054.
2. Copy together with copies of the budget statement forwarded to the **Accounts V Section**, ICMR for information and necessary action. The expenditure on this account may be met from the provision made under NTF scheme on grant-in-aid basis in the budget of the Council for the financial year 2017-2018.
3. Copy together with two copies of the budget forwarded to budget section (Fin.) ICMR for compilation of the Council's Budget.
4. IRIS Cell –
5. R.F.C No. CH/NTF/4/2017-18 dated 28.02.2018.
6. Smt. Jatinder Kaur, Prinicipal Technical Officer, ICMR, New Delhi.

Admn. Officer
For Director General

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

Annexure – I

File No. 5/7/1233/2014-RCH

RFC No. CH/NTF/4/2017-18 dated 28.02.2018

Duration: 02 years

Date of Start : 26th March 2018

(Dr. Shalini C Nooyi, Coordinating Unit)

Budget Statement for Two Years)

Period from (26.03.2018 to 25.03.2020)

Tim	Participants Name	1st year	2nd year	Total
1.	**Staff:**			
1.1	Field Investigator (4) @ Rs. 31,000/- p.m	496000 (for 4 months)	868000 (for 7 months)	1364000
1.2	Senior Research Fellow (1) @ Rs. 28,000/- + 8400/- (30% HRA) = Rs. 36,400/- p.m	436800	436800	873600
1.3	Upper Division Clerk (1) @Rs. 17,000/- p.m • 10% increment @ Rs. 760/- added in further year as per ICMR rules	204000	213120	417120
1.4	Statistician (1) @ Rs. 32,000/- p.m • 10% increment @ Rs. 1390/- added in further year as per ICMR rules	384000	400680	784680
	Sub Total of Staff (1.1 to 1.4) :	**1520800**	**1918600**	**3439400**
2.	**Contingencies (Recurring & Non- Recurring)**			
2.1	Stationeries	60000	60000	120000
2.2	Internet	24000	24000	48000
2.3	Contingencies	24000	24000	48000
	Sub total of Recurring (2.1 to 2.3)	**108000**	**108000**	**216000**
2.4	Laptop	40000	0	40000
2.5	Multi-function printer	15000	0	15000
2.6	Training of trainers workshop [PI and one co investigator] 30 PERSONS including field visit	50000	0	50000
2.7	Training material development and printing	7500	0	7500
2.8	Translation into kannada	15000	0	15000
2.9	Report preparation and printing	50000	0	50000
2.10	Health education material_poster	7500	0	7500
2.11	Health education material_pamphlet	10000	0	10000
2.12	Hand held device (4) for 11 sites + 1 more device for CCU, ICMR Hqrs	675000	0	675000
2.13	Software Development	250000	150000	400000
	Sub total of Non- Recurring (2.4 to 2.13)	**1120000**	**150000**	**1270000**
3.	**Travel:**			
3.1	Travel Task force meetings	50000	50000	100000
3.2	Observer visits for training and coordination to all sites	250000	0	250000
3.3	Accomodation in 10 sites	80000	0	80000
3.4	Preparatory visit to build rapport	8000	0	8000
3.5	Vehicle for team travel for supervisory field visits [1 urban 1 rural]	24000	48000	72000
3.6	Travel Allowance for Field Investigator	144000	96000	240000
3.7	Travel for field investigator - from field to PI's office for monthly review meeting	18000	12000	30000
3.8	Visits for health education by co investigator, after data collection	0	25000	25000
	Sub Total of Travel	**574000**	**231000**	**805000**
4.	**Over head Charges @ 5%**	**81440**	**101330**	**182770**
	Grand Total of (1+2+3+4)	**3404240**	**2508930**	**5913170**

Admn. Officer
For Director General

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

Annexure – II

File No. 5/7/1233/2014-RCH
RFC No. CH/NTF/4/2017-18 dated 28.02.2018
Duration: 02 years
Date of Start : 26th March 2018

(Dr. Shalini C Nooyi, Coordinating Unit)
Budget Statement for First Year)
Period from (26.03.2018 to 25.03.2019)

Sl.No.	Particpants Name	1st year
1. Staff:		
1.1	Field Investigator (4) @ Rs. 31,000/- p.m	496000 (for 4 months)
1.2	Senior Research Fellow (1) @ Rs. 28,000/- + 8400/- (30% HRA) = Rs. 36,400/- p.m	436800
1.3	Upper Division Clerk (1) @Rs. 17,000/- p.m • 10% increment @ Rs. 760/- added in further year as per ICMR rules	204000
1.4	Statistician (1) @ Rs. 32,000/- p.m • 10% increment @ Rs. 1390/- added in further year as per ICMR rules	384000
	Sub Total of Staff (1.1 to 1.4) :	**1520800**
2. Contingencies (Recurring & Non- Recurring)		
2.1	Stationeries	60000
2.2	Internet	24000
2.3	Contingencies	24000
	Sub total of Recurring (2.1 to 2.3)	**108000**
2.4	Laptop	40000
2.5	Multi-function printer	15000
2.6	Training of trainers workshop [PI and one co investigator] 30 PERSONS including field visit	50000
2.7	Training material development and printing	7500
2.8	Translation into kannada	15000
2.9	Report preparation and printing	50000
2.10	Health education material_poster	7500
2.11	Health education material_pamphlet	10000
2.12	Hand held device (4) for 11 sites + 1 more device for CCU, ICMR Hqrs	675000
2.13	Software Development	250000
	Sub total of Non- Recurring (2.4 to 2.13)	**1120000**
3. Travel:		
3.1	Travel Task force meetings	50000
3.2	Observer visits for training and coordination to all sites	250000
3.3	Accomodation in 10 sites	80000
3.4	Preparatory visit to build rapport	8000
3.5	Vehicle for team travel for supervisory field visits [1 urban 1 rural]	24000
3.6	Travel Allowance for Field Investigator	144000
3.7	Travel for field investigator - **from field to PI's office** for monthly review meeting	18000
3.8	Visits for health education by co investigator, after data collection	0
	Sub Total of Travel	**574000**
4.	**Over head Charges @ 5%**	**81440**
	Grand Total of (1+2+3+4)	**3404240**

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

Admn. Officer
For Director General

ANNEXURE-III

TERMS & CONDITIONS OF THE GRANT

i) Approval of the research proposal and the grant being released in for the specific sanctioned and should be exclusively spent on this project within the stipulated time.

ii) Expenditure should on no account exceed the budget sanctioned for the enquiry. Expenditure incurred over and above sanctioned amounts against one or more sub-heads of expenditure such as pay, allowances, contingencies etc. shall be met without reference to the ICMR by re-appropriation of savings under remaining sub-heads provided the total expenditure incurred during the financial year is within the overall sanctioned ceiling of the year.

iii) No expenditure shall be incurred on items not sanctioned by the Council. Savings should also not be reappropriated for meeting or incurring expenditure on staff has not been sanctioned by the Council.

iv) The grant paid by the Council shall be refunded in full be the Institution if and when the grantee concerned discontinues a scheme midway or does not follow the detailed technical programme laid down and approved.

v) Receipts realized by the Project Officer and the sale proceeds if any, will be remitted to the Council as Miscellaneous receipts and should not be utilized for meeting expenditure on the scheme.

vi) All facilities for the conduct of the research scheme, basic equipment and other ordinary laboratory chemicals, glassware furniture and other help as may be required for the smooth working of the scheme shall be provided by the institute.

STAFF

vii) The staff employed on the research scheme will not be treated as employees of the Council and the deployment of such staff at the time of completion or termination of the project will not be the concern/responsibility of the Council. They will be subjected to administrative control of the institution and will be appointed generally in accordance with the normal recruitment rules and procedure of the Institute.

viii) The Council will not be liable to bear any expenditure on Pension/Provident Fudn Contribution and/or leave salary contribution incurred or committed by the grantee Institution for persons appointed on deputation from other organization.

RELEASE OF FUNDS

ix) The first installment of the grant will be paid as soon as a report regarding the commencement of the project and appointment of staff is received by the Council. The demand for payment of the subsequent installment of the grant be placed with the Council in the prescribed form.

x) The Institute will maintain a separate audited account for this project. If it is found expedient to keep a part or whole of the grant in a bank account earning interest, the interest thus earned should be reported to the Council. The interest thus earned will be treated as a credit to be adjusted towards further installment of the grant.

xi) The accounts will be subject to audit by the authorized auditors of the Institution. In case facilities are not available for such auditing, the account will be audited by the Council's own internal auditors. Latest be the end of December, following the financial year for which the grant is paid, and audit certificate, from the auditors to the effect the "the account have been audited and that the money was actually spent on the objects for which it was sanctioned" shall be submitted to the Council.

PRINCIPAL AND Dir.
M.S.Ramaiah Medical Colleg.
& Hospital,
Bangalore - 560 054.

xii) Further grants will be stopped unless audited statements of accounts utilization certificates are received within a period of one year after the end of the financial year for which grant.

STORES

xiii) All expenditure and non-expendable articles required for work of the enquiry should be purchased in accordance with the procedure in vogue in the Institution. For permanent and semi-permanent assets acquired solely or mainly out the of the grant a separate audited record in the form of register in the prescribed Performa enclosed shall be maintained the Institute. The term "assets" means (i) immovable property and (ii) movable property of capital nature where the value exceeds Rs.1000/-

xiv) For other stores articles purchased from the Council's grant the Performa will be the same as is being used by the Institute. All the assets acquired from the grant will be *property of the Council and should not, without the prior sanction of the council will be* disposed of or encumbered or utilized for purposed other than those for which the grant has been sanctioned.

PUBLICATIONS

The financial assistance rendered by the Council should be acknowledged in the any published account of work of which the grant is give.

The Council published its own journal "Indian Journal of Medical Research" In Case it is proposed to publish the paper based on the work done under the auspices of the Council in Jomals other than the IJMR, the name of the Journal in which it is proposed to published the paper may please be intimate. A reprint of the paper when published may please be sent to the Council for information and records.

Prior permission of the Council should be obtained before publication of any such papers in the foreign journal.

PAYMENTS

The Council shall have the right to take out patents in respect of invention/discoveries made under a scheme/project financed by the Council. The Officer-in-Charge or the staff employed on ICMR schemes shall not apply or obtained patents for any invention/discovery made by without prior approval of the Council.

All patents will be registered in the name of the Indian Council of Medical Research.

TERMINATION OF ENQUIRY

Prior permission of the Council shall be obtained if the investigator d esired to discontinue the enquiry. The reasons for discontinuing the scheme should invariably be stated. The investigator should submit a complete and detailed report of work done by him on the project till the date of relief.

Any unspent balance out of the funds given to the Institute shall be refunded to the ICMR on termination of the Scheme.

A final report is required to be submitted within one month form the date of termination of the enquiry.

A list (in duplicate) of non expendable and expendable articles, together with property registers and suggestions for disposal of the articles should be sent to the Council within a month from the date of termination of the enquiry.

Yoha. 4/Mar

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

पी.ए.बी.एक्स./PABX : 26588980, 26588707, 26589336, 26589745, 26589873, 26589414
फैक्स/FAX : 011-26588662, 011-26589791, 011-26589258

तार / GRAM : विज्ञानी / SCIENTIFIC
Web-site : www.icmr.nic.in
E-mail : icmrhqds@sansad.nic.in

भारतीय आयुर्विज्ञान अनुसंधान परिषद
INDIAN COUNCIL OF MEDICAL RESEARCH

वी.रामलिंगस्वामी भवन, अन्सारी नगर, पोस्ट बॉक्स 4911, नई दिल्ली -110 029
V.RAMALINGASWAMI BHAWAN, ANSARI NAGAR. POST BOX 4911, NEW DELHI - 110 029

No. 5/7/1233/2014-RCH

Dated : 12.03.2018

Subject : Payment of 1st & final installment of grant-in-aid for the first year of ICMR 'NTF' project entitled: "Descriptive Epidemiology of unintentional childhood injuries in India: An ICMR Task Force Multisite Study" under Dr. Shalini C. Nooyi (Coordinating Unit) , M.S Ramaiah Medical College, Bangalore.

MEMORANDUM

Reference this office letter of even number dated 12.03.2018.

The Director General, ICMR sanctions the payment of Rs. 34,04,240/- (Rs. Thirty Four Lakhs Four Thousand Two Hundred Fouty only) as the 1st & final installment of 1st year. The grant for incurring expenditure in connection with the above mentioned research scheme. The amount of Rs. 34,04,240/- may be debited in the provision of Rs. 34,04,240/- made for the above mentioned research scheme for the current financial year 2017-2018 i.e from 26.03.2018 to 25.03.2019.

A formal bill for Rs. 34,04,240/- is sent herewith for payment through RTGS to Principal and Dean, M.S Ramaiah Medical College, Bangalore (as per attached mandate form along with Cancelled cheque)

This is issued with the concurrence of the finance year Divn. RFC No. CH/NTF/4/2017-18 dated 28.02.2018.

(Harjeet Kaur Bajaj)
Administrative Officer
For Director General

Accounts Sections V, ICMR
Copy to :-

1. The Principal and Dean, M.S Ramaiah Medical College, Bangalore – 560 054. An amount of Rs. 34,04,240/- being the 1st & final installment of 1st year will be sent to you through RTGS. The grant has been sanctioned on the condition laid down in our letter referred to above.
2. IRIS Cell –
3. Dr. Shalini C. Nooyi, Professor, Dept. of Community Medicine, M.S Ramaiah Medical College, Bangalore – 560 054.
4. Smt. Jatinder Kaur, Prinicipal Technical Officer, ICMR, New Delhi.

Admn. Officer
For Director General

PRINCIPAL AND DE.
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

ADDENDUM TO CLINICAL TRIAL AGREEMENT

THIS ADDENDUM ("the Second Addendum") is made at Mumbai and entered into on 26th day of October, 2016, effective as of 26/Oct/2016 ("Effective Date") by and between

NOVARTIS HEALTHCARE PRIVATE LIMITED, a company incorporated under the Companies Act, 1956 and having its registered office at Sandoz House, Dr. Annie Besant Road, Worli, Mumbai 400 018 (hereinafter referred to as "**the Sponsor**", which expression shall, unless repugnant to the context or meaning thereof, be deemed to mean and include its successors and assigns) of the First Part;

Dr. Pramila Kalra whose designation is Associate Professor and having her address at M.S. Ramaiah Medical College and Hospitals, New BEL road, MSRIT Post, Bangalore-560054, Karnataka, India (hereinafter referred to as "**the Investigator**", which expression shall, unless it be repugnant to the context ore meaning thereof, be deemed to mean and include his heirs, executors, administrators and successors) of the Second Part;

AND

M.S. Ramaiah Medical College and Hospitals, New BEL road, MSRIT Post, Bangalore-560054, Karnataka, India (hereinafter referred to as "**the Institution**", which expression shall, unless repugnant to the context or meaning thereof be deemed to mean and include its successors and assignee and permitted assigns) of the Third Part.

(The Sponsor, Investigator and Institution may be individually referred to as Party and collectively as Parties)

Whereas the Parties have entered into a Clinical Trial Agreement dated **27th Jan 2015** & addendum to the Clinical Trial agreement dated **18th May 16** (the "Agreement").
AND Whereas the Parties are now desirous of revising the agreement term in the Agreement be altered as per this Addendum on the terms and conditions hereinafter appearing

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

NOW THIS ADDENDUM WITNESSETH AND IT IS HEREBY AGREED BY AND BETWEEN THE PARTIES HERETO AS FOLLOWS:

1. The Parties agree that the following term of Addendum to Clinical Trial Agreement dated 18th May 16 to be substituted and replaced by **Annexure 1** hereto.
   a. **Clause A**

2. This Addendum shall be effective from **25th Oct 2016**.

3. The annexure hereto shall be read together with the Clinical Trial Agreement dated 27th Jan 2015 & addendum to the Clinical Trial agreement dated 18th May 16, same and except the aforestated all other terms and conditions of the Agreement shall remain valid and unchanged.

IN WITNESS WHEREOF the Parties hereto have hereunto set and subscribed their hands to these presents, the day and year first hereinabove written.

Novartis Healthcare Private Limited

By: Amitabh Dube
Name: Mr. Amitabh Dube 26/10/16
Title: BU Head-Oncology, India
Date:

By: M Mistry 25/10/16
Name: Dr. Manish Mistry
Title: Medical Director-Oncology, India
Date:

Researcher

By: PKalra
Name: Dr. Pramila Kalra
Title: ~~Associate~~ Professor
Date: 5/11/16 5/11/16

Institution

By:
Name:
Title: 8/11/16 DR. NARESH SHETTY
Date: President
M.S.Ramaiah Clinical Research Centre

Medha. GJ

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

Annexure 1

Study Title: A multi-center, randomized, open-label, Phase IV study to investigate the management of pasireotide-induced hyperglycemia with incretin based therapy or insulin in adult patients with Cushing's disease or acromegaly

Protocol number: CSOM230B2219

All the terms remain the same as in the original agreement dated **27th Jan 2015** & addendum to the Clinical Trial agreement dated **18th May 16**, except for the following

A. Clause A mentioned in addendum to the Clinical Trial agreement to be replaced with following:
to recruit a maximum of 15 patients who would be the subjects of the Trial (the "Study Patients") and to ensure their completion of the Trial as per the Protocol;

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

ಉಪನೋಂದಣಾಧಿಕಾರಿ
ಬೊಮ್ಮನಹಳ್ಳಿ

CLINICAL STUDY AGREEMENT – MANAGE

This Clinical Study Agreement (hereinafter the "Agreement") is entered into and effective this 4 day of November 2015 ("Effective Date) between

Hamilton Health Sciences Corporation, through the Population Health Research Institute with its offices at Population Health Research Institute (PHRI), Hamilton Health Sciences – DBCVSRI, Hamilton General Hospital Campus, 237 Barton Street East, Hamilton, Ontario, L8L 2X2, Canada (hereinafter "PHRI") represented by Beena Cracknell, Director of Finance and Contract Services

-and-

CBCI Society for Medical Education,**(CBCI)** established and registered under the Karnataka Societies Registration Act, 1980, having its address at St. John's National Academy of Health Sciences, John Nagar, Sarjapur Road, Koramangala, Bangalore-560034, Karnataka, India, represented by its Secretary (Hereafter referred as 'Society')

-and-

St. John's Research Institute, (SJRI) a unit of CBCI Society for Medical Education, having its address at St. John's National Academy of Health Sciences, John Nagar, Sarjapur Road, Koramangala, Bangalore-560034, Karnataka, India, represented by its Dean (hereafter referred as 'Institute')

-and-

Division of Clinical Research and Training ("DCRT"), a Division of St John's Research Institute (SJRI), with its administrative office at St. John's Research Institute, St. John's National Academy of Health Sciences, Bangalore-560 034 Karnataka; India, represented by, DCRT, Dr. Prem Pais , Adjunct Professor of Medicine, DCRT and Dr Denis Xavier, Professor and Head, Dept. of Pharmacology, St. John's Medical College and Head DCRT (hereafter called "National Coordinator")

-and-

Dr. Sanjay C Desai as the principal investigator at the Institution, with offices at M.S.Ramaiah Medical College and Hospitals, MSRIT Post, New BEL Road, ~~Bnagalore~~ Bangalore-560054, Karnataka, India (hereinafter the "Investigator")

-and-

M.S.Ramaiah Medical College and Hospitals with its principal place of business at M.S.Ramaiah Medical College and Hospitals, MSRIT Post, New BEL Road, ~~Bnagalore~~ Bangalore-560054, Karnataka, India (hereinafter the "Institution")

The Society, The Institute, National Coordinators, The investigator, PHRI and the Institution are each hereinafter referred to as a "Party" and collectively referred to as the "Parties".

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

WHEREAS, PHRI is the sponsor of the MANAGE study, "MANAGEMENT OF MYOCARDIAL INJURY AFTER NONCARDIAC SURGERY" (hereinafter the "Project"), the protocol (hereinafter the "Protocol", which term shall include any amendments made to the Protocol from time to time) for which has been developed by PHRI and the Steering Committee (as that committee is defined in the Protocol);

WHEREAS, PHRI has an agreement with DCRT to carry out national coordination activities in India for the Project;

WHEREAS, PHRI will be responsible for all payments to the National Coordinator and the Institution;

WHEREAS, DCRT, SJRI will be the National Coordination Office (NLO) with Dr Prem Pais, Adjunct Professor DCRT, SJRI as Chief mentor, Dr Denis Xavier, Professor and Head, Dept. of Pharmacology, St. John's Medical College as Head (hereafter referred to as "the National Coordinators");

WHEREAS, PHRI may also conduct substudies (hereinafter the "Substudy (ies)") in conjunction with the Study, and all references to the Study shall include any Substudy (ies) that are conducted and the references to the Protocol shall include any protocols related to such Substudy(ies);

WHEREAS, the Investigator and Institution possess the resources and expertise to carry out a portion of the Project for a prescribed fee and wish to assist PHRI and NLO by acting as a centre for the Project. The Investigator and Institution are hereinafter referred to jointly and severally as the "Centre" and the activities carried out by the Centre for the Project is referred to as the "Study";

AND WHEREAS, the Project has been approved by the Institutional Ethics Committee as applicable and as the case may be (wherein such committee would approve the conducting of Clinical Trial) at the Institution, and obtained Drugs Controller General of India approval and other regulatory approvals for conduct of clinical trial in human subjects and has been registered on the clinical trials registry of India.

The rights and obligations of the Parties are outlined below:

ARTICLE 1. PERFORMANCE OF THE STUDY

1.1 The Institution and the Investigator shall carry out the Study in strict conformance with: generally accepted standards of good clinical practice, including the Guidance for Good Clinical Practice of the International Conference on Harmonization (hereinafter the "ICH-GCP"); the Declaration of Helsinki (and its amendments); the customary principles of ethical research, the Protocol; this Agreement; all applicable requirements of Indian Drugs & Cosmetics Act (and its amendments), other governmental or regulatory body that have authority with respect to the performance of the Study (hereinafter the "Regulatory Authority(ies)"); all applicable laws, regulations and guidelines governing the conduct of clinical research and the protection of human subjects (hereinafter "Applicable Laws").

1.2 The Institution and the Investigator hereby represent and agree that they have, and at all times during the course of the Study will have, personnel with appropriate training, information, licenses, approvals, and certifications necessary to safely, adequately and lawfully perform the Study in accordance with the Protocol, ICH-GCP and Applicable Laws. The Study will be carried out under the direction and supervision of the Investigator.

1.3 The Investigator shall, prior to initiation of the Study and during the conduct of the Study if required, obtain written approval from the Institutional Ethics Committee (IEC) **Ethics Committee, M.S. Ramaiah Medical College and Hospitals** for the Protocol and the informed consent form to be used at the Institution (hereinafter the "Consent Form"). Any changes to the Consent Form must be approved by IEC, NLO and PHRI

1.4 The Investigator shall obtain a completed and signed Consent Form from each eligible subject ("Subject"). Eligibility will be defined by the Protocol. Each Subject is given a copy of the signed consent form and original is kept safely throughout the duration of the study. The Investigator shall follow local regulatory requirements

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be duly executed in three (3) counterparts, each of which shall be deemed to be an original, as of the day and year first above written.

Investigator:

Signature _____ Date: 2015-12-05 (YYYY-MM-DD)

Name: DR JANJAY DESAI

Hospital name and city: M.S. RAMAIAH MEDICAL COLLEGE AND HOSPITALS, BANGALOR
(Kindly handwrite in block letters)

-and-

On Behalf of the Institution:

Signature _____ Date: 2015-12-05. (YYYY-MM-DD)

Name: DR. D.C. SUNDARESH.

Hospital name and city: M.S. RAMAIAH MEDICAL COLLEGE AND HOSPITALS, BANGALORE
(Kindly handwrite in block letters)

-and-

On Behalf of CBCI:

Signature _____ Date: 30/11/2015 (YYYY-MM-DD)
Name: Rev. Dr Fr. Paul Parathazham
Secretary, CBCI Society for Medical Education
St. Johns' National Academy of Health Sciences
Bangalore

-and-

On Behalf of SJRI

Signature _____ Date: 26-11-15 (YYYY-MM-DD)
Name: Dr. George D'Souza
Dean, St John's Research Institute
Professor of Chest Medicine, St. John's Medical College

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

2015-1814-PHR1

-and-

On Behalf of NLO:

Signature
Dr. Denis Xavier, MD
Professor and Head, Dept. of Pharmacology
St. John's Medical College
Head, Division of Clinical Research & Training
St. John's Research Institute, Bangalore

Date: 2015-11-04
(YYYY-MM-DD)

Signature
Dr. Prem Pais MD
Adjunct Professor, Division of Clinical Research and Training
St. John's Research Institute

Date: 2015-11-21
(YYYY-MM-DD)

-and-

On Behalf of Hamilton Health Sciences Corporation ("PHRI")

Signature

Date: 2015-Nov-16
(YYYY-MM-DD)

Name: Beena Cracknell
Position: Director, Financial and Contract Services, Population Health Research Institute

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

2015-1814 PHRI

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

सत्यमेव जयते

Certificate No.	:	IN-KA86243002139159N
Certificate Issued Date	:	02-Jul-2015 02:31 PM
Account Reference	:	NONACC (FI)/ kaksfcl08/ NELAMANGALA2/ KA-BR
Unique Doc. Reference	:	SUBIN-KAKAKSFCL0821701830361527N
Purchased by	:	THE HIMALAYA DRUG COMPANY
Description of Document	:	Article 12 Bond
Description	:	AGREEMENT
Consideration Price (Rs.)	:	200 (Two Hundred only)
First Party	:	THE HIMALAYA DRUG COMPANY
Second Party	:	Dr KIRTHI KOUSHIK AND M S RAMAIAH MEDICAL COLLEGE
Stamp Duty Paid By	:	THE HIMALAYA DRUG COMPANY
Stamp Duty Amount(Rs.)	:	200 (Two Hundred only)

Please write or type below this line

This CLINICAL TRIAL TRIPARTITE AGREEMENT is made on this 27 Day of July 2015 by and between,

The Himalaya Drug Company, Research and Development Centre, Makali, Bangalore-562 162 [hereinafter referred to as the "SPONSOR" (1st party)] which mean and includes its successors and permitted assignees,

And

Dr. Kirthi Koushik, having his place of work at M S Ramaiah Medical College and Hospital, NEW BEL Raod, MSRIT Post, Bangalore, Karnataka, India., [hereinafter referred to as the "PRINCIPAL INVESTIGATOR"(2nd party)],

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

And

M S Ramaiah Medical College and Hospital having its principal place of business at New BEL Road, MSRIT Post, Bangalore, Karnataka, India., [herein after referred to as the "INSTITUTION" (3rd party)] which shall include its successors, assigns, representatives, affiliates, and subsidiaries.

(The "SPONSOR", "PRINCIPAL INVESTIGATOR" and "INSTITUTION" are collectively referred to as "Parties" and individually as "Party")

WHEREAS,

A) The SPONSOR is a pharmaceutical company involved in the research, development, manufacturing and sale of various Ayurvedic medicaments.

B) The INSTITUTION is a reputed medical college and hospital in Bangalore, provides a variety of clinical trial studies to evaluate the efficacy and the safety of the drugs.

C) The SPONSOR intend to perform study related duties and functions for the Project No. HDC/CP/PP/015/2014 entitled "*An Open Label, Comparative, Three Arm, Randomized, Parallel Clinical Study to Evaluate the Efficacy and Safety of Turmeric Oral Rinse in Oral Mucositis during Cancer Chemotherapy and Radiotherapy*"; and had a discussion with the INSTITUTION regarding the same.

D) In pursuant to the discussion, the INSTITUTION represents that it has adequate infrastructure and necessary expertise in performing and conducting such clinical trials in compliance with ICH-GCP and EC approved protocol. Further, the INSTITUTION agrees to conduct a clinical research study for the SPONSOR in accordance with the Protocol and on the following terms and conditions as given hereunder. The INSTITUTION in consultation and approval of SPONSOR has appointed Dr. Kirthi Koushik as the Principal Investigator to conduct the clinical trial for the SPONSOR in the premises approved by the INSTITUTION in compliance with ICH-GCP and EC approved protocol.

E) Principal Investigator is suitably qualified and experienced and working at the INSTITUTION. Principal Investigator has the authority and extends the willingness to conduct the Study at the INSTITUTION in compliance with ICH-GCP and EC approved protocol.

NOW THEREFORE, in consideration of the promises and mutual covenants contained in this Agreement, and other good and valuable consideration, the receipt, adequacy and legal sufficiency of which, are hereby acknowledged, the parties mutually agrees as follows:

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

1. DEFINITIONS

1.1 The following words and phrases have the following meanings:

a) "Agreement" means this agreement comprising its clauses, schedules and any appendices attached to it.

b) "Auditor" means a person being a representative of the SPONSOR who is authorised to carry out a systematic review and independent examination of Clinical Trial related activities and documents to determine whether the evaluated Clinical Trial related activities were conducted, and the data were recorded, analysed and accurately reported according to the Protocol, the SPONSOR's Standard Operating Procedures, ICH GCP and the applicable regulatory requirements.

c) "Clinical Trial/Study" means the investigation to be conducted at the Trial Site in accordance with the Protocol numbered HDC/CP/PP/015/2014

d) "Clinical Trial Subject" means a person recruited to participate in the Clinical Trial.

e) "Confidential Information" means any and all information, data and material of any nature belonging to the INSTITUTION or to the SPONSOR and/or its Affiliates which either Party may receive or obtain in connection with this Agreement which is Personal Data or Sensitive Personal or other information, the release of which is likely to prejudice the commercial interests of the INSTITUTION or the SPONSOR respectively, or which is a trade secret, including Know How.

f) "ICH GCP" means the International Conference on Harmonisation -Good Clinical Practices.

g) "Intellectual Property Rights" means patents, trade marks, trade names, service marks, domain names copyrights, moral rights, rights in and to databases (including rights to prevent the extraction or reutilisation of information from a database), design rights, topography rights and all rights or forms of protection of a similar nature or having equivalent or the similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered and including applications for registration of any of them.

h) "Investigational Medicinal Product" means the study drug or control materials as defined in the Protocol.

i) "Know How" means all technical and other information which is not in the public domain (other than as a result of a breach of confidence), including but not limited to information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, procedures, designs for experiments and tests and results of experimentation and testing, processes,

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital

Himalaya
WELLNESS SINCE 1930

SIGNATURE PAGE

Protocol Title	:	"An Open Label, Comparative, Three-Arm, Randomized, Parallel Clinical Study to Evaluate the Efficacy and Safety of Turmeric Oral Rinse in Oral Mucositis during Cancer Chemotherapy and Radiotherapy"
Protocol Number	:	HDC/CP/PP/015/2014
Protocol Version	:	1.1
Date	:	19/06/2015
Sponsor	:	The Himalaya Drug Company Research and Development, Makali, Bangalore -562 123 Tel: 08022169999

We approve the protocol as specified above

Sponsor Representative
Dr. Ramanand S. Nadig MD

Signature
03/07/2015

Principal Investigator
Dr. Kirthi Koushik

Signature
3/7/15.

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

Himalaya
WELLNESS SINCE 1930

Investigators statement of agreement

I have fully reviewed all the information available on the investigational product namely: Turmeric Oral Rinse. I consider it is safe and ethically justifiable to study the safety and efficacy of the investigational product mentioned above, according to the agreed protocol. I shall conduct the study in full accordance with this protocol and all applicable laws and regulations, including but not limited to current Good Clinical Practices.

Principal Investigator's Name: Dr. Kirthi Koushik

Signature:

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

30-08-2016

GOVT. OF KARNATAKA 64551 AUG 30 2016
DEPT. OF STAMP & REGISTRATION INDIA Rs.0000100 PB6941
STAMP DUTY KARNATAKA

AMENDMENT 4 TO THE CLINICAL TRIAL AGREEMENT

This Amendment 4 (the "Amendment") to the Clinical Trial Agreement is between:

M.S Ramaiah Medical College and Hospitals, having a place of business at MSRIT Post, New BEL Road, MSR Nagar Bangalore-560054, India (the **"Institution"**)

ಉಪ ನೋಂದಣಾಧಿಕಾರಿ
ಬಾಡಿಗಾ (ಬಾಡಿಗಾ), ಬೆಂಗಳೂರು

and

Dr. Anil Kumar N., having a place of business at Dept. of Medical Oncology M.S Ramaiah Medical College and Hospitals, MSRIT Post, New BEL Road, MSR Nagar Bangalore-560 054, India (the **"Investigator"**)

and

Ecron Acunova Limited (Formerly known as Manipal Acunova Limited), having registered office at Mobius Towers, SJR-I park, EPIP, Whitefield, Bangalore - 560066 India (the **"CRO"**)

This Amendment is effective as of the date last signed below.

WHEREAS, CRO, Investigator and Institution are parties to the Clinical Trial Agreement dated as of October 30, 2014 ("Agreement") and Amendment 1 dated February 11, 2015 and Amendment 2 dated June 10, 2015 and Amendment 3 dated July 29, 2015 in connection with the Protocol entitled "A Phase III Randomised, Double-Blind, Parallel Group, Multicentre Study to Compare the Efficacy, Safety, Pharmacokinetics and Immunogenicity between SB3 (proposed trastuzumab biosimilar) and Herceptin® in Women with Newly Diagnosed HER2 Positive Early or Locally Advanced Breast Cancer in Neoadjuvant Setting" under the protocol number SB3-G31-BC, dated November 08, 2013 as further amended, modified or otherwise supplemented (the "Protocol"); and the Parties desire to amend certain provisions of the Agreement.

NOW THEREFORE, in consideration of the mutual promises and covenants set forth herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree to amend the Agreement as follows.

A. <u>Change in Principal Investigator:</u>

Dr. Vinayak Maka who is one of the parties (Investigator) to the above mentioned Clinical Trial Agreements is no longer a part of the study team and has duly transferred all the study related responsibilities to Dr. Anil Kumar. With effect from the execution of this Agreement, Dr. Anil Kumar will be the new Investigator and Dr. Anil Kumar shall be liable for all the responsibilities of the Investigator mentioned in the Clinical Trial Agreement (CTA) and its Amendments dated October 30, 2014, June 10, 2015 and July 29, 2015 respectively.

B. <u>Payee Details:</u>

Section 1 mentioning the Payee Information under Exhibit A of the Agreement shall be amended as follows in accordance with the circular received from the institution dated February 01, 2016:

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

Payee Name	M S Ramaiah Clinical Research Centre
Payee Address	Gate no. 3, Gnanagangothri Campus, New BEL Road, MSRIT Post, Bangalore 560054
Tax ID Number	AAATG1779Q

All terms and conditions of the Agreement not expressly amended by this Amendment remain in full force and effect.

The Agreement shall be read and construed in conjunction with this Amendment as an integral part thereof.

IN WITNESS WHEREOF, this Amendment has been executed by the Parties hereto through their duly authorized officers on the date(s) set forth below:

ACKNOWLEDGED AND AGREED BY CRO:

BY: _____

Name: Dr. Sudheer Balaraju

Title: Head of Clinical Operations

Date: 30 Aug 2016

ECRON ACUNOVA LTD. Bangalore

AND

BY: _____

Name: Ms. Ankita Tiwari

Title: Company Secretary

Date: 30- Aug -2016

ACKNOWLEDGED AND AGREED BY Investigator:

BY: _____

Name: Dr. Anil Kumar

Title: Assistant Professor, M.S.Ramaiah Medical College and Hospitals

Date: 06- SEP- 2016.

ACKNOWLEDGED AND AGREED BY Institution:

BY: _____

Name: Dr. Naresh Shetty

Title: President, M.S.Ramaiah Clinical Research Centre

Date: 01- SEP- 2016.

PRINCIPAL AND DEAN
M.S. Ramaiah Medical College
& Teaching Hospital
Bangalore - 560 054.

Eli Lilly and Company (India) Pvt. Ltd.
Plot No. 92, Sector-32, Gurgaon - 122001 Haryana
Phone:+91-124-4753000
Fax:+91-124-4753012-13-14
CIN – U24239HR1993PTC034844
Website : www.lillyindia.co.in

OUS Templates
OUS LOA
Revised: 07 2014

21 Jul 16

Dr Nalini Kilara
M. S Ramaiah Medical College & Hospital
MSRIT Post, New BEL Road
Bangalore, Karnataka – 560054

Dear Dr Kilara:

This agreement ("Agreement") is by and between Eli Lilly and Company (India) Pvt. Ltd. ("Lilly"), Dr. Nalini Kilara, the principal investigator ("Investigator"), and M. S Ramaiah Medical College & Hospital, MSRIT Post, New BEL Road, Bangalore, Karnataka - 560054 ("Institution") for the performance of the study ("Study"), entitled, "*A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Compare NSAI (Anastrozole or Letrozole) plus Abemaciclib, a CDK4 and CDK6 Inhibitor, or plus Placebo, and to Compare Fulvestrant plus Abemaciclib or plus Placebo in Postmenopausal Women with Hormone Receptor-Positive, HER2-Negative Locoregionally Recurrent or Metastatic Breast Cancer*" *protocol* ***I3Y-CR-JPBQ*** ("Protocol"), which Protocol is incorporated herein by reference. Investigator is an employee of Institution. This agreement ("Agreement") sets forth the obligations of Lilly, the Investigator and Institution.

1. YOUR OBLIGATIONS

Investigator and Institution agree to assume the following obligations in executing this Agreement:

A. Conduct of the Study

Investigator and Institution agree that Investigator will personally conduct or supervise the Study at Institution and any Lilly-approved sub-sites or satellite sites (collectively "Study Sites"), if applicable. Investigator and Institution agree that Investigator and Institution will not use sub-sites or satellite sites in the conduct of the Study unless Lilly has given written approval for use of the sub-sites and satellite sites. If any portion of the Study is performed by Investigator or a sub-investigator at a facility or hospital other than Institution, Investigator and/or Institution shall be responsible for ensuring that any such Study Site is aware that it is involved in the Study and consents to such participation. Investigator and Institution (and colleagues, including sub investigators) agree to comply with the following: all conditions specified in the Protocol and Protocol amendments and/or addenda; Good Clinical Practice Guidelines; the approval of Ethical Review Board ("ERB"); and all other applicable national, state and local laws, regulations and standards. Investigator and Institution shall ensure that all of sub investigators, associates, colleagues and employees involved in the conduct of the Study at Study Sites also understand and agree to comply with these obligations and the provisions of this Agreement.

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

If the foregoing is acceptable, please sign the enclosed Agreement and return it to Lilly by: courier service to **Sanjay Majumdar, Eli Lilly and Company, Sec 32, Plot 92, Gurgaon, Haryana, 122001**. If you have any questions, please call **Sanjay Majumdar** at **+91 124 4753118**.

Sincerely,

ELI LILLY AND COMPANY (INDIA) PVT. LTD.

(Signature of Authorized Official)

Rajeev Sharan Srivastava -Associate Director, Clinical Research

21- JULY - 2016.

(Date)

AGREED AND ACCEPTED:
Investigator

Nkilara

Dr. Nalini Kilara

27/7/2016

(Date)

AGREED AND ACCEPTED:
M S Ramaiah Medical College & Hospital, Bangalore

Dr. NARESH SHETTY
PRESIDENT. MSRCH.

(Signature of Authorized Official)

26/7/2016

(Typed or Printed Name and Title)

(Date)

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

INDIA NON JUDICIAL

Government of National Capital Territory of Delhi

e-Stamp

सत्यमेव जयते

Certificate No.	:	IN-DL89093343092760N
Certificate Issued Date	:	04-Dec-2015 03:45 PM
Account Reference	:	IMPACC (IV)/ dl892503/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL89250376222889739128N
Purchased by	:	CENTRE FOR CHRONIC DISEASE CONTROL
Description of Document	:	Article Others
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	CENTRE FOR CHRONIC DISEASE CONTROL
Second Party	:	Not Applicable
Stamp Duty Paid By	:	CENTRE FOR CHRONIC DISEASE CONTROL
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

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

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

Statutory Alert:

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

Clinical Trial Agreement

This Clinical Trial Agreement ("**Agreement**") is executed on this 15th of December 2016("**Effective date**") by and between

The **Centre for Chronic Disease Control**, a not for profit organization incorporated pursuant to the laws of the New Delhi, India, through its Division of Clinical trials which has registered office at flat no-70, pocket-1sector-2, Dwaraka, New Delhi (hereinafter "CCDC" which expression shall, unless it be repugnant to the context or meaning thereof, mean and include its affiliates, successors and permitted assigns) (hereinafter referred to as **"CCDC"**, which expression shall, unless it be repugnant to the context or meaning thereof, mean and include its affiliates, successors and permitted assigns);

And

Dr Nagamalesh U. M. (**"Investigator"**)

Currently working at M S Ramaiah Medical College and Hospitals, Department of Cardiology, New BEL Road, MSRIT Post, Bangalore - 560054

And

M S Ramaiah Medical College and Hospitals, a Multispecialty Hospital having its office at New BEL Road, MSRIT Post, Bangalore, Karnataka, 560054 **("Institute"**, which expression shall, unless it be repugnant to the context or meaning thereof, mean and include its successors and permitted assigns)

Recitals

I. Whereas, **CCDC** is engaged in knowledge generation and knowledge translation for the prevention and control of chronic non communicable diseases in varied settings of the developing countries;

II. Whereas, **CCDC** along with the London School of Hygiene & Tropical Medicine (LSHTM) have been jointly awarded a grant by the Indian Council of Medical Research (ICMR) under ICMR- Medical Research Council, U.K (MRC) initiative on chronic non communicable diseases for the performance of the Study noted below.

III. Whereas, the **Investigator** is desirous of participating in the Study and has agreed to do so on the terms and conditions as contained in this Agreement.

IV. Whereas, the **Institute** has agreed to provide certain facilities to enable the **Investigator** to conduct the Study as per the terms and conditions contained in this Agreement.

V. Whereas, CCDC, based on the representations made to it by the **Investigator** and the **Institute**, wishes to engage the **Investigator** and **Institute** for the said purpose.

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

Now, therefore, in light of the mutual promises and consideration, the adequacy whereof is hereby acknowledged, the Parties agree and covenant as under:

Articles:

1. Definitions & Interpretation

1.1. As used anywhere in this Agreement, the following terms shall mean and be interpreted to convey the meanings ascribed thereto in this Article 1:

1.1.1. **"Confidential Information"** shall have the meaning as ascribed thereto in Article 6.1;

1.1.2. **"Effective Date"** shall mean 15/12/2016

1.1.3. **"Institute"** shall mean M S Ramaiah Medical College and Hospitals, and includes its directors, representatives, agents and employees and/or professional consultants;

1.1.4. **"Intellectual Property"** shall have the meaning as ascribed thereto in Article 7.1;

1.1.5. **"Materials"** shall mean clinical supplies or medical devices or IT hardware/software;

1.1.6. **"Party"** or **"Parties"** shall mean and refer to CCDC, the Institute and the Investigator as referred to individually or collectively, as the context permits;

1.1.7. **"Records"** shall have the meaning as ascribed thereto in Article 3.8;

1.1.8. **"Sponsors"** shall mean institutions which takes responsibility for the initiation, management and/or financing of the study i.e. CCDC and London School of Hygiene and Tropical Medicine (LSHTM) (hereinafter "Sponsors"))

1.1.9. "**Study**" shall mean the study titled "Effects of a yoga based cardiac rehabilitation programme (Yoga-CaRe) on cardiovascular Health : a clinical trial (India) and mechanistic study (U.K)" to be performed by CCDC in accordance with the provisions of the ICMR guidelines, declaration of Helsinki(2008) and ICH good clinical practice guidelines(1996),;

1.1.10. **"Study Intervention"** shall mean "yoga based cardiac rehabilitation programme (Yoga-CaRe)";

1.1.11. **"Study Term"** shall mean the period commencing from the Effective Date and ending on the date of completion of the Study.

1.1.12. "**Study Team Members"** shall include, without limitation, the Site Investigator, Co-investigators, Study coordinators, Yoga Instructor; and

1.1.13. **"Subjects"** shall have the meaning as ascribed thereto in Article 3.3.

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

12.11. No party shall waive any portion of the Agreement or any breach or default hereunder.

12.12. CCDC shall have reasonable access to site of the Investigator and/ or the Institute and project facilities, drug records, subject records, case reports, and other records directly related to this Study, subject to applicable laws and regulations, during regular business hours and with reasonable prior notice.

12.13. Any notices related to this Agreement or required herein shall be in writing and delivered by first class mail, postage prepaid, facsimile or by email to the parties as follows:

	CCDC	Investigator	Institute
Name	Dr. D. Prabhakaran	**Dr Nagamalesh UM**	**Dr Naresh Shetty**
Postal Address	Centre for Chronic Disease Control, Plot No47, Sector 44, Gurgaon-122002	M S Ramaiah Medical College and Hospitals, New BEL Road, MSRIT Post, Bangalore - 560054	M S Ramaiah Medical College and Hospitals, New BEL Road, MSRIT Post, Bangalore - 560054
Phone number	0124-4781400	**080-23602983**	**080-23602983**
Fax Number	0124-4722901	**080-23601983**	**080-23601983**
Email address	dprabhakaran@ccdcindia.org	**nmalesh@yahoo.co.in**	**nareshs8@gmail.com**

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

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

Centre for Chronic Disease Control(CCDC)	**Investigator**	**M S Ramaiah Medical College and Hospitals**
By Principal Investigator:	**By Site Investigator:**	**By Authorized Signatory:**
D. Prabhakaran, MD, DM, M.Sc	**Dr Nagamalesh U M**	**Dr Naresh Shetty**
Title: Executive Director Centre for Chronic Disease Control (CCDC)	**Title: Associate Professor, Department of Cardiology** **M S Ramaiah Medical College and Hospitals**	**Title: President - M S Ramaiah Clinical Research Centre**
Signature:	**Signature:**	**Signature:**
Date:	**Date:** 28/12/2016	**Date:** 27/12/16

DR. NARESH SHETTY
President
M.S.Ramaiah Clinical Research Centre

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

Appendix 1.

Site Budget (24 months)

Particulars	Amount (INR)
1.Site Manager (1) Rs 19481/-for 24 months	467544
2,Yoga trainer (1) Rs 15080/-for 24 months	361920
3.Physician Fee(Rs.250/- patient)	62500
4.Expense on yoga venue	20000
5.Communication and Postage (3300/- per month)	79200
6.Photocopying & other consumables (1250/- per month)	30000
7.Expenses towards travel reimbursement for participants/Refreshments	40625
Overheads @6.6%	75358
Total	**1137147**

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

2018-3

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement ("**Agreement**"), is entered into as of 17 January 2017 ("**Effective Date**") between Medical Technology Transfer and Services Hong Kong, located at No 26, Lane 41 An Duong Vuong, Tay Ho, Hanoi, Vietnam ("**MTTS**"), and M.S. Ramaiah Medical College and Hospitals, having its administrative offices at New Bel Road, MSRIT Post, Bangalore, 560054, India ("**Institution**") and sets forth the terms and conditions under which MTTS is willing to provide to Institution Product (as defined below) to conduct a clinical trial (the "**Study**") of MTTS's product comprising, incorporating or derived from any Continuous Positive Airway Pressure machines and associated products that are supplied by MTTS to Institution (the "**Product**"), in accordance with a mutually agreed protocol therefor and under the supervision of Dr. Pradeep G.C. Maralusiddappa (the "**Investigator**") all as set forth herein below:

NOW, THEREFORE, in consideration of the mutual covenants and premises herein contained, the parties hereto agree as follows:

1. **Third Parties**. The parties acknowledge that the Wellcome Trust Limited ("**Wellcome**") has provided funding for the Study under a funding agreement ("**Funding Agreement**") with MTTS. Wellcome has certain rights under the Funding Agreement as provided herein.

2. **Study Protocol**. Prior to initiation of the Study, Institution and MTTS shall mutually agree on the protocol for the Study. The mutually agreed protocol (the "**Protocol**") shall be attached to this Agreement as Exhibit A and incorporated herein by this reference. Institution shall not initiate the Study prior to mutual agreement of the Protocol and receiving training on use of the Product as described in Section 9. The Institution shall not, and shall procure that the Investigator shall not, use the Product provided under this Agreement for any purpose other than the Study.

3. **Access to Institution and Investigator**. Institution agrees that MTTS or its designee shall have reasonable access during normal working hours and at mutually agreed times to visit the premises where the Study is being conducted (the "**Study Site**"). Upon reasonable request by MTTS or its designee, Investigator and those employees, students, contractors and subcontractors of Institution working on the Study (collectively, including Investigator, the "**Study Personnel**") shall be available for discussion with MTTS or its designee. At MTTS's request, one or more Study Personnel may participate as observing members of a research steering group overseeing the Study.

4. **Applicable Law**. Institution shall, and shall procure that Investigator shall conduct the Study in accordance with the Protocol, the Wellcome Requirements, and all Applicable Laws. "**Applicable Laws**" means any statutes, rules, regulations and ordinances applicable to the Institution or MTTS, including the provisions of the Drugs and Cosmetics Act, 1940, the Drugs and Cosmetics Rules, 1945 and the Good Clinical Practice guidelines as issued by the Central Drugs Standard Control Organisation, Ministry of Health and Family Welfare, Government of India ("**GCP Guidelines**"), and the current highest standards of medical and clinical research practice. The "**Wellcome Requirements**" means the provisions set out in Exhibit D

5. **Ethical Approvals**. Institution and Investigator agree that research under the Study shall (a) comply with the World Medical Association's "Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects 2008" as amended from time to time; (b) be subject to appropriate ethical review procedures equivalent to those that would be required if the research were to be carried out in the UK; and (c) comply with all applicable local legislation including the GCP Guidelines; and (d) be approved by the local ethical review process. Prior to the initiation of the Study, Institution shall, and shall procure that Investigator shall (i) obtain all applicable ethical approvals, including approval by an Institutional Review Board ("**IRB**") of the Protocol, the investigator brochure and the informed consent form to be used in the Study and (ii) provide MTTS with a copy of such approvals.

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

6. **Informed Consent**. Institution shall, and shall procure that Investigator shall obtain a signed informed consent form from each subject or their authorized legal guardian in the Study (each a "**Study Subject**") and inform each Study Subject of possible side effects of the Product. Investigator shall promptly notify MTTS of any serious or unexpected event whether or not it has been determined to be attributable to the Product.

7. **Study Records**. Institution shall, and shall procure that Investigator shall collect and maintain appropriate records for each Study Subject including completing case report forms in a form mutually agreed by the parties for each visit (each, a "**CRF**"), and, as applicable, laboratory notebooks sufficient to establish any Inventions made (as defined in Section 13 below). Institution shall maintain such CRFs, laboratory notebooks and other information (including accountability records, signed informed consents and correspondence with applicable Regulatory Authorities) from the Study (collectively, "**Study Records**") in accordance with Applicable Laws and shall provide MTTS with copies of all CRFs, and upon MTTS's request and expense, Institution shall make available such other information for review and copy by MTTS or its designee. "**Regulatory Authorities**" means all national, supra-national, regional, state or local agency, department, bureau, commission, council or other governmental entity in any jurisdiction of the world with authority over the development, manufacture, use, marketing or sale of the Product. In addition, Institution shall allow Wellcome and Regulatory Authorities to inspect and copy such forms and information as they may request. Upon completion of the Study, Institution shall provide MTTS with copies of the clinical trial data and the Final Report (prepared by the Evaluation Director)within thirty (30) days from the last subject enrollment (the "**Final Report**").

8. **De-Identification of Personally Identifiable Information**. In making any portion of Study Records available to MTTS, Institution shall, and shall procure that Investigator shall fully de-identify all patient information in accordance with the U.S. Health Insurance Portability and Accountability Act, as amended ("**HIPAA**"). MTTS will not disclose protected health information or personal data, as defined by HIPAA, to others except for public health purposes, for auditing purposes, for emergencies, in submissions to Regulatory Authorities for product clearance or approval, when otherwise required by law or in any manner consistent with the terms of any applicable written authorization. Notwithstanding anything in this Agreement to the contrary, all information of each party to this Agreement containing personal data of any Study Subject shall be handled in accordance with all applicable privacy laws, rules and regulations.

9. **Supply of Product**. In consideration of the obligations of Institution and Investigator and the rights granted to MTTS hereunder and in support of the Study, MTTS agrees to provide the Product for the Study to Institution as follows:

   a. MTTS will provide to Institution the Product, as listed in Exhibit B and incorporated herein by reference, free of charge.

   b. MTTS shall deliver and provide technical and other training on use of the Product to staff at Institution.

10. **NO WARRANTY**. MTTS PROVIDES THE PRODUCT UNDER THIS AGREEMENT WITHOUT WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER WARRANTY, EXPRESS OR IMPLIED, AND WITHOUT ANY REPRESENTATION OR WARRANTY THAT THE USE OF THE PRODUCT WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK OR OTHER RIGHT.

11. **Compensation**. MTTS will compensate Institution for services performed pursuant to the Protocol in accordance with the payment schedule and budget attached hereto as Exhibit C. All payments made pursuant to this Agreement shall be made in Indian Rupees (INR). Such payments shall be made free and clear of any deduction or withholding, except that MTTS may deduct or withhold (i) any taxes, surcharges or other governmental charges or levies that MTTS is required by Applicable Laws to deduct or withhold and (ii) any monies that are the subject of a bona fide dispute between Institution and MTTS. All amounts paid to Institution by MTTS are expressed to be

Medh-490

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

Randomised trial comparing CPAP machines with reusable vs disposable circuits

STEERING COMMITTEE

Primary Investigator:
Dr Pradeep GCM, MS Ramaiah Medical College
Co-investigators:
Dr Sharan M, MS Ramaiah Medical College
Dr Prashanth MV, MS Ramaiah Medical College
Other Guidance:
The Wellcome Trust Research Steering Group provided assistance and guidance with protocol design. Members providing technical input included:

Dr David Millar, Neonatologist, in the role of Consultant to the Wellcome Trust
Dr Gaston Arnolda, Consultant to MTTS

PARTICIPATING SITES

M.S. Ramaiah Medical College, Bangalore, Karnataka, India.

TRIAL CONTACT

Dr Pradeep GCM
MS Ramaiah Medical College
Email: p_gcm@yahoo.com
Phone: +91 080 2360 5190

INSITUTIONAL ETHICS COMMITTEE

Shri Justice Venkatesha Murthy (Chairman)
Ethics Committee
M S Ramaiah Medical College and Hospitals
MSRIT Post, MSR Nagar
BANGALORE 560054
Email: msr_medical@dataone.in; msrmedical@gmail.com
Phone: +91 080 2360 5190

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

सत्यमेव जयते

Certificate No.	:	IN-KA23453090083465P
Certificate Issued Date	:	27-Oct-2017 02:18 PM
Account Reference	:	NONACC (FI)/ kaksfcl08/ PADMANABHA NAGAR/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKAKSFCL0896699173052325P
Purchased by	:	QUINTILES RESEARCH INDIA PVT LTD
Description of Document	:	Article 12 Bond
Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	QUINTILES RESEARCH INDIA PVT LTD
Second Party	:	M S RAMAIAH MEDICAL COLLEGE AND HOSPITAL
Stamp Duty Paid By	:	QUINTILES RESEARCH INDIA PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

SMT. SOUBHARDA PATTINA SAHAKARI NIYAMITA
R. No. ...RB/45/Sou/
Dt. 29.03.2009
BANGALORE

Please write or type below this line

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

Statutory Alert:

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

CLINICAL STUDY AGREEMENT

This Clinical Study Agreement ("**Agreement**") is made and entered into as of 03 Dec 2017 by and between, M S Ramaiah Medical College & Hospitals, M. S. Ramaiah Nagar, MSRIT Post, Bangalore - 560054, Karnataka, India ("**Study Site**"), Dr. Sanjay .C. Desai, M S Ramaiah Medical College & Hospitals, M. S. Ramaiah Nagar, MSRIT Post, Bangalore - 560054, Karnataka, India ("**Principal Investigator**"), and Daiichi Sankyo, Inc., located at 399 Thornall Street, Edison, New Jersey 08837 ("**DSI**"). Study Site and DSI are each referred to as a "**Party**" and collectively as the "**Parties**".

WITNESSETH:

WHEREAS, DSI desires that Study Site participate in the conduct of a multi-center clinical study (the "**Study**"), based on Protocol No. DU176b-D-U312 entitled "A Phase 3, Open-Label, Randomized, Multicenter, Controlled Trial To Evaluate The Pharmacokinetics Andpharmacodynamics Of Edoxaban And To Compare The Efficacy And Safety Of Edoxaban With Standard Of Care Anticoagulant Therapy In Pediatric Subjects From Birth To Less Than 18 Years Of Age With Confirmed Venous Thromboembolism (VTE)" (the "**Protocol**");

WHEREAS, the Study will utilize Edoxaban (the "**Study Drug**");

WHEREAS, the performance of the Study will benefit the Study Site and will further the Study Site's goals of research, teaching, education and public service; and

WHEREAS, the Study Site has represented that it has the resources to perform the Study in a competent manner, and in accordance with applicable law and industry practice.

WHEREAS, the Study Site agrees that DSI will engage Quintiles Research (India) Private Limited, located at having a place of business at B-101-106, Shapath IV, Opposite Karnavati Club, Sarkhej Gandhinagar Road, Ahmedabad - 380 051, Gujarat, India ("**CRO**") for doing certain monitoring works on behalf of DSI.

WHEREAS, pursuant to a letter dated 1 February 2016 from the Chairman of Gokula Education Foundation (Medical) ("**Payee**") to all stakeholders, the Institution will be operating as a unit of the Payee with effect from 1 February 2017.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. **Scope of Work.** The Study Site agrees to conduct the Study in accordance with the Protocol, based on the use of the Study Drug as described in the Investigators' Brochure. To the extent any terms of the Protocol are inconsistent with those of the Agreement, the terms of the Agreement shall govern the conduct of the Parties.

PRINCIPAL AND DE
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

IN WITNESS WHEREOF, the Parties have hereunto signed this Agreement in their official capacities as of the date first written above.

DAIICHI SANKYO, INC. (signed by Quintiles Research (India) Private Limited as an authorized signatory, on behalf of DSI)

By: Thatte

Name: Suneela Thatte

Title: Vice President, Global Operations

Date: 22 | Nov | 2017

M S Ramaiah Medical College and Hospitals:

By:

Name: Dr. Naresh Shetty

Title: President – M S Ramaiah Clinical Research Center

Date: 02 Dec 2017

PRINCIPAL INVESTIGATOR

By:

Name: Dr. Sanjay .C. Desai

Title: Principal Investigator

Date: 02 DEC 2017

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

ગુજરાત गुजरात GUJARAT

BH 760531

નંબર : S0731
તારીખ : 26 FEB 2018
નામ : LAMBDA THERAPEUTIC RESEARCH LTD.
ઠેકાણું : Plot No. 38, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad-382 481

ડી. આર. પાટીયા
લા. નં. અસા.એ. ૨૪૬, ૨૪૭/૧૯૯૬
અમદાવાદ મારફતપુરના સ્ટેમ્પ વેન્ડર
લેનારની સહી Dhirendra

Post Marketing Surveillance Study Agreement ("Agreement")

BETWEEN:

Lambda Therapeutic Research Ltd.
Plot No. 38, Survey no 388, Near Silver Oak Club,
S G Highway, Gota,
Ahmedabad 382481, Gujarat, India.
(Hereinafter referred to as "LAMBDA" or "CRO")

AND:

Stempeutics Research Pvt. Ltd.
3rd Floor, Manipal Hospitals Whitefield Pvt. Ltd.
#143, 212-215, EPIP Industrial Area
K R Puram Hobli
Bengaluru – 560 066, India
(Hereinafter referred to as the "Sponsor")

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College & Hospital,
Bangalore - 560 054.

Dr. Sanjay C Desai

LAMBDA
Research Accelerated

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

LAMBDA:

Sign: _____ **Date:** 13/Mar/18

Mr. Naresh Khemani
AGM, Finance,
Lambda Therapeutic Research Ltd

Witness:

Sign: Rakesh **Date:** 13/MAR/2018

Witness Name : **Dr. Rakesh Patel/Dr. Ravi Panchal**

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

Ravi Panchal
13/MAR/2018

Stempeutics Research Pvt. Ltd.,

Sign: PKGupta **Date:** 19 Mar 2018

Dr Pawan Kumar Gupta
Vice President – Medical Affairs

Institute:

Sign: _____ **Date:** 21/3/18

Dr. Naresh Shetty
President
M S Ramaiah Medical College and Hospitals,
M S Ramaiah Nagar MSRIT Post,
Bangalore 560054, Karnataka, India

Naresh Shetty

Dr. Sanjay C Desai

LAMBDA
Research Accelerated

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospitals
Bangalore - 560 054.

Witness:

Sign: Jayashree.l **Date:** 21/3/18

Witness Name: Ms Jayashree.l

Designation: Clinical Research Coordinator

Department/Work Unit: M.S. Ramaiah Clinical Research Center

Institute Name: M S Ramaiah Medical College and Hospitals,

Investigator: Dr. Sanjay C Desai

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

Principal Investigator:

Sign: _____ **Date:** 21 MARCH 2018

Dr. Sanjay C Desai
Professor and HOD
M S Ramaiah Medical College and Hospitals,

Witness:

Sign: Reetu Singh **Date:** 21/03/2018

Witness Name : Dr. Reetu Singh

Witness Address : M S Ramaiah Clinical Research Center
First Floor, M.S. Ramaiah Advanced Learning Center,
M S Ramaiah Nagar MSRIT Post,
Bangalore 560054, Karnataka, India

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

Schedule A

Study Protocol

Protocol No: 0486-17Dated

Version: 03 Dated 05 Dec 2017

"An open label, multicenter Post Marketing Surveillance Study in India to assess safety and efficacy of Intramuscular administration of stempeucel® in patients with critical limb ischemia due to Buerger's disease"

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

महाराष्ट्र शासन

GOVERNMENT OF MAHARASHTRA

ई-सुरक्षित बँक व कोषागार पावती

e-SECURED BANK & TREASURY RECEIPT (e-SBTR)

Bank/Branch: PNB/BKC BANDRA(7538)
Pmt Txn id : 140617M187060
Pmt DtTime : 14-06-2017@11:22:35
ChallanIdNo: 03006172017061350284
District : 7101/MUMBAI

Stationery No: 16111826004188
Print DtTime: 14-06-2017@17:13:12
GRAS GRN : MH002313794201718S
Office Name : IGR182/BOM1_MUMBAI CITY 1

StDuty Schm: 0030045501-75/Sale of Other NonJudicial Stamps SoS
StDuty Amt : R 5,000/-(Rs Five, Zero Zero Zero only)

RgnFee Schm:
RgnFee Amt :

Article : 13/Bond
Prop Mvblty: N.A
Consideration: R 25,00,000/-
Prop Descr : 101-A Wing,Fulcrum,Hiranandani,Business ParkSahar RoadAndheri East, Mumbai,Maharashtra

Duty Payer: (PAN-AADCP2043E) PPD Pharmaceutical Development India PVT LTD
Other Party: (PAN-AAATG1779Q) M S Ramaiah Clinical Research Centre

Bank official1 Name & Signature

Bank official2 Name & Signature

--- --- Space for customer/office use - - - Please write below this line --- ---

CLINICAL TRIAL AGREEMENT

THIS CLINICAL TRIAL AGREEMENT ("Agreement"), is entered into as of 20 day of July MONTH 2017 YEAR ("Effective Date") by and between PPD Pharmaceutical Development India Private Limited, 101-A Wing, 'Fulcrum', Hiranandani Business Park, Sahar Road, Andheri East Mumbai 400 099, India ("PPD"), and the M S Ramaiah Medical College and Hospitals ("Institution"), with its principal place of business at M S Ramaiah Medical College and Hospitals, M S Ramaiah Nagar, MSRIT Post, Bangalore-560054, Karnataka, represented by Dr.Naresh Shetty, a duly authorized representative with authority to contract on behalf of the Institution and Dr.Mahesh Eswarappa ("Principal Investigator"), with his/her offices located at M S Ramaiah Medical College and Hospitals, M S Ramaiah Nagar, MSRIT Post, Bangalore-560054, Karnataka

PPD, Institution and Principal Investigator are herein referred to each as a "Party" and, collectively, as the "Parties".

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

temperature (2 in quantity).PPD, GSK and the Institution agree that any of these measures that may be provided by PPD or GSK are not intended to be for the exclusive benefit of the Clinical Trial or of GSK studies generally, or to induce the Institution to participate in the Clinical Trial or to induce or reward any use, purchase, recommendation, or prescription of GSK products. GSK and the Institution also agree that any of these measures that may be provided by PPD or GSK are intended to be sustainable by the Institution and the local community following the Clinical Trial.

(c) GSK and the Institution have sought agreement with key interested external parties, including ethics committees, research investigators, national government, health ministry, local health authorities, ethics groups, non-governmental organisations, or representatives of the communities who might participate in the Clinical Trial, that it is appropriate to conduct the Clinical Trial at the Institution, including discussion of the standard of care to be provided during the study, the scientific rationale for interventions (including placebo), the provision of healthcare for subjects after the study, and the fate of any capacity built for the conduct of the study.

(d) The Institution agrees that any nationally-licensed medicinal products that are not the subject of the Clinical Trial but are required for the routine care of a Clinical Trial subject during and after the Clinical Trial for the disease or condition to which the Clinical Trial relates are expected to be available to the Clinical Trial subject and funded through the usual operations of the local healthcare system independently from the Clinical Trial and without expectation of GSK support.

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

M S Ramaiah Medical College And Hospitals

Name:Dr. Naresh Shetty
Position: President
Date: 12/7/2017
Stamp:

DR. NARESH SHETTY
President
M.S.Ramaiah Clinical Research Centre

PPD Pharmaceutical Development India Private Limited

20-JUL-2017

Name: Rashmi Chitgupi
Position:
Date:
Stamp:

Rashmi Chitgupi
Associate Director - Clinical Management
PPD Pharmaceutical Development India Pvt. Ltd.
101-A Wing, Fulcrum, Hiranandani Business Park
Sahar Road, Andheri East
Mumbai – 400 099, India.

Dr.Mahesh Eswarappa

Name: Dr.Mahesh Eswarappa
Position: Principal Investigator
Date: 13/Jul/2017
Stamp:

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College & Hospital,
Bangalore - 560 054.

WHEREAS

I. PPD is a global contract research organization that is currently assisting GlaxoSmithKline Research & Development Limited,980 Great West Road Brentford, Middlesex TW8 9GS,United Kingdom ("GSK") or one of its Affiliates in the conduct of the clinical trial in accordance with the protocol entitled "A Phase 3 randomized, open-label, active-controlled, parallel-group, multi-center, event driven study in dialysis subjects with anemia associated with chronic kidney disease to evaluate the safety and efficacy of GSK1278863 compared to recombinant human erythropoietin, following a switch from erythropoietin-stimulating agents" ("Clinical Trial"), Protocol Number: "PHI200807" and any amendments thereto ("Protocol"). GSK is the Sponsor of the Clinical Trial. PPD is an Affiliate of PPD International Holdings Inc and has been engaged by PPD International Holdings Inc to support the performance of the Clinical Trial;

II. The Institution and Principal Investigator desire to participate in the conduct of the Clinical Trial, in accordance with the Protocol, herein attached as **Schedule 1**;

III. The Parties agree to conduct the Clinical Trial in accordance with the terms and conditions hereinafter set forth.

THEREFORE, IT IS AGREED AS FOLLOWS:

1. Clinical Trial Performance

1.1 Institution and Principal Investigator shall provide certain services ("Services") related to the conduct of the Clinical Trial, in accordance with the Protocol, hereto attached as **Schedule 1** (and any subsequent amendments made thereto in accordance with this Agreement, and with all applicable laws, rules and regulations relating to the Clinical Trial. The Protocol is subject to approval by the appropriate Institutional Review Board or Ethics Committee or equivalent body (collectively "IRB"). The informed consent ("Informed Consent") is subject to approval by the IRB. If there is any discrepancy or conflict between the terms contained in the Protocol and this Agreement, the terms of the Protocol shall govern and control with respect to clinical matters and the terms of the Agreement shall govern and control with respect to all other matters.

1.2 Prior to the commencement of the Services, Institution and Principal Investigator shall review the Protocol and notify PPD if they cannot comply with any of the terms contained therein. If in the course of performing the Services, in accordance with generally accepted standards of clinical research and medical practice relating to the benefit, well-being and safety of the subjects ("Subject(s)") a deviation from the Protocol is required, such standards will be followed. In such case, the Party aware of the need for a deviation shall immediately notify PPD and GSK of the facts supporting such deviation as soon as the facts are known to such Party. The notification shall also be confirmed in writing within three (3) working days of the original notification being made to PPD and GSK.

1.3 The Institution and Principal Investigator agree to carry out the Services in strict compliance with:

(a) all specifications and timelines established in this Agreement;

(b) the Protocol and any amendments to the Protocol;

(c) the provisions of the current version of the World Medical Association's Declaration of Helsinki, in particular, neither the Institution nor the Principal Investigator must at

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

2017-19 (1)

CLINICAL STUDY AGREEMENT

This Clinical Study Agreement (hereinafter 'Agreement') is made,

BETWEEN

Roche Products (India) Private Limited, an Indian Company, having it's registered office at "The Capital", 15th Floor, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, INDIA, (hereinafter called as **"RPIPL",** which expression unless repugnant to the context shall mean and include its successors-in-interest and permitted assigns) of the FIRST PART;

AND

M.S.Ramaiah Medical College and Hospitals (hereinafter referred to as **"Institution"**, which expression unless repugnant to the context shall mean and include its successors-in-interest and permitted assigns) of the SECOND PART;

AND

Dr.Nalini Kilara working as Senior Prof.And Head, having his place of business at, **M S Ramaiah Medical College and Hospital, New BEL Road, (Gokula extension) MSR Nagar, Bangalore 560094** (hereinafter called as **"Principal Investigator or P.I."**, which expression unless repugnant to the context shall mean and include his legal heirs, representatives, successors and permitted assigns) of the THIRD PART;

(each a "Party" and collectively "Parties)

WHEREAS, Roche Group has the Intellectual Property Rights in respect of the product - **Perjeta RO4368451**) (hereinafter called as "Product")

WHEREAS, RPIPL wishes to engage the P.I., to carry out the research in respect of clinical study titled **"A Phase IV, Multicenter, Open-Label, Single-Arm Study Of Pertuzumab (In Combination With Trastuzumab And Docetaxel) In First Line Treatment Of Indian Patients With Her2-Positive Advanced (Metastatic Or Locally Recurrent) Breast Cancer"** (hereinafter "The Study") as defined in the Protocol No. "ML29282" {'Protocol'};

WHEREAS, the PI and Institution are willing to conduct the Study on the terms and conditions set forth in this Agreement. The P.I. shall conduct the Study at Institution. ("PI and Institution collectively called as Site");

NOW THEREFORE, the Parties hereto have agreed as follows.

EFFECTIVE DATE: This Agreement will become effective on the date of approval of the Study by Drugs Controller General of India or on the date of approval of the Study by the Ethics Committee or on the date on which this Agreement is last signed by the parties, whichever date is later, and shall continue until completion of study or until terminated in accordance with the provision in Clause 14

1. PROTOCOL AND INVESTIGATOR BROCHURE

The scope and nature of the clinical study to be performed under the responsibility of the P.I. and Institution will be in accordance with Protocol number **"ML29282"**.

THE KAPOL CO-OP. BANK LTD. FORT BRANCH AUTHORISED SIGNATORY

PRINCIPAL AND DEAN M.S.Ramaiah Medical College & Hospital, Bangalore - 560 054.

IN WITNESS WHEREOF, Parties through their authorized representatives have signed this Agreement.

I. **Signed on behalf of Roche Products (India) Pvt. Ltd.**

11 Aug 2015

Dr. Aditi P. Parekh Date
Associate Director – Clinical Operations

11 August 2015

Mr. Sachin Bobhate Date
Senior Manager – Legal and Admin.

II. **I hereby agree to the above conditions:**

Principal Investigator (P.I.) Date
Dr.Nalini Kilara
M.S.Ramaiah Medical College and Hospitals
New BEL Road , MSRIT Post
Bangalore -560054

III. **Signed on behalf of M.S.Ramaiah Medical College and Hospitals**

18/8/15

Date

Authorized signatory from Institution

Name: Dr.D.C.Sundaresh

Designation: President- MSRCRC

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College & Hospital, Bangalore - 560 054.

2019 - 8

GOVT. OF KARNATAKA

DEPT. OF STAMP & REGISTRATION

भारत 188256 FEB 18 2016

15:37

INDIA Rs.0000100 PB6935

STAMP DUTY KARNATAKA

ಉಪನೋಂದಣಾಧಿಕಾರಿ

ಪುರ, ಬೆಂಗಳೂರು

INVESTIGATOR AGREEMENT
NOVO NORDISK SPONSORED CLINICAL TRIAL
Trial ID: NN9068-4228

This Investigator Agreement (the "**Agreement**") is made and entered at Bangalore on this the 03 March 2016 (the "**Effective Date**") by and between:

Novo Nordisk India Private Limited, a company registered under the Companies Act, 1956 having its registered office at Plot No. 32, 47-50, EPIP Area, Whitefield, Bangalore - 560 066 (herein after referred to as "**Sponsor**", which expression where the context so admits shall include its successors and assigns) of the ONE PART;

AND

Dr. Pramila Kalra, [PAN: AIYPK5041M] having her office at M.S. Ramaiah Medical College and Hospitals, New BEL Road, MSRIT Post, Bengaluru - 560 054 (herein after referred to as "**Principal Investigator**", which expression where the context so admits shall include its successors and assigns) of the SECOND PART;

AND

M.S. Ramaiah Medical College and Hospitals, [PAN: AAATG1779Q] having its office at New BEL Road, MSRIT Post, Bengaluru - 560 054, (herein after referred to as "Institution", which expression where the context so admits shall include its successors and assigns) of the THIRD PART.

In the following, Sponsor, Principal Investigator and Institution are also referred to individually as "Party" and collectively as "Parties".

WHEREAS

1. The Sponsor wishes to conduct the following clinical trial in India: A 104 week clinical trial comparing long term glycaemic control of insulin degludec/liraglutide (IDegLira) versus insulin glargine therapy in subjects with type 2 diabetes mellitus. **Protocol ID:** NN9068-4228 (the "Trial"). The nature of the Trial is further elaborated upon in this Agreement;

2. The Sponsor wishes to conduct the Trial in cooperation with Principal Investigator at the Institution;

3. The Principal Investigator has the expertise and the Institution has the necessary resources relating to clinical trial design, conduct, evaluation and analysis.

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

16. ASSIGNMENT

16.1 This Agreement shall not be assigned by either Party, in whole or in part, without the prior written consent of the Parties hereto.

16.2 Sponsor shall have the right at any time to assign or transfer any or all of its rights and obligations under this Agreement to any of its Affiliates. For the purpose of this Agreement "Affiliate" means any corporation, company, partnership, joint venture or other entity which controls, is Controlled by, or is under common Control with a person or entity. "Control" means the ownership of more than fifty percent (50%) of the issued share capital or the legal power to direct or cause the direction of the general management and policies of the party in question. For the avoidance of doubt, none of Novo A/S, Novozymes A/S nor any entity, which Controls, is Controlled by, or is under common Control with such entities, other than entities within the Novo Nordisk group of companies, will be deemed to be an "Affiliate" of Novo Nordisk. This shall bind the Parties, their successors and permitted assigns.

17. INDEPENDENT CONTRACTOR

17.1 In the performance of the Trial hereunder:

a) Principal Investigator shall be deemed to be and shall be an independent contractor and, as such, Principal Investigator shall not be entitled to any benefits applicable to employees of the Sponsor.

b) Principal Investigator and Institution on one side, and Sponsor on the other side acknowledge that the relationship between them is that of independent contractors, and not that of employer and employee, nor principal and agent, nor partners in a joint venture, nor any similar relationship whatsoever. Neither Party shall exercise control over the business of the other Party, and neither Party is granted any right or authority to assume or to create any obligation or responsibility, express or implied, on behalf of, or in the name of the other Party, or in any other way to act on behalf of, or to bind, the other Party.

17.2 IN WITNESS HEREOF, the Parties have executed and delivered this Agreement,

Date: 23 Feb '16	Date: 3/03/2016
On behalf of Sponsor:	Principal Investigator:
Name: **Dr. M.V. Srishyla**	Name: **Dr. Pramila Kalra**
Title: Director – Clinical, Medical, Regulatory Affairs & Quality	Title: Principal Investigator
Date: 23 FEB 2016	Date: 3/3/2016
On behalf of Sponsor:	On behalf of Institution:
Name: **Mr. Melvin Oscar D'Souza**	Name: **Dr. Naresh Shetty**
Title: Managing Director	Title: President, MSRCRC

PRINCIPAL AND DEA
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

GOVT. OF KARNATAKA

DEPT. OF STAMP & REGISTRATION

INDIA R 0000200 PB6935

STAMP DUTY KARNATAKA

INVESTIGATOR AGREEMENT
NOVO NORDISK SPONSORED CLINICAL TRIAL
Trial ID: [NN9535-4270]

This Investigator Agreement (the "**Agreement**") is made and entered at Bangalore on this the 04 JUL 2017 (the "**Effective Date**") by and between:

Novo Nordisk India Private Limited, a company registered under the Companies Act, 1956 having its registered office at Plot No. 32, 47-50, EPIP Area, Whitefield, Bangalore - 560 066 (herein after referred to as "**Sponsor**", which expression where the context so admits shall include its successors and assigns) of the ONE PART;

AND

Dr. Mala Dharamalingam, a healthcare professional (PAN: ADGPD4890A) having her office at M S Ramaiah Medical College and Hospitals, New BEL Road, MSRIT Post, Bangalore-560054. (herein after referred to as the "**Principal Investigator**", which expression where the context so admits shall include its successors and assigns) of the SECOND PART;

AND

Gokul Education Foundation (Medical), through its units M S Ramaiah Clinical Research Centre, and M S Ramaiah Medical College and Hospitals (PAN No: AAATG1779Q) having its office at First Floor, M.S. Ramaiah Advanced Learning Center, Gnanagangothri Campus, Gate-4, New BEL Road, MSRIT Post, Bangalore 560 054, (herein after referred to as the "**Institution**", which expression where the context so admits shall include its successors and assigns) of the THIRD PART.

In the following, Sponsor, Principal Investigator and Institution are also referred to individually as "Party" and collectively as "Parties".

WHEREAS

1. The Sponsor wishes to conduct the following clinical trial in India: Efficacy and safety of semaglutide versus canagliflozin as add-on to metformin in subjects with type 2 diabetes; **Protocol ID:** NN9535-4270 (the "Trial"). The nature of the Trial is further elaborated upon in this Agreement;

2. The Sponsor wishes to conduct the Trial in cooperation with Principal Investigator at the Institution;

The Principal Investigator has the expertise and the Institution has the necessary resources relating to clinical trial design, conduct, evaluation and analysis. The Institution has agreed to assist The Sponsor in the conduct of the Trial at the Institution under the supervision of its employee, the Principal Investigator, under the terms and conditions of this Agreement.

PRINCIPAL AND DEPT. M.S. Ramaiah Medical College & Hospital, Bangalore - 560 054.

17.2 IN WITNESS HEREOF, the Parties have executed and delivered this Agreement,

Date: 10 Jul 2017

On behalf of Novo Nordisk:

Name: Dr. M.V. Srishyla
Title: Director- Clinical, Medical, Regulatory Affairs & Quality

Date: 11-July-2017

Date:

[Principal Investigator]:

Name: Dr. Mala Dharamalingam
Title: Principal Investigator

Date: 13-JULY-2017

On behalf of Novo Nordisk:

Name: Melvin Oscar D'Souza
Title: Managing Director
Date:

On behalf of [Institution]:

Name: Dr. Naresh Shetty
Title: President, M S Ramaiah Clinical Research Centre
Date: 12-Jul-2017

DEVC
Galog.

PRINCIPAL AND DEA.
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

07/JULY/2017

Clinical Trial Agreement

ARTICLES OF AGREEMENT made at Mumbai, this 27th day of Feb 2017

BETWEEN:

NOVARTIS HEALTHCARE PRIVATE LIMITED, a company incorporated under the Companies Act, 1956 and having its registered office at Sandoz House, Dr. Annie Besant Road, Worli, Mumbai 400018, hereinafter referred to as "**Sponsor**" (which expression shall, unless repugnant to the context or meaning thereof, be deemed to mean and include its successors and assigns) of the First Part;

Dr Srinivasa Rangashetty, designation being Prof and Head Dept of Neurology and having his/her address at M S Ramaiah Medical College and Hospital, Dept of Neurology, New Bel Road, MSRIT Post Bangalore, Karnataka 560054, ,hereinafter referred to as "**Investigator**", (which expression shall, unless it be repugnant to the context ore meaning thereof, be deemed to mean and include his or her heirs, executors, administrators and successors) of the Second Part;

AND

Dr Naresh Shetty, whose designation is President at M.S Ramaiah Clinical Research Centre, New Bel Road, MSRIT Post Bangalore, Karnataka 560054 registered under the provisions of the medical council of India, ACT 1956, and hereinafter referred to as "**Institution**", (which expression shall, unless repugnant to the context or meaning thereof be deemed to mean and include its successors and assignee and permitted assigns) of the Third Part.

(Sponsor, Investigator and Institution may be individually referred to as Party and collectively as Parties)

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College & Hospitals
Bangalore - 560 054.

and distribution of a wide range of drugs and pharmaceutical products in India;

B. The Sponsor is interested in conducting the following clinical trial as per protocol namely **Protocol No. COMB157G2301;**

Protocol Title: A randomized, double-blind, double-dummy, parallel-group study comparing the efficacy and safety of ofatumumab versus teriflunomide in patients with relapsing multiple sclerosis.

as may be amended from time to time by the Sponsor at its sole discretion (hereinafter referred to as **"Protocol"**) and has approached the Investigator for the conduct and supervision of the Clinical trial in accordance with the Protocol.

C. The Investigator is a qualified medical practitioner inter alia, engaged in medical research and clinical practice of Neurology in the M S Ramaiah Medical College and Hospital, the Investigator has agreed to conduct the above clinical trial as per the Protocol and has represented to the Sponsor that it shall obtain the approval of the Ethics Committee where the clinical trial shall be conducted;

D. The Institution has agreed to provide all the necessary infrastructure including but not limited to laboratory investigations, ECG etc. with a view to facilitate and enable the Investigator and Sponsor to perform the clinical trial in accordance with the Protocol.

E. The Investigator has been informed by the Sponsor that prior approval of the Drugs Controller General (India) (DCGI) for its no objection to conducting the clinical trial has been applied for and will be procured prior to conducting the clinical trial . The Investigator, on his/her part, irrevocably consents to undertake and conduct the Clinical trial and has agreed to execute this Agreement. It is agreed between the Parties hereto that commencement and conduct of the clinical trial /clinical trial in terms

PRINCIPAL AND I/C
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

महाराष्ट्र MAHARASHTRA ◑ 2017 ◑ RY 646673

प्रधान मुद्रांक कार्यालय, मुंबई
- 1 AUG 2017
सक्षम अधिकारी

श्री. हेमंत सावंत

AMENDMENT NO. 01 TO CLINICAL TRIAL SERVICE AGREEMENT

DATED 11TH TH DAY OF SEPTEMBER 2017
BETWEEN
M S RAMAIAH MEDICAL COLLEGE & HOSPITALS
AND
DR. PRASANNA KUMAR T

INPLCT16050

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

This Amendment No. 01 to the Clinical Trial Service Agreement ("Agreement") is made this 11th day of September 2017 by and between:

Glenmark Pharmaceuticals Limited, a company incorporated under the laws of India and having its registered office at B/2, Mahalaxmi Chambers, 22, Bhulabhai Desai Road, Mumbai - 400 026, India and having its corporate office at Glenmark House, B. D. Sawant Marg, Chakala, Andheri East, Mumbai – 400 099, India (hereinafter referred to as "**Glenmark**" which expression shall unless repugnant to the context or meaning thereof be deemed to mean and include its successors and assigns) of the One Part;

And

M S Ramaiah Medical College & Hospitals, an institution incorporated under the laws of India having its registered office at New BEL Road, MSRIT Post, Bangalore - 560054, Karnataka, India (hereinafter referred to as the "**Institution**" which expression shall unless repugnant to the context or meaning thereof shall be deemed to mean and include its successors and permitted assigns) of the **SECOND PART;**

And

Dr. Prasanna Kumar T, a Indian, residing at No 20, opp Lakshmi venkateshwara temple, RMV II stage, Nagasettyhalli, Bangalore – 560094. India (hereinafter referred to as the "**Investigator**" which expression shall unless repugnant to the context or meaning thereof shall be deemed to mean and include his heirs and legal representatives) of the **THIRD PART.**

And

In this Agreement, Glenmark, Institution and Investigator are collectively referred to as "**Parties**" and severally as "**Party**".

WHEREAS

a. Glenmark, Institution and Investigator had entered into a Clinical trial service Agreement dated 04th January 2017 (**"Clinical Trial Service Agreement"**) whereby the Investigator has agreed to undertake clinical study in accordance with the provisions of the Clinical trial Agreement and Protocol No. GPL/CT/2016/003/III mentioned therein [for Glenmark's Phase III trial named "A 12-week treatment, multi-centre, randomized, double-blind, parallel-group, active-controlled study to assess the efficacy, safety, and tolerability of a fixed dose combination of glycopyrronium (12.5 mcg)/formoterol fumarate dihydrate (12 mcg) in a dry powder inhaler in comparison with Glenmark AirzTM Glycopyrronium powder for inhalation 50 mcg in subjects with chronic obstructive pulmonary disease" (Study)] on the terms and conditions more specifically mentioned therein;

b. The Parties wish to carry out certain amendments to the said Clinical Trial Service Agreement.

NOW, THEREFORE, in consideration of the mutual covenants and obligations contained herein, the sufficiency of which are hereby acknowledged, Glenmark and Institution, Investigator agree as follows:

1. Unless explicitly provided for otherwise in this Agreement, all capitalized terms in this Agreement shall have the same meaning as defined in the said Clinical Trial Services Agreement.

2. The Parties agree that the said Clinical Trial Services Agreement hereby stands amended to the intent and effect and purpose as follows:-

   a. Clause 6 'Payment' stands deleted and replaced with following :

   "6. **Payment**:

   6.1 In consideration of the performance of the Services by the Institution and the Investigator pursuant to this Agreement, Institution and the Investigator shall submit to Glenmark for payment, pursuant to the following terms, an invoice for those sums identified in **Annexure 5** when the relevant event or time period set out in **Annexure 4** occurs.

   6.2 Glenmark will pay the Institution and the Investigator for all sums properly invoiced in accordance with Section 6.1 and Annexure 5 within 30 days of receipt of such invoice.

   6.3 Glenmark may suspend payment of an invoice if it raises a bona fide dispute as to the accuracy of any invoice submitted by the Institution and the Investigator. If the dispute cannot be resolved between the Parties it will be referred to arbitration in accordance with Section 17.2.

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

Glenmark Pharmaceuticals Limited
by its duly authorized representative,
as s/he so declares

Name: Suyog Shetty
Title: General Manager - Legal

For the Institution
by its duly authorized representative,
as s/he so declares

Name: Dr. Naresh Shetty
Title: President - MSRCRC

Investigator
by its duly authorized representative,
as s/he so declares

Name: Dr. Prasanna Kumar T
Title: Principal Investigator

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

महाराष्ट्र MAHARASHTRA ◑ 2016 ◑ RM 442371

CLINICAL TRIAL AGREEMENT
("Agreement")

प्रधान मुद्रांक कार्यालय, मुंबई
प. मू. वि. क्र. ८०००११
31 JAN 2017
सक्षम अधिकारी

Between

Boehringer Ingelheim India Private Limited
1102, Hallmark Business Plaza,
Gurunanak Hospital Road,
Bandra (East), Mumbai- 400051
[Please insert relevant affiliate and address]
VAT-ID-No. resp. Taxpayer Ident. No.: MUMB12332F
CIN : U24230MH2003PTC143499
("Sponsor")

श्री. रा. कृ. पोटले

And

M. S. Ramaiah Medical College and Hospitals,
M S Ramaiah Nagar, MSRIT Post, Bangalore -560054, Karnataka.
Responsible unit: Department of Respiratory Medicine
VAT-ID-No. resp. Taxpayer Ident. No.: NA
("Institution")

And

Dr. Gayathri Devi H. J.
Department of Respiratory Medicine,
M. S. Ramaiah Medical College and Hospitals,
M S Ramaiah Nagar, MSRIT Post, Bangalore -560054, Karnataka.
VAT-ID-No. resp. Taxpayer Ident. No.: NA
("Investigator")

PRINCIPAL AND DE
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

RECITALS

WHEREAS, Sponsor, a research-driven pharmaceutical company, is sponsoring and conducting a clinical trial of Nintedanib (the "Investigational Product") according to the Clinical Trial Protocol for BI Trial No. 1199.214 including all documents attached thereto and referenced therein (the "Protocol") entitled "A double blind, randomized, placebo-controlled trial evaluating efficacy and safety of oral Nintedanib treatment for at least 52 weeks in patients with 'Systemic Sclerosis associated Interstitial Lung Disease'(SSc-ILD)" as amended (the "Trial"), incorporated herein by reference and provided to Institution and/or Investigator by the Sponsor under separate cover in the regulatory document package; and

WHEREAS, Sponsor seeks to engage the services of Institution and Investigator to carry out the Trial in accordance with the Protocol; and

WHEREAS, Institution operates a facility engaged in research activities and services including the creation, implementation and documentation of clinical research, testing and trials and desires to participate as a site for the conduct of the Trial, as contemplated by this Agreement; and

WHEREAS, Investigator is engaged in medical research on behalf of Institution and desires to participate in and serve as the principal Investigator on behalf of Institution and to conduct clinical investigations as part of the Trial, as contemplated by this Agreement.

NOW, THEREFORE, the Parties hereto agree as follows:

1. OBLIGATIONS OF INSTITUTION AND INVESTIGATOR

1.1 Conduct of the Trial.

1.1.1 **Protocol.** Investigator will conduct the Trial at Institution's facility located at M. S. Ramaiah Medical College and Hospitals, M S Ramaiah Nagar, MSRIT Post, Bangalore-560054, Karnataka. in accordance with the Protocol.

1.1.2 **Trial Staff and Facilities.** Institution and/or Investigator will provide an adequate number of qualified Trial Staff, and adequate facilities and will require the Trial Staff and facilities to conduct the Trial properly and safely and in accordance with the Protocol and Applicable Law (as defined below under Section 1.1.4). Trial Staff means any employees of Institution or Investigator, and/or contractors engaged by Institution or Investigator, who are involved in performing the Trial, including any sub-investigator(s), study coordinator(s), and any other contractors, agents and employees of Institution or Investigator who assist Institution and Investigator with the Trial. Institution and Investigator shall inform Sponsor promptly in writing about all changes impacting the Trial Staff and/or facilities.

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

IN WITNESS WHEREOF, the Parties have executed this Agreement in 3 originals by their duly authorized representatives.

Boehringer Ingelheim India Pvt. Ltd.

By: _____

Name: Dr. Partha Gokhale

Title: Head, Clinical Operations

Date: 10 Apr 2017

By: _____

Name: Mr. Sharad Tyagi

Title: Managing Director

Date: _____

INSTITUTION

By: _____

Name: Dr. NARESH SHETTY

Title: PRESIDENT, NSRCRC

Date: 25/04/2017

INVESTIGATOR:

By: _____

Name: Dr GAYATHRI DEVI H.J.

Date: 20/4/2017

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College & Hospital,
Bangalore - 560 054.

PPD

STATEMENT OF AGREEMENT

(Clinical Trial Agreement)

Between

Dr Rangasetty Srinivasa
(hereinafter referred to as the "Investigator")

And

Gokula Metropolis Clinical Research Centre,
M.S. Ramaiah Memorial Hospital,
New BEL Road, MSRIT Post
Bangalore – 560054
Karnataka, India
(hereinafter referred to as the "Institution")

And

PPD PHARMACEUTICAL DEVELOPMENT INDIA PRIVATE LIMITED, trading as PPD,
801-804, Powai Plaza,
Hiranandani Business Park,
Powai, Mumbai- 400076, India
(hereinafter referred to as "PPD")

Protocol number: [UCB] [N01199]

1 Introduction

1.1 PPD, a clinical research organization, is pleased that our discussions have resulted in your agreement to participate in and conduct this collaborative clinical research trial, described below, sponsored by UCB Pharma SA (the "Study" and the "Sponsor" respectively)

1.2 In order to make this Study mutually rewarding, it is essential that we are in agreement with regard to the basic policies applicable to the Study. Accordingly, this Clinical Trial Agreement in conjunction with Sponsor's protocol no. N01199 entitled An open-label, multicenter, follow-up trial to evaluate the long-term safety and efficacy of brivaracetam used as adjunctive treatment at a flexible dose up to a maximum of 150 mg / day in subjects aged 16 years or older suffering from epilepsy." (and any amendments thereto from time to time) (the "Protocol"), which is incorporated by reference herein, will serve together as an agreement, delineating the terms and conditions applicable (the "Agreement").

2 Study Conduct

2.1 The scope and nature of the Study and services to be performed at **M.S. Ramaiah Memorial Hospital, Bangalore – 560054 Karnataka** (the "Site") will be in accordance with the Protocol.

2.2 The Institution and Investigator each warrants to PPD that they have the education, experience, capabilities, adequate patient population, adequate personnel, equipment and other resources to conduct the Study in a professional and competent manner, and that they are fully aware of applicable regulations; furthermore, they agree that they will not participate in any other Study that by its nature will prevent them from fulfilling their obligations in the Study hereunder or is otherwise

801 - 804, Powai Plaza *Hiranandani Business Park, Powai* *Mumbai 400 076, India*
voice +91 22 2571 2900 *fax +91 22 2571 2999* *www.ppdi.com*

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

INSTITUTION AND INVESTIGATOR UNDERSTAND AND ACKNOWLEDGE THAT FABRICATION, FALSIFICATION OR ALTERATION BY INSTITUTION, INVESTIGATOR OR ANY EMPLOYEES OR AGENTS OF INSTITUTION OF ANY PATIENT DATA OR OTHER INFORMATION PROVIDED BY INSTITUTION OR PRINCIPAL INVESTIGATOR PURSUANT TO THIS AGREEMENT CAN RESULT IN CRIMINAL ACTIONS AND SANCTIONS AGAINST INSTITUTION AND INVESTIGATOR AND IN CIVIL LIABILITY TO PPD AND SPONSOR.

19 Agreement

19.1 The fee quoted in the budget schedule appended is exclusive of any taxes, if applicable, chargeable thereon.

19.2 It is the Institution and Investigator's responsibility to ensure that the hospital Trust management is made aware of their participation in this Study and approval is obtained prior to commencing the Study.

We hereby agree to the conditions in this Agreement:

Signed for and on behalf of the Investigator:

..... 5/8/08

Investigator's signature **Date**
Dr R. Srinivasa

Signed for and on behalf of PPD:

..... 16-Jun-2008

Signature **Date**
Sanjay Kabra, Head - Clinical Management

Signed for and on behalf of M.S. Ramaiah Memorial Hospital, Bangalore – 560054, Karnataka

..... 5 Aug 08

Signature **Date**

Name: Dr SHAKUNTALA G
Title: Head of Operations.
Address: Ramaiah metropolis Clinical Research Centre.

2018 - 39

भारतीय गैर न्यायिक

एक सौ रुपये

Rs. 100

रु. 100

ONE HUNDRED RUPEES

सत्यमेव जयते

भारत INDIA

INDIA NON JUDICIAL

ગુજરાત ગુજરાત GUJARAT

AV 685563

નંબર : 03 ૨૫૫ રૂ. 30 APR 2016

તારીખ : માર્ચ ૨૦૧૬

નામ : LAMBDA THERAPEUTIC RESEARCH LTD.
Plot No. 38, Near Silver Oak Club,

ઠેકાણું : S. G. Highway, Gota,
Ahmedabad-380 061.

Clinical Trial Agreement

BETWEEN:

Lambda Therapeutic Research Ltd.

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

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

Acting as agent for

Intas Pharmaceuticals Ltd.

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

Dr. T K Sumathy

LAMBDA
Research Accelerated

2nd Floor, Chinubhai Center,
Ashram Road,
Ahmedabad-380009, Gujarat, India

(Hereinafter referred to as the "Sponsor")

AND:

Name of Principal Investigator
Dr. T K Sumathy

Address of Site
M S Ramaiah Medical College and Hospitals;
MSRIT Post, New BEL Road
Bangalore 560054, Karnataka, India
(Hereinafter referred to as the "Investigator")

AND:

Name of Institute
M S Ramaiah Medical College and Hospitals;

Address of Institute
M S Ramaiah Memorial Hospital;
MSRIT Post, New BEL Road
Bangalore 560054, Karnataka, India

(Hereinafter referred to as the "Institute")

WHEREAS:

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

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

LAMBDA on behalf of Sponsor wishes the Investigator and Institute to participate in a clinical trial entitled **"A Double blind, Randomized, Placebo controlled, Parallel Group,**

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College & Hospital, Bangalore - 560 054.

Prospective, Multicentre Clinical Trial for Evaluation of Efficacy and Safety of Fixed Dose Combination of Minoxidil (5%) + Finasteride (0.1%) Lipid Solution in Comparison with Minoxidil (5%) Lipid Solution and Finasteride (0.1%) Lipid solution in Adult Male Patients with Androgenetic Alopecia."("Clinical Trial") to be conducted under the direction and supervision of the Investigatorusing the facilities of the Institution; and,

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

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

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

1 Definitions

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

Term	Meaning
"Compound"	Fixed dose combination of Minoxidil (5%) + Finasteride (0.1%) **(Test product)** as Lipid Solution
"CRF"	Case Report Form
"CRO"	Contract/Clinical Research Organization
"Declaration of Helsinki"	The 2013 version of the Helsinki Declaration of the World Medical Association and amendments.
"DCGI"	Drug Controller General of India.
"Ethics Committee"	The relevant properly constituted ethics committee as organized by the Hospital Authority or independent, which has reviewed or will review the application for conducting the Clinical Trial.

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

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

LAMBDA:

Sign: _____ **Date:** 12/May/16

Mr. Naresh Khemani
AGM, Finance
Lambda Therapeutic Research Ltd

Witness (Lambda):

Sign: _____ **Date:** 12 May 2016

Dr. Dharmesh Domadia
Lambda Therapeutics Research Ltd.

Institute:

Sign: _____ **Date:** 28/MAY/2016

Name: Dr Naresh Shetty
Address: M S Ramaiah Medical College and Hospitals;
MSRIT Post, New BEL Road
Bangalore 560054, Karnataka, India

Witness:

Sign: _____ **Date:** 28/05/2016

Witness Name: Dr Reetu Singh
Designation: Clinical Team Lead
Institute Name: M S Ramaiah Medical College and Hospitals;
MSRIT Post, New BEL Road
Bangalore 560054, Karnataka, India

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.

Consolidated Amount in Lakhs

Year	Total amount in Lakhs
2019-20	497.38252
2018-19	460.67919
2017-18	618.07784
2016-17	109.86424
2015-16	234.73913
Total	1920.74292

ACCOUNTS OFFICER
M.S. RAMAIAH MEDICAL COLLEGE
M.S.R. NAGAR
M.S.R.I.T. POST
BANGALORE - 560 054

PRINCIPAL AND DEAN
M.S.Ramaiah Medical College
& Hospital,
Bangalore - 560 054.