INDIAN COUNCIL OF MEDICAL RESEARCH
POST BOX NO. 4911, ANSARI NAGAR, NEW DELHI –110029

No.Coord/7(1)/CARE-KD/18-NCD-II

Dated: 28.02.2019

The Director,
SGPGIMS,
Rai Bareli Road,
Lucknow, U.P-226014

Subject: "CARE on Kidney Diseases- Biomarkers & newer therapeutic" under Dr. Swasti Tiwari, Lucknow

Sir/Madam,

The Director General of the Council sanctions the above mentioned research scheme initially for a period of one year from **01.03.2019** 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. 1,66,66,900/- (Rupees one crore sixty six lakhs sixty six thousand nine hundred only)** as detailed in the attached statement for the period ending the **28.02.2020.**

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

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

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

3. The approved duration of the scheme is **5(five)** year. 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,

(Ishwar Likhar)
Admn. Officer
For Director-General

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

This issues with the concurrence of Finance Section vide RFC No. (P-37) NCD/CARE/2/2018-19 dated 12.02.2019

No.Coord./7(1)/CARE-KD/18-NCD-II

1. Copy together with a copy of the budget statement forwarded for information Dr. Swasti Tiwari, Professor, Department of Molecular Medicine and Biotechnology, SGPGIMS,Rai Bareli Road, Lucknow, U.P-226014
2. Copy together with a copy of the budget statement forwarded to the **Accounts Section** for information and necessary action.

A. O.
Mr. Hemant (Sr. T.O.)

For Director-General

Prof. Rakesh Kapoor
Director
Sanjay Gandhi Post Graduate Institute

1479/S.P
6/3/2019

Date 6/3/19
Time 9.pm

Mol. Med. & Biotechnology

CAR RECEIVED

	neous	
	shipping Charges from different sites (within	1,50,000
	rtisements/camps/ workshop for subject recruitments n community and awareness generation stationary mposium and workshops to disseminate scientific owledge gathered towards the end.	5,00,000
	atent fee, Publication and Abstract submission charges, License fee	2,00,000
	Sub-total (A+B)	**21,50,000**
	Over-head charges	
	5% of cost of the project (excluding travel and non-recurring) i.e. 5% of (1+A+B)	**2,88,900**
	Non-Recurring (equipments)	
	Sample storage (-80 and -20 degrees, one/each)	10,00,000
	Ultracentrifuge (high capacity) with rotors	85,00,000
	Small equipments for lab or field analysis like spin centrifuge, hand held tissue homogenizer, hand held ABG analyzer ad Nanodrop etc.	10,00,000
	Sub total (Non-Rec. –Equip.)	**1,05,00,000**
4.	**Travel**	
i.	Travel during camp activity, travel by the consultant for project monitoring and evaluation; travel by staff team during community camp activities, travel by PI or research staff (RAIII, Statistician or JRF) to attend national conferences	**1,00,000**
5.	**Grand Total (1+2(i)+2(ii)+3+4)**	**1,66,66,900**

Rs. 1,66,66,900/-(Rupees one crore sixty six lakhs sixty six thousand nine hundred only)

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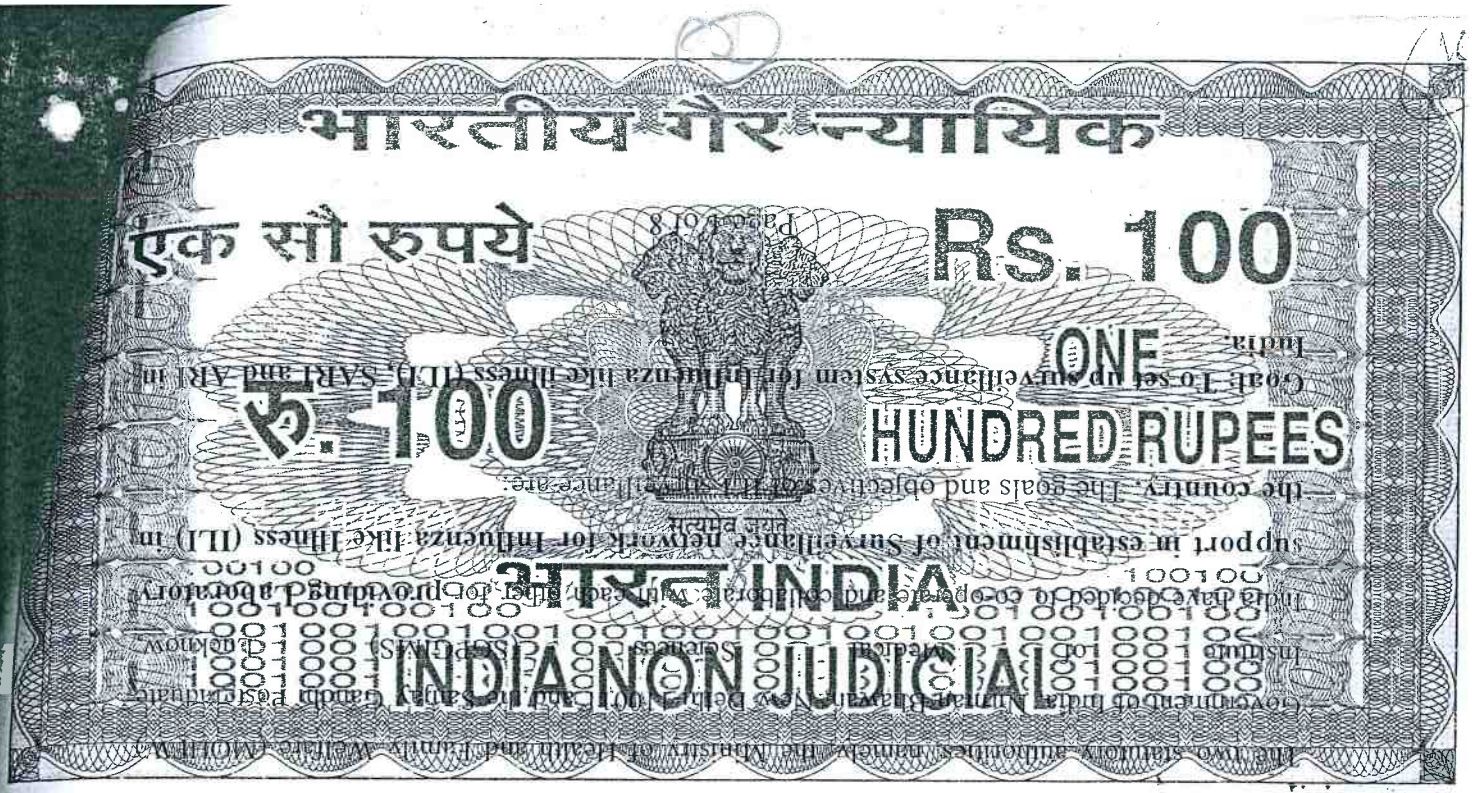

उत्तर प्रदेश UTTAR PRADESH

EB 659898

Memorandum of Understanding

Between

The Ministry of Health and Family Welfare, Government of India

And

Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS)

Lucknow, India

By Which

The two statutory authorities, namely, the Ministry of Health and Family Welfare (MOHFW) Government of India, Nirman Bhawan, New Delhi-110011 and the Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS) Lucknow, India have decided to co-operate and collaborate with each other for **providing Laboratory support in establishment of Surveillance network for Influenza like Illness (ILI) in the country.** The goals and objectives of ILI surveillance are:

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Executive Registrar
SGPGIMS,Lucknow

Goal: To set up surveillance system for Influenza like illness (ILI), SARI and ARI in India.

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Executive Registrar
SGPGIMS,Lucknow

156

Objectives of Sentinel Surveillance for SARI, ILI and ARI

I. To provide data for better informed action regarding national and local influenza prevention and control efforts, including vaccination campaigns. These include data on:
   - epidemiology and seasonality data of influenza;
   - groups at high risk for severe outcomes, including hospitalization and deaths;

II. To provide a platform for surveillance that includes additional common respiratory pathogens (e.g. Respiratory syncytial virus (RSV), Adenovirus, Para influenza viruses, and Rhinovirus);

Post 12th five year Plan Period MOHFW has allocated funds for Integrated Diseases Surveillance Programme, a portion of this fund is eligible for payment under this MOU. The scope of the MOU will cover on the part of **SGPGIMS Lucknow,** processing and analysis of samples and Quality Assurances functions for ensuring the highest level of technical soundness, including but not limited to:

1. Receiving and processing of clinical samples.
2. Analyzing and collating clinical data for early warning signals.
3. Sharing clinical data and laborat results with National Centre for Disease Control (NCDC) and State Surveillanc Officer of IDSP.
4. Preserving the pooled/paired samples for future need.

Set out below are the terms and conditions under which agrees to carrying out the above mentioned assignment.

1. For administrative purpose Project Director, IDSP has been assigned to administer the assignment and **SGPGIMS Lucknow** to provide with relevant information needed to carry out the assignment;
2. This MOU shall come into force from the date of signature of both the parties;
3. The MOHFW may, if find necessary, postpone or cancel the assignment and/or shorten or extend its duration. However, every effort will be made to give **SGPGIMS Lucknow** as early as possible, notice of any changes. In the event of termination, the shall be paid for the services rendered for carrying out the assignment to the date of termination, and the **SGPGIMS Lucknow,** will provide

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Executive Registrar
SGPGIMS,Lucknow

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Executive Registrar
SGPGIMS,Lucknow

the MOHFW with any reports thereof, or any other information and documentation gathered under the contract prior to the date of termination.

4. This contract, its meaning and interpretation and the relation between the parties shall be governed by the Laws of Union of India.
5. All final plans, drawings, specifications, designs, reports and other documents or software submitted by **SGPGIMS Lucknow,** in the performance of the services shall become and remain the property of the MOHFW. The **SGPGIMS Lucknow,** may retain a copy of such documents but shall not use them for purpose unrelated to this contract without the prior written approval of MOHFW.
6. The **SGPGIMS Lucknow,** undertakes to carry out the assignment in accordance with the highest standards of professional and ethical competence and integrity, having due regards to the nature and purpose of the assignment, and to ensure that the staff assigned to perform the services uinder the Contract, will conduct themselves in a manner consistent herewith.
7. The **SGPGIMS Lucknow,** shall pay the taxes, duties fee, levies and other impositions levied under the applicable law and the MOHFW shall perform such duties in regards to the deduction of such tax, as may be lawfully imposed.
8. The **SGPGIMS Lucknow,** also agrees that all knowledg and information not within the public domain which may be acquired during carrying out of this Contract, shall be, for all time and for all purpose, regarded as strictly confidential and held in confidence, and shall not be directly or indirectly disclosed to any person whatsoever, except with MOHFW's written permission.
9. The **SGPGIMS Lucknow,** will be responsible for appropriate insurance cover. In this regards **SGPGIMS Lucknow,** maintains workers compensation, employment liability insurance for their staff on the assignment. The **SGPGIMS Lucknow,** shall also maintain comprehensive general liability insurance, including contractual liability coverage adequate to cover the indemnity of obligation against all damages costs to any property arising out of or in connection with the services which result from the fault of **SGPGIMS Lucknow,** or its staff. The **SGPGIMS Lucknow,** shall provide the MOHFW with certification thereof upon request;

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Executive Registrar
SGPGIMS,Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

154

10. In case of any dispute or difference arising out of this MOU or interpretation of the terms and conditions of this MOU both the parties agree to settle the matter through mutual discussion by Project Director, Integrated Diseases Surveillance Project (MOHFW) and Director/Dean **of SGPGIMS Lucknow,** and on failure of such discussions the matter shall be referred to a sole arbitrator to be appointed by both the parties by mutual agreement. The venue of the arbitrator shall be binding on both the parties. The arbitration shall be subject to the provisions of the Arbitrations and Conciliation Act, 1996.
11. This MOU will be operative with effect from the date of its signing by the parties concerned and will remain in force till March 31st, 2019. This MOU may be terminated before the expiry of its term by mutual consent of the parties concerned.
12. The following deliverables are expected from the assignment;
    I. Collate and analyze data for early warning signals and epidemiological trends.
    II. Laboratory results should be informed to NCDC on daily/weekly basis.
    III. Quarterly/Annual project report should be submitted regularly.
13. An amount of up to **Rs. 11.2 lakhs (Rupees eleven lakhs and twenty thousand only)** will be made available by the MOHFW to as advance for one year of operation towards recurring expenditure as under;

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Executive Registrar
SGPGIMS,Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

a)	Operating Expenditure covering all expenses of local purchase of plastic wares, supportive reagents and chemicals; AMC of equipment; other contingencies including internet connection, local conveyance for collection of specimen; minor expenditure on photocopy, purchase of stationary and other miscellaneous expenditure.	**Rs. 9,40,000/-**
b)	Salary of contractual staff i.e. hiring of specialized lab technician @Rs. 15,000/-per month	**Rs. 1,80,000/-**
	Total	**Rs. 11,20,000**

14. A non recurring expenditure on equipment as given in Table A has been done while establishing this lab.
15. An annual recurring expenditure on kits as given in Table B of Annex, these would be procured centrally and supplied to the lab.
16. For the purpose of maintenance of accounts relating to above funds, **SGPGIMS Lucknow** shall open a separate savings bank account, maintain books of accounts separately and submit on quarterly basis within 15 days of the close of each calendar quarter, a statement of expenditure with the original payment vouchers, bills paid, purchase orders, etc., to IDSP, New Delhi: which will then be adjusted against the advance paid to **SGPGIMS Lucknow** in the books of IDSP Delhi. While these actual expenditures will be included in the FMR to be submitted to CSU, IDSP; the expenditure will be audited by CAG at the central level as a part of GoI project expenditure.
17. Non-Compliance of the commitment and obligations set above and/or upon failure of **SGPGIMS Lucknow** to make satisfactory progress may require MOHFW/ **SGPGIMS Lucknow** to review the SITUATION COMMITTED THROUGH THIS MOU leading to suspension, reduction or cancellation thereof.

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Executive Registrar
SGPGIMS,Lucknow

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Executive Registrar
SGPGIMS,Lucknow

In case of unsatisfactory progress in the project, every effort would be made by MOHFW and **SGPGIMS Lucknow** to bring the project back to rail through mutual consultations. In the event of irretrievable situation the funding may be suspended and MOU terminated.

18. The MOU will be valid till March 31st, 2019

IN WITNESS WHEREOF, THE PARTIES HAVE EXECUTED THIS AGREEMENT ON THIS 25 DAY OF May (Month) & (Year) 2018

Signature of the Head of Institute

DIRECTOR
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Project Director-IDSP
For & behalf of the Government of India
Ministry of Health and Family Welfare
Directorate General of Health Services,
Nirman Bhawan, New Delhi

Signed in the presence of (Witness)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

1. _____

Prof. T.N. DHOLE
Prof. & Head
Dept. of Microbiology
S.G.P.G.I.M.S., Lucknow

2. _____

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

पी.ए.बी.एक्स./PABX : 26588980, 26588707, 26589336, 26589745, 26589414
फैक्स/FAX :

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

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 02

No.VIR/1/2019/ECD-I(Vol-I) **Dated: 15.05.2019**

To

The Director,
Sanjay Gandhi Postgraduate Institute of Medical Sciences
Raebareli Road, Lucknow-226014.

Subject: - Sanction and budget allotment for the New Schemes Entitled, "Host determinants of Hepatitis E Disease Severity".

Sir,

In partial modification of this office letter of even number dated 29th March 2019
The Director General of the Council sanctions the above mentioned research scheme initially for a period of one year from **29.03.2019** to **28.03.2020** 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. 15,59,250 (Rupees Fifteen lakh fifty nine thousand two hundred & fifty only)** as detailed in the attached statement for the year 2018-2019.

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

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

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

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

Contd/-

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar, Lko.
SGPGIMS,Lucknow

Budget Statement
(29.03.2019 to 28.03.2020)

The new project entitled, "**Host determinants of Hepatitis E Disease Severity**" under Dr. Amit Goel, Associate Professor, Department of Gastroenterology, SGPGI, Lucknow-226014.

S. No.	Item		Year 1
1	Staff,	JRF @ Rs. 25,000 + HRA 20%	3,60,000
2	Contingency	Contingency grants are requested to cover any unanticipated price rise of research reagents or equipment due to inflation and data recording	25,000
3	Recurring	Funds are requested for DNA extraction kits, Exome sequencing of samples and NGS Services at a commercial provider. Reagents for standard cloning	11,00,000
		Total	**14,85,000**
4	Overhead 5%		74,250
5	Travel	Travel funds are requested for discussion of project progress and data analysis.	0
		Total	15,59,250

(Rupees Fifteen lakh fifty nine thousand two hundred & fifty only)

File No. VIR/1/2019/ECD-I(Vol-I)
RFC No. ECD/Adhoc/17/2018-19
Dated 29.03.2019

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

INDIAN COUNCIL OF MEDICAL RESEARCH
ANSARI NAGAR, NEW DELHI-110029

No.VIR/1/2019/ECD-I **Dated: 29.03.2019**

Subject: - Payment of **1st& Final Installment** of grant-in-aid for the research scheme entitled, "**Host determinants of Hepatitis E Disease Severity**"

MEMORANDUM

Reference this office letter No.VIR/1/2019/ECD-I(Vo-I) dated

The Director-General, ICMR sanctions the payment of **Rs. 15,59,250 (Rupees Fifteen lakh fifty nine thousand two hundred & fifty only)** as the **1st & Final installment** of the grant for incurring expenditure in connection with the above mentioned research scheme. The amount **Rs. 15,59,250/-** may be debited in the provision of **Rs. 15,59,250/-** made for the above mentioned research scheme for the current financial year.

A formal bill for **Rs. 15,59,250/-** is sent herewith for payment by cheque/demand to the **Director Research Scheme Account,** Sanjay Gandhi P.G. Inst. Of Medical Sciences, Lucknow-226014.

RFC No. ECD/Adhoc/17/2018-19
Dated 29.03.2019

Yours faithfully,

(Renu Rai Kubba)
Administrative Officer,
for Director General.

2123/Gen
6/4/2019

Accounts Section-V (Mandate form Enclosed)

The Diretor, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Raebareli Road, Lucknow-226014. A bank draft/cheque for the amount of **Rs. 15,59,250/- 1st & Final installment** will be sent to you in due course. The grant has been sanctioned on the conditions laid down in our letter referred to above.

Dr. Amit Goel, Associate Professor, Department of Gastroenterology, SGPGI, Lucknow-226014. It is requested that an audited statement of accounts together with utilization certificate for the grant received and utilized in may be sent to this office in due course.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

IRIS Cell (P & I) Section, ICMR.

Sr. T.O (2)

for Director General.

Prof. Rakesh Kapoor
Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

2123

(16)

Declaration & Attestation

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

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

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

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

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

vi. 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.

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

Signature of the:

a) Principal Investigator

b) Co-Investigator(s)

c) Head of the Department

Dr. Amit Goel
Associate Professor
Dept. of Gastroenterology
SGPGI, Lucknow

Dr. V. A. Saraswat, MD, DM
Prof. & Head
Department of Gastroenterology
SGPGIMS, Lucknow

Date: 04.02.19

Signature of the Head of the Institution with seal

DIRECTOR
S.G.P.G.I.M.S.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

No. BT/Med/NIDAN- Trg/02/2018
GOVERNMENT OF INDIA
MINISTRY OF SCIENCE & TECHNOLOGY
DEPARTMENT OF BIOTECHNOLOGY

Block 2, 6-8th Floors
CGO Complex, Lodhi Road,
New Delhi- 110 003
Dated: 9th May 2019

ORDER

Sanction of the President is hereby accorded, under Rule 18 of the Delegation of Financial Powers Rules ,1978 , for the implementation of the project entitled **"Training of in-service Clinicians from Government Hospitals and Outreach Program for Aspirational Districts"** for a period of 3 Year 0 Month at a total cost of Rs. 395.92 **(Rupees Three Crore Ninty Five Lakhs Ninty Two Thousand Only)** on the terms and conditions detailed here under:-

2 **The Project :**

2.1 **Title :** **"Training of in-service Clinicians from Government Hospitals and Outreach Program for Aspirational Districts"**

2.2 **Details of the Investigators:**

Principal Investigators:

Prof Shubha Rajendra Phadke,
M D [Pediatrics], D M [Medical Genetics]
Department of Medical Genetics
Sanjay Gandhi Postgraduate Institute of Medical Sciences,
Raebareli Rd, Haibat Mau Mawaiya,
Lucknow, Uttar Pradesh 226014

Co- Investigators:

Dr Kausik Mandal,
Associate Professor
Department of Medical Genetics
Sanjay Gandhi Postgraduate Institute of Medical Sciences,
Raebareli Rd, Haibat Mau Mawaiya,
Lucknow, Uttar Pradesh 226014

Dr Deepti Saxena,
Assistant Professor
Department of Medical Genetics
Sanjay Gandhi Postgraduate Institute of Medical Sciences,
Raebareli Rd, Haibat Mau Mawaiya,
Lucknow, Uttar Pradesh 226014

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Dr Amita Moirangthem,
Assistant Professor
Department of Medical Genetics
Sanjay Gandhi Postgraduate Institute of Medical Sciences,
Raebareli Rd, Haibat Mau Mawaiya,
Lucknow, Uttar Pradesh 226014

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

95

2.3 Objectives:

COMPONENT I : Training of in-service Clinicians

Title of the training course: **Training Course for Clinicians cum Creation of Genetic Diagnostic Unit in Human Genetics under UMMID Initiative** (***Skill Development in Management of Chromosomal, Monogenic Disordersand Congenital Malformation***)

Objectives of the course: The program will provide the trainee with competence in the application of genetic diagnostics for patient care in modern medical practice and exposure to the relevant research in this area. This will include laboratory training in cytogenetic and molecular techniques, indications for genetic testing; understand the principles of the tests, interpretation of results and communication of the results to the patient and families with genetic disorders. For candidates with clinical background, the course will provide approach to the patients with genetic disorders, principles of genetic counselling and exposure to the procedures for prenatal diagnosis.

COMPONENT II: Outreach Program for Aspirational Districts

State : Uttar Pradesh
District : Shrawasti

COMPLEMENTARY PROGRAM WITH THE FELLOWSHIP TRAINING PROGRAM FOR ASPIRATIONAL DISTRICTS: Taking Genetics to Population "Screening and Counseling for Genetic disorders: *Incorporating Prevention of Genetic Disorders in Maternal & Child Health Program*

Objectives:

1. To establish these services at district hospital and provide patient care,
2. To train the medical officers for the preventive program for genetic disorders.
3. To train the nursing staff and other paramedical workers in the process, to increase the awareness about genetic disorders (This can be done by on site direct training without structured training program).

2.4 **Time Schedule:** The duration of the project is 3 Year 0 Month from the date of this sanction order.

2.5 **Project Cost:** The total cost of the project is Rs. **395.92 (Rupees Three Crore Ninty Five Lakhs Ninty Two Thousand Only)** as per details given below:

Institute wise Budget details are as follows:

Budget Head	Year I	Year II	Year III	Total(Rs.)
COMPONENT I : Training of in-service Clinicians:				
Equipment	2500000.00	0.00	0.00	2500000.00
Consumables	1200000.00	1200000.00	1200000.00	3600000.00
Travel	25000.00	25000.00	25000.00	75000.00
Contingency	50000.00	50000.00	50000.00	150000.00
Displacement allowance	720000.00	720000.00	720000.00	2160000.00
Overhead	100000.00	100000.00	100000.00	300000.00
Total (Rs.)	4595000.00	2095000.00	2095000.00	8785000.00

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Executive Registrar
SGPGIMS,Lucknow

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Budget Head	Year I	Year II	Year III	Total(Rs.)
COMPONENT II: Outreach Program for Aspirational Districts				
Manpower	1680000.00	1680000.00	1680000.00	5040000.00
Consumables	7750000.00	7750000.00	7750000.00	23250000.00
Travel	200000.00	200000.00	200000.00	600000.00
Contingency	150000.00	150000.00	150000.00	450000.00
Overhead	489000.00	489000.00	489000.00	1467000.00
Total (Rs.)	10269000.00	10269000.00	10269000.00	30807000.00

2.6 **Equipment:**
The details of the Equipment sanctioned for the implementation of the project at **Annexure-I**

2.7 **Manpower** :
The details of the manpower sanctioned for the implementation of the project at **Annexure-II**

2.8 Detailed descriptions of objectives are at **Annexure-III**

3. **Head of Account:**

The **Recurring** expenditure involved is debitable to:

Demand No. 85	Department of Biotechnology
3425	Other Scientif Research 2019-2020
3425.60	Others (Sub Major Head)
3425.60.200	Assistance to othe Scientific Bodies (Minor Head)
3425.60.200.29	Biotechnology Research and Development
3425.60.200.29.17	Assistance for Research and Development
3425.60.200.29.17.31	Grants-in-Aid General
3425.60.200.29.17.35	Grants for creation of capital assets

4. **Terms & Conditions:**

Considering the time bound nature of the project, the project will be monitored by the Task Force / Committee constituted by DBT. In addition, the PI will submit half yearly progress report as per format in **Annexure-IV.**

4.1 The other terms and conditions governing this sanction are attached at **Annexure- V.**

4.2 A Memorandum of Agreement (MoA) will be signed between the Department of Biotechnology and the grantee institution on Non-Judicial stamp paper Rs. 100/- in the enclosed format and the second release/installment will be made only after signing of MoA between the grantee institutions and DBT. In case of NGO's and Private Institution's, execution of MOA is mandatory before first release. A format of the MoA is enclosed **in Annexure-VI**

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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Executive Registrar
SGPGIMS,Lucknow

(93)

4. The Institute/Agency will keep the whole of the grant in a Bank Account earning interest, and the interest so earned should be reported to DBT in the Utilization Certificate and Statement of Expenditure. The Interest so earned will be treated as created to the institute/Agency and shall be adjusted towards further installment of the grant and or at the time of Final Settlement of Accounts.

5. No International Travel will be undertaken from the sanctioned project grant unless specified otherwise.

6. The Director, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, Uttar Pradesh would be responsible for submission of Statements of Expenditure (SoE), utilization certificates (UC), Assets Certificates, Manpower staffing & expenditure details in prescribed DBT formats to DBT in respect of grants released in this project from time to time.

7. PI's of DBT sponsored projects can consider appointment of JRF from Category-II merit list of DBT-BET exam so that candidates can be paid fellowships at par with NET/GATE/BET qualified candidates as per DST OM No. A.SR/S9/Z-08/2018 dated 17 Mar 2018. However, there is no compulsion on PI's to select candidates for JRF in their projects from Category-II of DBT-BET.

8. As per Rule 236 (1) of GFR 2017, the accounts of all Grantee Institutions or Organizations shall be open to inspection by the sanctioning authority and audit, both by the Comptroller and Auditor General of India under the provision of CAG (DPC) Act 1971 and internal audit by the Principal Accounts Office of the Ministry or Department, whenever the Institution or Organizations is called upon to do so.

9. If the Research Project involves biological resources, the obligations under the Biological Diversity Act 2002 as applicable shall be complied with by the Project Investigator, the details of such obligations can be accessed at www.nbaindia.org

10. If this project works involve any statutory clearance (such as Ethical Committee Clearance, IBSC approval, NBA approval etc.). Project investigators and Host institution shall compulsory comply the same without undertaking such activities.

11. This issues, under the power delegated to this Department and with the concurrence of IFD vide their SAN No. **102/IFD/SAN/343/2019-2020** dated **08/05/2019.**

12. This sanction order has been noted at serial no. 21 in the Register of Grants.

(Dr. Onkar N Tiwari)
Scientist 'E'

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

World Health Organization

COVERING LETTER
LETTRE D'ACCOMPAGNEMENT

GLOBAL PROCUREMENT AND LOGISTICS
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHQ Reference/ *Référence OMS*

WHO Registration	2018/815204-0
Purchase Order	202045323
Unit Reference	HS, WCO-I

HU_PROFRakesh Aggarwal
SANJAY GANDHI POST GRADUATE
INSTITUTE OF MEDICAL SCIENCES
LUCKNOW
C Block,SGPGIMS
Raibareilly road
Lucknow
226014
India

AGREEMENT FOR PERFORMANCE OF WORK (APW)

Re: SGPGIMS, Lucknow -To generate evidence and promote the use of safety engineered syringes in therapeutic care in a tertiary care health institution in Uttar Pradesh, India

We are enclosing the Agreement for Performance of Work between the World Health Organization and SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW, in the amount of INR 744,500.00 (Seven Hundred Forty-Four Thousand Five Hundred), for conducting the above-mentioned work. We also enclosed two attachment(s) referenced in the Agreement.

Kindly acknowledge your acceptance of this contract by returning the email with a copy of duly signed Purchase Order (all pages).

For any technical questions relating to this Agreement, please contact the responsible technical officer, Chandrakant LAHARIYA, lahariyac@who.int.

Invoicing Instructions for Contractors who are legal entities (Company Contractors):
Invoices must be sent via email to accountspayable@who.int. Other than invoices, please do not send any enquiry to this email address. You may contact the above responsible technical officer for enquiries.

In order to ensure timely and accurate payment, invoices must include:

- Invoice number
- Purchase Order number against each invoice line;
- Invoice descriptions matching with PO descriptions
- Invoice currency same as the Purchase Order Currency also corresponding with the currency of the bank account provided to WHO;
- Supplier name as in the PO

Invoices shall be clearly readable and stamps or any other additional markings should not obscure the original invoice content. Invoices shall not be handwritten.

On behalf of the World Health Organization, we would like to thank you for your collaboration.

cc: WHO India

WHO Global Service Centre

Concerne: SGPGIMS, Lucknow -To generate evidence and promote the use of safety engineered syringes in therapeutic care in a tertiary care health institution in Uttar Pradesh, India

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Veuillez trouver ci-joint l' Accord pour Exécution de Travaux entre l'Organisation Mondiale de la Santé et SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW, pour un montant de INR 744,500.00, vous permettant de mener à bien le travail susmentionné. Veuillez également trouver 2 pièce(s) jointe(s) mentionnée(s) dans l'Accord.

Merci de confirmer votre acceptation de ce contrat en nous retournant le courriel et une copie dûment signee du Bon de Commande (complet)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

World Health Organization

AGREEMENT FOR PERFORMANCE OF WORK
ACCORD POUR EXECUTION DE TRAVAUX

GLOBAL PROCUREMENT AND LOGISTICS
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Registration	2018/815204-0
Purchase Order	202045323
Unit Reference	HS, WCO-I

Pour toutes questions à caractère technique ayant trait à cet Accord, veuillez contacter le responsible Chandrakant LAHARIYA, lahariyac@who.int.

Instructions concernant la facturation pour les contractants qui sont des personnes morales.(Personne Morale):
Les factures doivent être envoyées par courriel à accountspayable@who.int Outre les factures, n'envoyez aucune enquête à cette adresse courrier électronique.Vous pouvez contacter le responsable technique responsable ci-dessus pour toute demande de renseignements.

De manière à garantir un paiement exact et ponctuel, les factures doivent impérativement comporter:

- Le Numéro de facture
- Le Numéro du bon de commande , répété à chaque ligne de facturation
- Des descriptifs des produits identiques à ceux du Bon de commande
- Une devise de facturation identique à celle du Bon de commande et à celle du compte en banque fourni à l'OMS
- Un intitulé de facture (nom de fournisseur) identique à celui du Bon de commande.

Les factures doivent être parfaitement lisibles. Le contenu de la facture ne doit en aucun cas être masqué par un tampon ou tout autre marquage. La facture ne doit pas être manuscrite.

Au nom de l'Organisation mondiale de la Santé, nous vous remercions de votre collaboration.

cc: OMS India

Centre mondial de services de l'OMS

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

World Health Organization

AGREEMENT FOR PERFORMANCE OF WORK
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GLOBAL PROCUREMENT AND LOGISTICS
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(5)

WHO Reference/ *Référence OMS*

WHO Registration	2018/815204-0
Purchase Order	202045323
Unit Reference	HS, WCO-I

The WORLD HEALTH ORGANIZATION hereby agrees to provide to
L'ORGANISATION MONDIALE DE LA SANTÉ s'engage par la présente à fournir à
SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES
LUCKNOW
Professor-Gastroenterology
Lucknow
INDIA

The Maximum amount of/*Un montant Maximum de*: INR 744,500.00 (Seven Hundred Forty-Four Thousand Five Hundred) **in respect of/*en vue de*:** SGPGIMS, Lucknow -To generate evidence and promote the use of safety engineered syringes in therapeutic care in a tertiary care health institution in Uttar Pradesh, India

For the period financed by this Agreement
***Période du projet** financée par le présent Accord*
From/*De*: 26-JUL-2018
To/*A*: 25-JAN-2019

Summary of work/ *Description sommaire des travaux:*

Description of work under this Agreement/ *Description des travaux faisant l'objet du présent Accord:*

SGPGIMS, Lucknow, the contractual partner, shall carry out activities to generate evidence and promote the use of safety engineered syringes in therapeutic care in a tertiary care health institution in Uttar Pradesh, India, as per the Terms of Reference at Annex-1 and within the approved budget at Annex-2 . These Annexes form an integral part of this agreement.

During the course of the contract and on its conclusion, the contractual partner shall ensure to submit the stipulated deliverable mentioned under "Financial arrangements".

Financial arrangements/ *Dispositions financières:*

Payments will be made as follows/*Les versements seront effectués comme suit:*

	Deliverable/ Résultat	Due date/ *Date remise*	%	Currency amount/ *Montant en devise*
1	Upon submission of countersigned contract.	26-JUL-2018	40.00	297,800.00
2	Upon submission of policy brief on injection uses and practices in UP state	15-SEP-2018	40.00	297,800.00
3	Upon submission of final technical report (both hard and soft copies) and certified Statement of Expenditure (Financial Statement)	25-JAN-2019	20.00	148,900.00

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Annexes

The following annexes form an integral part of this Agreement/ *Les annexes listées ci-dessous font partie intégrante de l'Accord:*

Annex/Annexes	File Name/ *Nom du fichier*
1	2018/815204 | Contractual - Budget Breakdown |
2	2018/815204 | Contractual - Terms of Reference |

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

World Health Organization

AGREEMENT FOR PERFORMANCE OF WORK
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WHO Reference/ *Référence OMS*

WHO Registration	2018/815204-0
Purchase Order	202045323
Unit Reference	HS, WCO-I

In the event that the annexes contain any provisions which are contrary to the terms of this Agreement, the terms of this Agreement shall take precedence/ *En cas de contradiction entre les dispositions des annexes et celles de l'Accord, les dispositions de l'Accord prévaudront dans tous les cas.*

The undersigned parties, having read the terms and General Conditions, hereby conclude the present Agreement and confirm their agreement and acceptance thereof.

Les parties soussignées, ayant lu les modalités et les Conditions Générales, ratifient l'Accord et confirment leur acceptation.

ON BEHALF OF WHO/ *POUR L'OMS*

Responsible WHO Technical Officer:
Fonctionnaire technique responsable de l'OMS:

Chandrakant Lahariya
National Professional Officer
SE_IND WR Office, India

Approved by:
Approuvé par:

Hendrik Jan BEKEDAM
WHO Representative
SE_IND WR Office, India

Authorized Signatory:
Signataire autorisé:

Mr Motohiro Ogita
Coordinator
Global Procurement and Logistics
(WHO/GMG/GSC/GPL)

Katerina Gnanapragasam
Senior Procurement Assistant
HQ/GSC Global Service Centre
31 JUL 2018

CONTRACTOR/ CONTRACTANT

Signature .....

Date: 31 July 2018

Name & Title/ Nom & Fonction :

RAKESH AGRAWAL

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

File No. DST/NSTMIS/05/207-1/2016-17 (CC)
Government of India
Ministry of Science and Technology
Department of Science and Technology

Technology Bhawan
New Mehrauli Road
New Delhi-110016
Dated: 08.08.2018

To

The Pay and Accounts Officer,
Department of Science & Technology,
New Delhi - 110 016.

ORDER

Sub: Release of First Instalment of grant to the project entitled "Evaluation of Impact of DST-FIST Program" for Central Coordinating Unit by Dr. C. M. Pandey, Sanjay Gandhi Postgraduate Institute (SGPGI) of Medical Sciences, Lucknow.

Sanction of the President is hereby accorded to the approval of the above mentioned project at a total cost of Rs. 24,84,350/- (Rupees twenty four lakhs eighty four thousand three hundred fifty only) to Sanjay Gandhi Postgraduate Institute (SGPGI) of Medical Sciences, Lucknow for a duration of 18 months.

The detailed breakup of the grant for **18 months** is given as under:-

Central Coordinating Unit (Dr. C. M. Pandey, Sanjay Gandhi Postgraduate Institute (SGPGI) of Medical Sciences Lucknow)				
S .No.	Items	Sanctioned amount in Rs.		
		First Year	Second Year (6 months)	Total
1.	Salaries/wages			
	I. Chief Coordinator @ 55,000/- pm	---	3,30,000	3,30,000
	II. One Consultant (Coordinator-1) @ 55,000/- pm	6,60,000	3,30,000	9,90,000
	III. One Project Assistant (IT) @ 22,000/- pm	2,64,000	1,32,000	3,96,000
	IV. One Office Assistant (Part time) @ 5,000/-	60,000	30,000	90,000
2.	Consumables Items	60,000	30,000	90,000
3.	Travel	60,000	15,000	75,000
4.	Equipment			
	I. One Tablet	20,000	---	20,000
	II. One Desktop	50,000	---	50,000
	III. One Laser Printer	25,000	---	25,000
5.	Report Preparation &printing	80,000	---	80,000
6.	Development of Data Collection Site	112,500	---	1,12,500
	Total	**13,91,500**	**8,67,000**	**22,58,500**
7.	Overhead Charges @10%	1,39,150	86,700	2,25,850
	Grand Total	**15,30,650**	**9,53,700**	**24,84,350**

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

2. Sanction of the President is hereby accorded for the payment of Rs. 15,00,000/- (Rupees fifteen lakhs only) as First instalment of grant to the above mentioned project.

3. The sanction of the President is also accorded to the release of Rs.15,00,000/- (Rupees fifteen lakhs only) to the Director, Sanjay Gandhi Postgraduate Institute (SGPGI) of Medical Sciences Lucknow.

4. This sanction is subject to the condition that the grantee organisation will furnish to the Department of Science & Technology, financial year wise Utilization Certificate (UC) in the proforma prescribed as per GFR 2017 and audited statement of expenditure (SE) along with up to date progress report at the end of each financial year duly reflecting the interest earned / accrued on the grants received under the project. This is also subject to the condition of submission of the final statement of expenditure, utilization certificate and project completion report within one year from the scheduled date of completion of the project.

contd....2/-

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

5. The grantee organisation will have to enter & upload the Utilization Certificate in the PFMS portal besides sending it in physical form to this Division. The subsequent/final instalment will be released only after confirmation of the acceptance of the UC by the Division and entry of previous Utilization Certificate in the PFMS.

6. If the grant has been released under capital head through separate sanction order under the same project for purchase of equipment(s), separate SE/UC has to be furnished for the released Capital head grant.

7. The grant-in-aid being released is subject to the condition that

(a) a transparent procurement procedure in line with the Provisions of General Financial Rules 2017 will be followed by the Institute/Organisation under the appropriate rules of the grantee organisation while procuring capital assets sanctioned for the above mentioned project and a certificate to this effect will be submitted by the Grantee organisation immediately on receipt of the grant:

(b) While submitting Utilisation Certificate/Statement of Expenditure, the organisation has to ensure submission of supporting documentary evidences with regard to purchase of equipment/capital assets as per the provisions of GFR 2017. Subsequent release of grants under the project shall be considered only on receipt of the said documents.

8. The grantee organisation will maintain separate audited account for the project and **the entire amount of grant will be kept in an interest bearing bank account**. The interest earned / accrued should be reported to DST (financial year wise) while submitting the Statement of Expenditure/Utilization Certificate.

9. As per the GFR 2017 Rule 230(8) the Grantee Institute should ensure that all the interests or other earnings against Grant-in-Aid or advances (other than reimbursement) released to any Grantee Institution should be mandatorily remitted to the Consolidated Fund of India immediately after finalisation of the accounts. Such advances will not be allowed to be adjusted against future releases.

10. DST reserves sole rights on the assets created out of grants. Assets acquired wholly or substantially out of government grants (except those declared as obsolete and unserviceable or condemned in accordance with the procedure laid down in GFR 2017), shall not be disposed of without obtaining the prior approval of DST.

11. **PI/ Coordinator shall not draw any emoluments/ salary/fellowship from any other project either supported by DST or by any other funding agency for this project.**

12. The account of the grantee organisation shall be open to inspection by the sanctioning authority and audit (both by C&AG of India and Internal Audit by the Principal Accounts Office of the DST), whenever the organisation is called upon to do so, as laid down under Rule 236(1) of General Financial Rules 2017.

13. Due acknowledgement of technical support / financial assistance resulting from this project grant should mandatorily be highlighted by the grantee organisation in bold letters in all publications / media releases as well as in the opening paragraphs of their Annual Reports during and after the completion of the project.

14. Failure to comply with the terms and conditions of the Bond will entail full refund with interest in terms of Rule 230 (2) of GFR 2017.

15. The expenditure involved is debitable to Demand No.84, Department of Science & Technology for the year 2018-19:

3425	Other Scientific Research (Major Head),
60	Others (Sub-Major Head),
60.200	Assistance to other Scientific Bodies (Minor Head),
68	Science & Technology Institutional and Human Capacity Building
68.00.31	Grant-in-aid General for the year 2018-19 (voted)
	(**Previous**: Policy Research Cell 3425.60.200.54.01.31)

contd...3/-

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

16. The amount of **Rs. 15,00,000/- (Rupees fifteen lakhs only)** will be drawn by the Drawing and Disbursing Officer, DST and will be disbursed to **Director, Sanjay Gandhi Postgraduate Institute (SGPGI) of Medical Sciences Lucknow.**

The bank details for electronic transfer of funds through RTGS are given below:-

Account holder	: Director, SGPGIMS Research
Name of the Bank	: State Bank of India
Address of the Bank	: SGPGI Branch, Raebareli Road, Lucknow – 226 014
Account No.	: 10095237491
IFSC Code	: SBIN0007789
MICR Code	: 226002034
Darpan Unique ID No.	: NA

17. As per Rule 234 of GFR 2017, this sanction has been entered at S. No. 19 in the register of grants maintained in the Division for the scheme (Science & Technology Institutional and Human Capacity Building).

18. This issues with the concurrence of IFD Vide their Concurrence Dy. No. **C-1798**/IFD/2018-19 dated 07.08.2018.

(Dr. A.N. Rai)
Scientist `F'

Copy forwarded for information and necessary action to:

1. Director of Audit (CW&M), Indraprastha Estate, AGCR Building, New Delhi – 110002.
2. Cash Section (Three copies including original one).
3. IFD.
4. Dr. C. M. Pandey, **Sanjay Gandhi Postgraduate Institute (SGPGI) of Medical Sciences Lucknow**
5. Director, **Sanjay Gandhi Postgraduate Institute (SGPGI) of Medical Sciences Lucknow.**
6. Sanction Folder/File.

(Dr. A.N. Rai)
Scientist `F'

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

301:Budget Year wise				
	Items	First Year	Second Year	Total
East and North East	Salary	2208000	444000	2652000
	Consumables	200000	0	200000
	Travel	950000	50000	1000000
	Printing	50000	50000	100000
	Equipment	75000	0	75000
	Total	3483000	544000	4027000
	Overhead Charges @10%	348300	54400	402700
	Sub Total E & NE Zone	**3831300**	**598400**	**4429700**
Western				
	Salary	396000	396000	792000
	Consumables	160000	125000	285000
	Travel	200000	100000	300000
	Equipment	165000	0	165000
	Total	921000	621000	1542000
	Overhead Charges @10%	92100	62100	154200
	Sub Total Western Zone	**1013100**	**683100**	**1696200**
North				
	Salary	1544000	780000	2324000
	Consumables Items	30000	45000	75000
	Orientation Meeting	25000	0	25000
	Travel: Chief Coordinator and Co-PI	250000	150000	400000
	Miscellaneous& Contingencies	75,000	25,000	100000
	Equipment	70000	0	70000
	Total	1994000.00	1000000.00	2994000
	Overhead Charges @10%	199400.00	100000.00	299400
	Sub Total North Zone	**2193400.00**	**1100000.00**	**3293400**
South				
	Salary	1944000	180000	2124000
	Consumables	100000	200000	300000
	Travel	900000	300000	1200000
	Contingency	100000	50000	150000
	Equipment	200000	0	200000
	Total	3244000	730000	3974000
	Overhead Charges @10%	324400	73000	397400
	Sub Total South Zone	**3568400**	**803000**	**4371400**
Central				
	Salaries/wages	594000	0	594000
	Consumables Items	70000	30000	100000
	Travel: Chief Coordinator and Co-PI	872500	27500	900000
	Equipment	60000	0	60000
	Training of Project Assistant(Field)	35000	0	35000

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

	Total	1631500	57500	1689000
	Overhead Charges @10%	163150	5750	168900
	Sub Total Central Zone	**1794650**	**63250**	**1857900**
Central Coordinating Unit				
	Salaries/wages	984000	822000	1806000
	Consumables Items	50,000	50,000	100000
	Travel: Chief Coordinator and Co-PI	50000	50000	100000
	Equipment	95,000	0	95000
	Report Preparation & printing	0	100000	100000
	Development of Data Collection Site	125,000		125000
	Total	1304000	1022000	2326000
	Overhead Charges @10%	130400	102200	232600
	Sub Total CC Unit	**1434400**	**1124200**	**2558600**
	Grand total	**13835250.00**	**4371950.00**	**18207200.00**

Financial Responsibility: The allocated amount will be transferred directly to the respective regional PI's. All regional PI's are responsible for their respective allocated find and its utilization.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

VIII. Format for submission of projects (*To be filled by appli*

101	Project Title :	Evaluation of Impact of DST-FIST improvement of infrastructure, enviro facilities to attract fresh talent and research and development in emerging area
102	Name and Address of the Institute/organization where the project will be Implemented.	1. Department of Biostatistics and Informatics, Sanjay Gandhi Post Gra Institute of Medical Sciences (SGPGI Raebareli road, Lucknow-226014 2. Centre for Knowledge, Ideas and Developme Studies (KnIDS), 38G Maharaja Tagore Road, Kolkata 700031 3. Department of Statistics, Sant Gadge Baba Amravati University, Amravati, Maharastra 4. Global Projects & Services Pvt. Lts.707, Ansal Chamber-II, 6- Bhikaji Cama Place, New Delhi. 5. JSS Academy of Technical Education, Bengalure
103	Chief Coordinator (PI) (Name, Designation, Age, Gender)	Dr. C.M.Pandey, Professor and Head, 63 years, Male
104	Category :	General
105	Institute Name (Address, City, Pin code, State, Phone No. (landline & mobile) and Email.)	Department of Biostatistics and Health Informatics, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow-226014, Uttar Pradesh Landline: 0522-2494920 (O), 0522-2443900 (R) Mobile: 09450097977 Email: cmpandey@sgpgi.ac.in, cmpandeylko@yahoo.com
106	Co-Investigator(s):	
		1. Dr Uttam Singh, Professor, 56 years, Male, General, Department of Biostatistics and Health Informatics, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow-226014, Uttar Pradesh Landline: 0522-2494922 (O), 0522-2494923 (R) Mobile: 08004904477 Email: uttam@sgpgi.ac.in, 2. Dr Anup Kumar, Assistant Professor, 34 years, Male, OBC, Department of Biostatistics and Health Informatics, Sanjay Gandhi Postgraduate Institute of Medical Sciences,

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

	Lucknow-226014, Uttar Pradesh Landline: 0522-2495276 (O), Mobile: 08004221413 Email: anup@sgpgi.ac.in,
	3. Dr Jai Kishun, Assistant Professor, 35 years, Male, SC, Department of Biostatistics and Health Informatics, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow-226014, Uttar Pradesh Landline: 0522-2494924 (O), Mobile: 08004221406 Email: jaikishun@sgpgi.ac.in,

107	Total Cost (in Rupees) :	**Rs 18207200.00**
108	Duration (in months):	18 months
109	**Ideation of the study** DST-FIST has supported 1733 projects across 172 institutions till 2011 with financial input of around 1924 crores. The proposed study will assess the impact of this investment in education, research and development. The tools and indicators of impact have been evolved in consultation with DST and a core group of national experts in the field. Data for each project supported under the program will be collected using complete enumeration approach. The project will be implemented in partnership with regional coordinators and institutions in each region identified in consultation with DST and national expert group meeting held on 28-29 August 2017 and 16 November 2017 (Appendix-I & II). The identified partners for each region are mentioned below.	
	East and NE region	PI: Dr. Pradosh Nath , Director, Ex-Chief Scientist, CSIR – NISTADS New Delhi Centre for Knowledge, Ideas and Development Studies (KnIDS), Maharaja Tagore Road, Kolkata 700031. Phone: +91-11-22622343; Mobile: +91-9811283822
	Western region	PI: Prof. Rajesh Singh Department of Statistics, Sant Gadge Baba Amravati University Amravati, Maharastra Phone: +91-9422840360
	Northern Region	PI: Dr. J. S. Juneja Chairman, Global Projects & Services Pvt. Lts. 707, Ansal Chamber-II, 6- Bhikaji Cama Place, New Delhi. Phone: +911-11-26170146, 26178443

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

	Southern Region	PI: Prof. D R Swami Department of Industrial Engineering & Management JSS Academy of Technical Education, Bengaluru – 560060 Phone: +91-80-28612797
	Central Region	PI: Prof. CM Pandey, HOD Biostatistics and Health Informatics, SGPGIMS, Lucknow – 226014 Phone: 0522-2494920, Cell: +91-9450097977
201	**Introduction :** **Background of FIST program:** Fund for Improvement of Science & Technology (FIST) is an ongoing project of Department of Science & Technology (DST), Government of India initiated in the year 2000. DST announced this project "FIST" with major objective to develop R&D tools, rebuild the science and technology infrastructure in universities & higher educational institutions. It was envisaged to upgrade the departments requiring further strengthening of their infrastructure to enhance their visibility both nationally and internationally. The duration of support for each project was for a period of 5 years and was extendable for next 5 years if progress from the first grant was found suitable. Specific objective of the project are: To provide basic infrastructure, enabling facilities, environment for promoting R&D in new and emerging areas and attracting fresh talent. **Why FIST was needed :** In recent past, scientific community had expressed great concern about the lack of infrastructure facilities for imparting good quality of higher education and conducting research in emerging fields of science and engineering in our country. Considering the status of S&T sector in the universities and related academic institutions that were in dire need for strengthening the existing S&T infrastructure support with adequate funding and associated flexibility, program like FIST has become necessary to extend infrastructure support to higher technical and medical educational institutions to develop it at national and international level. **Need for Impact Evaluation:** Impact evaluation is an assessment of *how the intervention under evaluation affects the outcomes*. Whether these effects of intervention are intended or unintended? The proper analysis of impact requires the level of outcomes in the absence of the intervention. Results of Impact evaluation may provide information for **lesson-learning** and **accountability** as well. The impact evaluation is useful for the following situations: • Interventions having solid evidence of impact in the given context	

Lt Col Varun Bajpai VSM
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SGPGIMS,Lucknow

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SGPGIMS,Lucknow

S.R.O. Med. Genetic Registry

(7)

(76)

No. BT/PR26428/MED/12/783/2017
GOVERNMENT OF INDIA
MINISTRY OF SCIENCE & TECHNOLOGY
DEPARTMENT OF BIOTECHNOLOGY

Block 2, 6-8th Floors
CGO Complex, Lodhi Road,
New Delhi- 110 003
Dated: **21/09/2018**

ORDER

Sanction of the President is hereby accorded, under Rule 18 of the Delegation of Financial Powers Rules, 1978, for the implementation of the project entitled: **"The Indian Movement Disorder Registry and Biobank: Clinical and genetic evaluation of movement disorders in Indian patients"** for a period of 3 Years at a total cost of Rs. 28772170.00 (Rupees Two Crores Eighty Seven Lakhs Seventy Two Thousand One Hundred and Seventy Only) on the terms and conditions detailed here under:-

2 **The Project :**

2.1 **Titie :** **"The Indian Movement Disorder Registry and Biobank: Clinical and genetic evaluation of movement disorders in Indian patients"**

2.2 **Details of the Investigators:**

Project Co-Ordinator

Dr. Roopa Rajan
Assistant Professor
Department of Neurology
All India Institute of Medical Sciences
Room 703, Ansari Nagar
New Delhi-110029

Principal Investigators:

Dr. Roopa Rajan
Assistant Professor
Department of Neurology
All India Institute of Medical Sciences, Delhi
Room 703, Ansari Nagar, New Delhi-110029,

Dr. Akhilesh Pandey
Adjunct Professor and Wellcome Trust DBT Margdarshi Fellow
Department of Clinical Neuroscience
National Institute of Mental Health & Neuro Sciences
Bangalore-560066, Bangalore, Karnataka

Prof. Pramod Kumar Pal
Professor and Head
Department of Neurology
National Institute of Mental Health & Neuro Sciences
Bangalore- 560029, Bangalore, Karnataka

Prof. Sanjay Pandey
Professor
Department of Neurology
G.B. PANT HOSPITAL
Room No. 507, Academic Block
Govind Ballabh Pant Institute of Postgraduate medical education and research
JLN Marg, New Delhi-110002

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(75)

Prof. Shubha Rao Phadke
Professor and Head
Department of Medical Genetics
Sanjay Gandhi Post Graduate Institute of Medical Sciences
Lucknow-226014, Uttar Pradesh

Prof. Thelma BK
Professor
Department of Genetics
University of Delhi, South Campus
South Campus, New Delhi- 110 021

CO-PI:

Dr. Vinod Scaria
Senior Scientist
GN Ramachandran Knowledge Centre for Genome Inform
CSIR Institute of Genomics and Integrative Biology, Mall Road, Delhi 110 007

Dr. Aruna Devi Naorem
Assistant Professor
Department Of Genetics
University of Delhi, South Campus
Benito Juarez Road, New Delhi-110021

Dr. Binukumar BK
Senior Scientist
CSIR-Institute of Genomics and Integrative Biology, Mathura Road, Sukhdev Vihar, New Delhi,110020

Prof. Achal Srivasatava
Professor
Department of Neurology
All India Institute of Medical sciences
Room no 60, Cardio Neuro Centre, Ansari Nagar, Delhi - 110029, Delhi

Dr. Ravi Yadav
Additional Professor
Department of Neurology
National Institute of Mental Health & Neuro Sciences
Bangalore - 560029, Karnataka

Dr. Babylakshmi Muthusamy
Research Scientist
Institute of Bioinformatics 7th Floor, Discoverer Building International Tech Park Ltd Whitefield
Bangalore- 560066, Karnataka

Dr. Remya Raja
Research Scientist
Institute Of Bioinfromatics
7th floor, Discoverer Building International Tech Park Ltd, Whitefield, Bangalore - 560066, Karnataka

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SGPGIMS,Lucknow

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Executive Registrar
SGPGIMS,Lucknow

Part 6. DECLARATION/ CERTIFICATION

It is certified that

1. The research work proposed in the scheme/project entitled **"The Indian Movement Disorder Registry and Biobank: Clinical and genetic evaluation of movement disorders in Indian patients"** does not in any way duplicate the work already done or being carried out elsewhere on the subject.
2. The same project proposal has not been submitted to any other agency for financial support.
3. The emoluments proposed for the manpower are as admissible to persons of corresponding status employed in the institute/university or as per the Ministry of Science & Technology guidelines.
4. Necessary provision for the scheme/project will be made in the Institute/ University/ Organization budget in anticipation of the sanction of the scheme/project.
5. If the project involves the utilization of genetically engineered organisms, we agree to submit an application through our Institutional Bio safety Committee. We also declare that while conducting experiments, the Bio safety Guidelines of the Department of Biotechnology would be followed into.
6. If the project involves field trials/experiments/exchange of specimens, etc. we will ensure that ethical clearances would be taken from concerned ethical Committees/ competent authorities and the same would be conveyed to the Department of Biotechnology before implementing the project.
7. If the Project requires any statutory permission(s) for any authority to carry out the project, the same would be obtained and intimated to DBT before taking up research activities.
8. It is agreed that any research outcome or intellectual property right(s) on the invention(s) arising out of the project shall be taken in accordance with the instructions issued by Department of Biotechnology, Govt. Of India.
9. We agree to accept the terms and conditions of Department of Biotechnology, Govt. Of India.
10. The institute/university agrees that the equipment, other basic facilities and such other

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SGPGIMS,Lucknow

administrative facilities as per terms and conditions of the grant will be extended to investigator(s) throughout the duration of the project.

11. The Principal Investigator(s) involved in the project has sufficient service duration to carry out the project. In case his tenure get expire before completion of project necessary provision would be made to allow him to complete the project for its logical conclusion.
12. The Institute assumes to undertake the financial and other management responsibilities of the project.
13. The details & information given in the Project proposal are true & factual.

Signature of Executive Authority of "Sanjay Gandhi Post Graduate Institute of Medical Sciences" with stamp

Date: 12.08.17

DIRECTOR
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Prof. Shubha R Phadke
Principal Investigator
Date: 12.08.17

Dr. Shubha R. Phadke
Professor & Head
Deptt. of Medical Genetics
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
Lucknow-226014, INDIA

Dr. KausikMandal
Co-Investigator
Date: 12.08.17

Dr. Kausik Mandal
Associate Professor
Department of Medical Genetics
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
Lucknow-226014 (U.P.) INDIA
Registration No. 69033 (UPMC)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

उत्तर प्रदेश UTTAR PRADESH

BU 274405

MEMORANDUM OF AGREEMENT

This MEMORANDUM OF AGREEMENT is made on this ....., **Two thousand and Nineteen** BY AND BETWEEN President of India, acting through **Secretary,** Department of Biotechnology, Ministry of Science and Technology, Government of India, New Delhi, hereinafter referred to as the 'DBT' (which expression unless excluded by or repugnant to the subject shall mean and include its successor-in-office and assigns) of the ONE PART;

AND

Sanjay Gandhi Postgraduate Institute of Medical Sciences an autonomous institution created by act of state legislature of UP (Act no 30 of 1983) having its registered office at Raebareli Road, Lucknow, 226014 hereinafter referred to as SGPGI (which expression shall where the context so admits include its successors and permitted assigns) of the OTHER PART;

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

WHEREAS DBT being desirous **of Medical Biotechnology** decided to support a project submitted by Amita Aggarwal for the attainment of the objectives, hereinafter described in the Annexure I annexed hereto;

Prof. Amita Aggarwal
Head
Rheumatology

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(289)

उत्तर प्रदेश UTTAR PRADESH BU 274406

This Memorandum of Agreement (MoA) defines the role and responsibilities of the participating agencies, monitoring and other matters related to the **Multi-institutional Network Program on Systemic lupus Ervthematosus Understanding the diversity of SLE**

NOW THE PARTIES HERETO AGREE AS FOLLOWS:-

1.0 . ROLE OF DEPARTMENT OF BIOTECHNOLOGY, NEW DELHI

To provide funds to the extent of Rs 33738828 over a period of 5 years from the date of sanction of the project, to **August 30, 2018** for undertaking activities as detailed in Annexure I. Details of the funds to be provided are given in Annexure II.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

2.0. ROLE OF SGPGI

2.1. To provide their contribution of none for 5 years from date of sanction of the project as detailed in Annexure – II. *(if a jointly supported project)*

2.2. To provide existing facilities as mentioned in the project document.

2.3. To be responsible for accomplishing objectives identified and activities listed.

Amita Aggarwal

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

2.4. To allow the Scientists authorized by DBT to work with the Research & Development team of the center in all stages of process development and production.

2.5. To recruit all scientific and non-scientific staff as sanctioned by DBT.

2.6. To prepare and submit all periodical reports and other documents that would be required by DBT.

2.7. To maintain a separate audit head of account for the grants received from DBT for the project.

2.8. To submit an annual audited statement of expenditure incurred under the project.

2.9. To ensure effective utilization of the grant given by DBT for the purpose for which it was granted and to ensure timely progress of project work.

2.10. The manpower, both scientific and non-scientific, recruited shall be purely on contractual terms & conditions such hat the contract for engagement of the manpower shall run concurrently with the said project period only.

3.0 DURATION OF PROJECT

3.1 Duration of project shall be 5 years from the date the Project has been sanctioned by DBT.

4.0 RIGHTS OF OWNERSHIP/TECHNOLOGY TRANSFER AND UTILIZATION

4.1 The know-how generated from the project by Dr Amita Aggarwal will be the joint property of SGPGI- and DBT, Government of India. It shall be the responsibility of SGPGI to take necessary action for protection of the intellectual property arising out of the PROJECT through proper instruments, such as, patents, copy rights, etc.

4.2 The know-how developed may be transferred to other entrepreneurs on a non-exclusive basis on such terms and conditions as may be determined by DBT.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Amita Aggarwal

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

286

IN WITNESS WHEREOF the parties hereto have signed, sealed and delivered this Agreement on the day, month and year first above written in presence of:

Witnesses:

1.

2.

Signed by ----------

(Designation)

For and on behalf of The President of India

Witnesses:

1. Dr. Sudhir Sinha
2. Mr. Arnnd Srivastava

Signed by ----------

(Designation)

For and on behalf of SGPGI, Lucknow

DIRECTOR
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Prof. Amita Aggarwal
Head
Clinical Immunology & Rheumatology
SGPGIMS, Lucknow-226 014 (U.P.)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

18-19 (8) (35)

PROFORMA – I

PROFORMA FOR SUBMISSION OF PROJECT PROPOSALS ON RESEARCH AND DEVELOPMENT, PROGRAMME SUPPORT
(To be filled by the applicant)

PART I: GENERAL INFORMATION

1. Name of the Institute/University/Organisation submitting the project Proposal: **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow**

2. State: **UP**

3. Status of the Institute: **Autonomous Government Institution**

4. Name and designation of the Executive Authority of the Institute/University forwarding the application **Prof R Kapoor, Director**

5. Project Title: **Multi-institutional Network Program on Systemic lupus Erythematosus Understanding the diversity of SLE**

6. Category of the Project (Please tick):.R&D/ **Program Support**

7. Specific Area *(Please see Annexure - II)*: ***Chronic disease biology/autoimmune disease***

8. Duration : **5 Years**

9. Total Cost (Rs.) **4,89,00,000**

10. Is the project Single Institutional or Multiple-Institutional (S/M) ? : **Multiple**

11. If the project is multi-institutional, please furnish the following:

Name of Project Coordinator: **Dr Amita Aggarwal**

Affiliation: **Professor**

Address: **Department of Clinical Immunology, Sanjay Gandhi Postgraduate Institute of Medical Education and Research, Lucknow, India 226014.**

12. Scope of application indicating anticipated product and processes
The study will help us understand the spectrum of the disease and variables affecting the phenotype and outcome of lupus from different geographical areas of the country and the impact of low cost interventions like vitamin D and metformin on outcome.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Copy - RN Mishra

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(36)

PART VI: DECLARATION/CERTIFICATION

It is certified that

a) the research work proposed in the scheme/project does not in any way duplicate the work already done or being carried out elsewhere on the subject.

b) the same project proposal has not been submitted to any other agency for financial support.

c) the emoluments for the manpower proposed are those admissible to persons of corresponding status employed in the institute/university or as per the Ministry of Science & Technology guidelines (Annexure-III)

d) necessary provision for the scheme/project will be made in the Institute/University/State budget in anticipation of the sanction of the scheme/project.

e) if the project involves the utilisation of genetically engineered organisms, we agree to submit an application through our Institutional Biosafety Committee. We also declare that while conducting experiments, the Biosafety Guidelines of the Department of Biotechnology would be followed in toto.

f) if the project involves pre-clinical/clinical trials/experiments/exchange of biological samples etc. we will ensure that ethical clearances and other clearances (as applicable on case by case basis) would be taken from concerned ethical Committees/Competent authorities and the same would be conveyed to the Department of Biotechnology before implementing the project.

g) it is agreed that any research outcome or intellectual property right(s) on the invention(s) will be joint property of the host institution and DBT, GOI.

h) we agree to accept the terms and conditions as enclosed in Annexure-IV. The same is signed and enclosed.

i) the institute/university agrees that the equipment, other basic facilities and such other administrative facilities as per terms and conditions of the grant will be extended to investigator(s) throughout the duration of the project.

j) the Institute assumes to undertake the financial and other management responsibilities of the project.

Signature of Project Coordinator
(applicable only for multi-institutional projects)
Date : 26/11/2016

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Signature of Executive Authority of Institute/University with seal
Date :

DIRECTOR
Sanjay Gandhi Post Graduate Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Signature of Principal Investigator
Date : 27/12/2016

Signature of Co-Investigator
Date : 27/11/2016

Signature of Co-Investigator
Date : 5/12/16

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

प्रेषक,

मिशन निदेशक
राष्ट्रीय स्वास्थ्य मिशन
उ0प्र0 लखनऊ।

सेवा में,

मुख्य चिकित्सा अधिकारी
लखनऊ।

पत्रांक: एस0पी0एम0यू0/ब्लड सर्वि0/हीमोफीलिया/2018–19/9013 दिनांक 29-11-2018

विषय: हीमोफीलिया ट्रीटमेन्ट सेन्टर पर संविदा पर कार्यरत मानव संसाधन के मानदेय हेतु धनराशि आवंटन के सम्बन्ध में।

महोदय,

अवगत कराना है कि हीमोफीलिया से ग्रसित मरीजों के जॉच, उपचार एवं प्रबन्धन हेतु के0जी0एम0यू0, एवं एस0जी0पी0जी0आई0एम0एस0, लखनऊ हेतु एच0टी0सी0 की स्थापना एवं उन पर संविदा पर 01 जूनियर रेजीडेन्ट, 01 फीजियोथिरेपिस्ट, 01 परामर्शदाता एवं आउटसोर्स के सपोर्ट स्टाफ एवं डाटा इन्ट्री आपरेटर की स्वीकृत भारत सरकार से प्रदान की गई थी। के0जी0एम0यू0, लखनऊ के क्लीनिकल हिमैटोलाजी विभाग में एच0टी0सी0 स्थापित है एवं उस पर संविदा पर मानव संसाधन भी कार्यरत है व एस0जी0पी0जी0आई0एम0एस0, लखनऊ द्वारा अभी एच0टी0सी0 हेतु संविदा पर मानव संसाधन पर चयन करना है।

भारत सरकार से पूरक कार्ययोजना 2018–19 के एफ0एम0आर0 मद संख्या 8.1.15.10. पर प्राप्त स्वीकृत के क्रम में के0जी0एम0यू0, लखनऊ में कार्यरत एच0टी0सी0 के मानव संसाधन हेतु 12 माह के मानदेय हेतु रू0 11.52 लाख एवं एस0जी0पी0जी0आई0एम0एस0, लखनऊ के एच0टी0सी0 के मानव संसाधन हेतु 04 माह के मानदेय (दिसम्बर 18 से मार्च 19) हेतु रू0 3.83 लाख की धनराशि कुल रू0 15.35 लाख की धनराशि जिला स्वास्थ्य समिति, लखनऊ को निम्नानुसार स्वीकृत की जा रही है। उक्त का व्यय जनपद पर उपलब्ध धनराशि से किया जायेगा एवं डैप के सापेक्ष व्यय का विवरण प्रेषित किया जायेगा।

Institution Name	HR Detail	Total Fund
KGMU Lucknow	01 junior Residents @ Rs. 43995/month,01 physiotherapists @ Rs. 21000/month 01 Counselor @ 12600/month for 12 month and lump sum of (Rs. 2.20 lakhs for support staff and DEO) which may be outsourced	11,51,140.00
SGPGIMS Lucknow	01 junior Residents @ Rs.43995/month,01 physiotherapists @ Rs. 21000/month, 01 Counselor @ 12600/month for 04 month and lump sum of (Rs. 73334 for support Staff and DEO) which may be Outsourced	3,83,714.00
कुल धनराशि		15,34,854.00

अतः आपसे अनुरोध है कि उपरोक्तानुसार आवंटित धनराशि को जनपद स्तर पर उपलब्ध धनराशि से सम्बन्धित चिकित्सा संस्थानों को प्राथमिकता पर हस्तान्तरित करने का कष्ट करें एवं आवंटित धनराशि का समायोजन डैप के सापेक्ष कराना सुनिश्चित करें।

भवदीय

ह0/- (पंकज कुमार)
मिशन निदेशक

पत्रांक: एस0पी0एम0यू0/ब्लड सर्वि0/हीमोफीलिया/2018–19/9013-6 तद्दिनांक

प्रतिलिपि निम्न को सूचनार्थ एवं आवश्यक कार्यवाही हेतु प्रेषित–

1. प्रमुख सचिव, चि0 स्वा0 एवं परिवार कल्याण, उ0प्र0, शासन।
2. महानिदेशक, चि0 शिक्षा, चिकित्सा शिक्षा महानिदेशालय, इन्दिरा भवन, लखनऊ।
3. निदेशक, एस0जी0पी0जी0आई0एम0एस0, लखनऊ को चिकित्सा संस्थान के नियमानुसार प्राथमिकता पर एच0टी0सी0 हेतु स्वीकृत संविदा पर मानव संसाधन के चयन हेतु।
4. कुलपति, के0जी0एम0यू0, लखनऊ।
5. डा0 ए0के0 त्रिपाठी, विभागाध्यक्ष क्लीनिकल हिमैटोलाजी, के0जी0एम0यू0, लखनऊ।
6. जिला कार्यक्रम प्रबन्धक/जिला लेखा प्रबन्धक, जिला कार्यक्रम प्रबन्धन ईकाई, एन0एच0एम0 लखनऊ को आवश्यक कार्यवाही हेतु ।

ह0/- (डा0 ए0बी0 सिंह)
उपमहाप्रबन्धक, ब्लड सेल

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(And)

From,
mission director
National Health Mission

to,
chief medical officer

Bank S.P.A.00/RDS/Hemophilia/2018-19/9013 Dated 29-11-2018 Subject:
Regarding allocation of funds for honorarium of human resources working on contract at Hemophilia Treatment Center

Sir,

It is to be informed that 01 Junior Resident, cancellation month or 01 Faugiotypist, 01 Consultant and [illegible] support staff and Data Entri Operator have been appointed on contract basis for the establishment of KGMU and [illegible] MS Sahuraj Datu ADTC for the investigation, treatment and management of the poor suffering from Hemophilia. Approval was provided by the Government of India. HTC is established in the Clinical Hematology Department of KGA, Nakhnau and human resources are also working on it on contract and EraGP GIMS, Lucknow is yet to select human resources on contract for HTC.

FMR item number 8.1.15.10 of Supplementary Action Plan 2018-19 from Government of India, under the approval received, Rs 11.52 lakh for 12 months' honorarium for the human resources of MTC working in KGMPU, Lucknow and Rs 3.03 lakh for 4 months' honorarium (December 18 to March 19) for the song resources of HTC of SGP GIMS, Lucknow. A total amount of Rs 15.35 lakh is being sanctioned to the District Health Committee, Lucknow as follows. The above expenditure will be made from the funds available in the district and details of expenditure regarding SAP will be sent.

Institution Name	HR Detail	Total Fund
KGMU Lucknow	01 Junior Residents @ Rs 47955/month,01 physiotherapists @ Rs 21000/month 01 Counselor @ 12000/month for 12 month and lump sum of (Rs. 2.29 lakh) for support staff and DEO's which may be outsourced	11,51,160.00
SGPGIMS Lucknow	01 Junior Residents @ Rs 47955/month,01 physiotherapists @ Rs 21000/month 01 Counselor @ 12000/month for 04 month and lump sum of (Rs. 73334 for support Staff and DEOs which may be Outsourced	3,83,694.00
	sum of money	15,34,854.00

Therefore, you are requested to transfer the funds allocated as above to the Chanchalya medical institutions on priority from the funds available at the district level and ensure adjustment of the allocated funds in relation to the sub.

Yours

[illegible]
mission director

Letter: SPMU/Blood Serv/Haemophilia/2016-19/90/3-6 दिनांकित

Copy sent to the following for information and necessary action:

1. Principal Secretary, Chhattisgarh Health and Family Welfare, GOI, Govt.
2. Director General, Medical Education, Directorate General of Medical Education,
3. [illegible] Lucknow, Director, SGP GIMS, Lucknow on priority as per rules of Medical Institute For selection of human resources on approved contract for HTC
4. Vice Chancellor, KGMU, Lucknow
6. Dr. A.K. Tripathi, Head of the Department of Clinical Hematology, KGMU, Lucknow
7. Program Manager/District Accounts Manager, District Program Management Unit, for necessary action. NHM Lucknow

(Dr. A.P. Sindh)
Deputy General Manager (Health)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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Executive Registrar
SGPGIMS,Lucknow

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No. BT/PR13584/COE/34/29/2015
GOVERNMENT OF INDIA
MINISTRY OF SCIENCE & TECHNOLOGY
DEPARTMENT OF BIOTECHNOLOGY

Block 2, 6-8th Floors
CGO Complex, Lodhi Road,
New Delhi- 110 003
Dated: 10 /05/2018

ORDER

Sanction of the President is hereby accorded, under Rule 18 of the Delegation of Financial Powers Rules ,1978 , for the implementation of the project entitled: "**Centre of Excellence on Translational Research on Bioinspired Nanomaterials and Drugs from Endophytes**" for a period of 5 Year 0 Month at a total cost of Rs. **39539200** (Rupees Three Crores Ninety Five Lakhs Thirty Nine Thousand Two Hundred Only) on the terms and conditions detailed here under:-

2 **The Project :**

2.1 **Title :** "**Centre of Excellence on Translational Research on Bioinspired Nanomaterials and Drugs from Endophytes**"

2.2 **Details of the Investigatiors:**

Project Cordinator

Dr. Absar Ahmad
Senior Principal Scientist
Division of Biochemical Sciences
Aligarh Muslim University
Division of Biochemical Sciences,
Aligarh Muslim University, AMU,
Aligarh - 202002 Uttar Pradesh

Principal Investigators:

Dr. Absar Ahmad
Senior Principal Scientist
Division of Biochemical Sciences
Aligarh Muslim University
Division of Biochemical Sciences,
Aligarh Muslim University, AMU,
Aligarh - 202002, Uttar Pradesh

Dr. Dhanasekaran Shanmugam
Principal Scientist (E II)
Biochemical Sciences Division
CSIR-National Chemical Laboratory
Biochemical Sciences Division
CSIR-National Chemical Laboratory
Dr. Homi Bhabha Road, Pune, Maharashtra, 411008

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Dr. Mahesh J Kulkarni
PI
Biochemical Sciences
CSIR-National Chemical Laboratory
Pune, Maharashtra, 411008

Dr. Sanjay Gambhir
Professor & Head
Nuclear Medicine
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
Institute/University: S.G.P.G.I.M.S
Address: Rai-Bareli Road, Lucknow,
,Uttar Pradesh, 226014

2.3 Objectives:

1. Mass production of chemically and physically difficult to synthesize nanoparticles using 'bottom-up' bioinspired approaches like biosynthesis, etc. (Nodal Lab-AMU).
2. Mass production of chemically and physically difficult to synthesize nanoparticles using 'top-down' bioinspired approaches like biosynthesis, etc. (Nodal Lab-AMU).
3. Studies on metal accumulation in plants and employing them for the bleaching of technologically important nanoparticles. (Nodal Lab-AMU).
4. Conjugation of our nanoparticles with various anti-diabetic, anti-malarial, etc. drugs. (Nodal Lab-AMU).
5. Radiolabelling of nanoparticles/nano-drug formulates and animal studies to see their bio-distribution and clearance time from blood. (Co-PI: Dr. Sanjay Gambhir, SGPGIMS, Lucknow).
6. Biological sunthesis of carbon supported metal/oxide/sulfide/quantum dots nanoparticles. (Nodal Lab-AMU)
7. Nanomaterails embedded in fungal biofilm for uptake studies. (Nodal lab-AMU).
8. Evaluating the exact target site, uptake and location of nanoparticles inside cells samples. (Nodal Lab-AMU).
9. Evaluation of anti-bacterial/fungal/algal activity of our nanoparticles. (Nodal lab AMU).
10. Evaluation of biosynthesized inorganic nanomaterials for ant-diabetic properties and translation into related products (project 1: study of bioinspired nanomaterials in Diabetes: Dr. Mahesh Kulkarni, CSIR-NCL, Pune)
11. Evaluation of biosynthesized inorganic nanomaterials for anti-malarial properties and translation into related products (project 2: Study of bioinspired nanomaterials in Malaria: Dr. Dhanasekaran Shanmugam, CSIR-NCL, Pune)

2.4 Time Schedule:
The duration of the project is 5 Year 0 Month from the date of this sanction order.

2.5 Project Cost:
The total cost of the project is Rs. **39539200**/-(Rupees Three Crores Ninety Five Lakhs Thirty Nine Thousand Two Hundred Only) as per details given below :

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SGPGIMS,Lucknow

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Executive Registrar
SGPGIMS,Lucknow

Institute	Year I	Year II	Year III	Year IV	Year V	Total Cost(Rs.)
1. Aligarh Muslim University	9421000	4721000	4807400	4807400	4807400	28564200
2. CSIR-National Chemical Laboratory	1320000	1320000	1320000	1320000	1320000	6600000
3. Sanjay Gandhi Post Graduate Institute of Medical Sciences	875000	875000	875000	875000	875000	4375000
Total (Rs.)	11616000	6916000	7002400	7002400	7002400	39539200

Institute wise details are:

Budget Head	Year I	Year II	Year III	Year IV	Year V	Total(Rs.)
1. Aligarh Muslim University						
Equipment	4700000.00					4700000.00
Manpower	2196000.00	2196000.00	2282400.00	2282400.00	2282400.00	11239200.00
Contingency	50000.00	50000.00	50000.00	50000.00	50000.00	250000.00
Overhead	100000.00	100000.00	100000.00	100000.00	100000.00	500000.00
Consumables	2000000.00	2000000.00	2000000.00	2000000.00	2000000.00	10000000.00
Travel	75000.00	75000.00	75000.00	75000.00	75000.00	375000.00
Workshop Training for 2,00,000 and 1,00,000 for PMC onsite visit	300000.00	300000.00	300000.00	300000.00	300000.00	1500000.00
Total (Rs.)	9421000.00	4721000.00	4807400.00	4807400.00	4807400.00	28564200.00
2. CSIR-National Chemical Laboratory						
Manpower	600000.00	600000.00	600000.00	600000.00	600000.00	3000000.00
Travel	80000.00	80000.00	80000.00	80000.00	80000.00	400000.00
Contingency	40000.00	40000.00	40000.00	40000.00	40000.00	200000.00
Consumables	600000.00	600000.00	600000.00	600000.00	600000.00	3000000.00
Total (Rs.)	1320000.00	1320000.00	1320000.00	1320000.00	1320000.00	6600000.00
3. Sanjay Gandhi Post Graduate Institute of Medical Sciences						
Manpower	300000.00	300000.00	300000.00	300000.00	300000.00	1500000.00
Consumables	500000.00	500000.00	500000.00	500000.00	500000.00	2500000.00
Travel	25000.00	25000.00	25000.00	25000.00	25000.00	125000.00
Contingency	50000.00	50000.00	50000.00	50000.00	50000.00	250000.00
Total (Rs.)	875000.00	875000.00	875000.00	875000.00	875000.00	4375000.00

2.6 Equipment:

The details of the equipment sanctioned for the implementation of the project at Annexure-I

2.7 Manpower:

The details of the manpower sanctioned for the implementation of the project at Annexure-II

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Executive Registrar
SGPGIMS,Lucknow

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Executive Registrar
SGPGIMS,Lucknow

3. Head of Account:

The **Non-Recurring** expenditure involved is debitable to:

Demand No. 85	Department of Biotechnology
3425	Other Scientific Research 2018-2019
3425.60	Others (Sub Major Head)
3425.60.200	Assistance to other Scientific Bodies (Minor Head)
3425.60.200.29	Biotechnology Research and Development
3425.60.200.29.17	Assistance for Research and Development
3425.60.200.29.17.35	Grants for creation of capital assets

The **Recurring** expenditure involved is debitable to:

Demand No. 85	Department of Biotechnology
3425	Other Scientific Research 2018-2019
3425.60	Others (Sub Major Head)
3425.60.200	Assistance to other Scientific Bodies (Minor Head)
3425.60.200.29	Biotechnology Research and Development
3425.60.200.29.17	Assistance for Research and Development
3425.60.200.29.17.31	Grants-in-Aid General

4. Terms & Conditions:

[I] Considering the time bound nature of the project, the progress made in the project will be monitored once a year by the Task Force Constituted by DBT. [II] The Date of release of the grant is the date of implementation of the Project. [III] Extension proposal, if any should be submitted before 6 month from the probable date of completion of the project. [IV] It is the responsibility of the PI and the Institute to ensure that support of DBT is suitably acknowledged in the publications i.e. papers, reports etc. arising out of the project. [V] As per GFR the equipment sanctioned under the project should be purchased within 18 months from the date of release of the grant. [VI] The grantee institute is permitted to carry forward the unspent balance from the previous financial year after furnishing UC/SE in the DBT format to the Department for the previous financial year ending. [VII] In case the whole or a part of the amount of the grant-in-aid is being refunded, an interest at the rate of ten per cent annum there on shall be recovered

4.1 The other terms and conditions governing this sanction are attached at Annexure- III.

4.2 A Memorandum of Agreement (MoA) will be signed between the Department of Biotechnology and the grantee institution on Non-Judicial stamp paper Rs. 100/- in the enclosed format and the second installment will be made only after signing of MoA by the grantee institutions and its acceptance by DBT. In case of NGO or Private Institution, MOA signed is mandatory first release. A format of the MoA is enclosed in Annexure-IV

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS Lucknow

The Institute/Agency will keep the whole of the grant in a Bank Account earning interest, and the interest so earned should be reported to DBT in the Utilisation Certificate and Statement of Expenditure. The Interest so earned will be treated as created to the institute/Agency and shall be adjusted towards further installment of the grant and or at the time of Final Settlement of Accounts.

5. No International Travel will be undertaken from the sanctioned project grant unless specified otherwise.

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Executive Registrar
SGPGIMS,Lucknow

6. The Director, CSIR-National Chemical Laboratory, Pune, Maharashtra and The Director, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow, Uttar Pradesh and The Registrar, Aligarh Muslim University, Aligarh, Uttar Pradesh would be responsible for submission of Statements of Expenditure (SoE), utilization certificates (UC), Assets Certificates, Manpower staffing & expenditure details in prescribed DBT formats to DBT in respect of grants released in this project from time to time.

7. PI's of DBT sponsored projects can consider appointment of JRF from Category-II merit list of DBT-BET exam so that candidates can be paid fellowships at par with NET/GATE/BET qualified candidates as per DST OM No. A.SR/S9/Z-09/2012 dated on 21 Oct 2014. However, there is no compulsion on PI's to select candidates for JRF in their projects from Category-II of DBT-BET.

8. As per Rule 236 (1) of GFR 2017, the accounts of all Grantee Institutions or Organisations shall be open to inspection by the sanctioning authority and audit, both by the Comptroller and Auditor General of India under the provision of CAG(DPC) Act 1971 and internal audit by the Principal Accounts Office of the Ministry or Department, whenever the Institution or Organisation is called upon to do so.

9. If the Research Project involves biological resource, the obligations under the Biological Diversity Act 2002 as applicable shall be complied with by the Project Investigator, the details of such obligations can be accessed at www.nbaindia.org

10. This issues under the power delegated to this Department and with the concurrence of IFD vide their SAN No. **102/IFD/SAN/295/2018-2019** dated **May, 10 2018.**

11. This sanction order has been noted at serial no. 6 in the Register of Grants.

(Dr. D K Tewary)
Scientist 'E'

To,
The Pay & Accounts Officer,
Department of Biotechnology,
New Delhi - 110 00

Copy to:

1 The Principal Director of Audit (Scientific Departments), DACR Building, New Delhi- 110 002.
2 Dr. Absar Ahmad(Project Co-ordinator), Nanobiotechnology Group, Biochemical Sciences Division, Aligarh Muslim University, AMU, Aligarh - 202002, Uttar Pradesh
3 The Director, CSIR-National Chemical Laboratory, CSIR-National Chemical Laboratory, Dr. Homi Bhabha Road , Pune - 411008, Maharashtra
4 The Director, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raibarelly Road, Lucknow - 226014, Uttar Pradesh
5 The Registrar, Aligarh Muslim University, AMU, Aligarh - 202002, Uttar Pradesh
6 Dr. Dhanasekaran Shanmugam, Principal Scientist (E II), Biochemical Sciences Division, CSIR-National Chemical Laboratory, Biochemical Sciences Division CSIR-National Chemical Laboratory Dr. Homi Bhabha Road, Pune, Maharashtra, - 411008,
7 Dr. Mahesh J Kulkarni, PI, Biochemical Sciences, CSIR-National Chemical Laboratory, , Pune - 411008, Maharashtra
8 M. Sanjay Gambhir, Professor & Head, Nuclear Medicine, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Institute/University: SGPIMS Address: Rai-Bareli Road, Lucknow, - 226014
9 Cash Section, DBT (2 copies).
10 Sanction Folder.
11 File Copy.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(Dr. D K Tewary)
Scientist 'E'

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

IndiaAlliance
DBT wellcome

REVISED PROVISIONAL GRANT PAYMENT PROFILE

NO COST EXTENSION

Applicant's Name : Dr. Chandra Chaturvedi
Type of Grant : INTERMEDIATE
Host Institute Name : SGPGIMS, UP
IA Reference No : IA/I/16/2/502374
Host Institute Ref. No: SGPGIMS, LUCKNOW
Grant Award Amt. ₹ 3,60,55,580
A vard Letter Date: 14-03-2017 (04-07-2022)
Grant Start Date: 01-04-2017 (01-04-2022)
Grant End Date: 31-03-2022 (31-03-2023)
Bank A/c Details: SBI/SB#10095237491
F&A Contact Details: Prof. U C Ghoshal- Faculty In -Charge email:sgpgiresearch@gmail.com

Note: *(FS) Fixed till 'MARCH' Only, for current FY

Equipment Cost (E)	Removable Exp.(R)	Inst. Sal Actg Period
47,00,000	-	Apr - Mar

202223 Basic 70

Work Outside Host. Inst. (OA)		Year (FY)	IA Fellow Personal Support Details
6 Months pm @ (+)Travel ₹1.50 L	$3,000		Estimated FIXED Personal Support (FS)* p.m. (will be revised every year at beginning of FY)
Exchange Rate	No. of Months		IA Salary Cap / Institute Salary / Top-up / IA PS
		2017-18	115200 / 0 / 1,15,200
		2018-19	115200 / 0 / 1,15,200
		2019-20	115200 / 198756 / 0
70		2020-21	115200 / 205686 / 0
70	6	2021-22	115200 / 205686 / 0
		2022-23	115200 / 205686 / 0
(+) O Travel	1,50,000	2023-24	115200 / 205686 / -

Particulars	AWARD AMT.	2017-18	2018-19	2019-20	2020-21	2021-22	2022-23	2023-24	RETENTION (R)	Adjustment	NET AWARD
No. of Months	60	12	12	12	12	12	0	0			
Ring-fenced Funds (R-f)											
Revised Fellow Salary (FS)	69,12,000	13,82,400	13,82,400	0	0	0	0	0		-41,47,200	27,64,800
Adj. of Unspent/DISALLOWED / Reduction in Top-u		0	0	-5,06,880			0	0		-5,06,880	-5,06,880
Net Release of (FS) (a)	69,12,000	13,82,400	13,82,400	-5,06,880	0	0	0	0	0	-46,54,080	22,57,920
Overseas All. (Work outside Host Inst.) (OA)	14,10,000	0	0				0	0		-14,10,000	0
Adj. of Unspent / Reduction in (OA)	0	0	0	0	0	0	0	0		0	0
Net Release of (OA) (b)	14,10,000	0	0	0	0	0	0	0	0	-14,10,000	0
Net R-f Fund (C) = (a+b)	83,22,000	13,82,400	13,82,400	-5,06,880	0	0	0	0	0	-60,64,080	22,57,920
Add: Institutional O.H. Cont. @10%											
OH on R-f Fund (c)	8,32,200	1,38,240	1,38,240	-50,688	0	0	0	0	0	-6,06,408	2,25,792
OH on T-Fund (g)	24,45,580	8,65,116	3,95,116	63,857	6,77,463	3,95,116	5,79,723	0	60,743	5,91,554	30,37,134
Adjustment of Interest Earned on IA Funds			-3,28,351	-1,44,859	-1,52,304	-33,096	-55,477	0		-7,14,087	-7,14,087
Overheads Retained					-6,77,463				6,77,463		
Total Institutional O.H. Cont. (d)	32,77,780	10,03,356	2,05,005	-1,31,690	-1,52,304	3,62,020	5,24,246	0	7,38,206	-7,28,941	25,48,839
Total - Ring-fenced Funds (RF) (e	1,15,99,780	23,85,756	15,87,405	-6,38,570	-1,52,304	3,62,020	5,24,246	0	7,38,206	-67,93,021	48,06,759
Transferable Funds (TF)	2,44,55,800	86,51,160	39,51,160	39,51,160	39,51,160	39,51,160	0	0		0	2,44,55,800
Adj: Other Adjustments +/(-)										0	0
Adj. of Ecess/Un Spent TF Funds +/(-)	0			-33,12,590	33,12,590		59,15,541			59,15,541	59,15,541
Net Transferable Funds	2,44,55,800	86,51,160	39,51,160	6,38,570	72,63,750	39,51,160	59,15,541	0	0	59,15,541	3,03,71,341
Less: Retention Amt. @2% on TF (R)					-4,89,116		-1,18,311		6,07,427	0	0
Net Release of (T	2,44,55,800	86,51,160	39,51,160	6,38,570	67,74,634	39,51,160	57,97,230	0	6,07,427	59,15,541	3,03,71,341
Grand Total (GT) ₹	3,60,55,580	1,10,36,916	55,38,565	0	66,22,330	43,13,180	63,21,476	0	13,45,633	-8,77,480	3,51,78,100
ADD: SUPPLEMENTARY FUNDS:	-										
TOTAL - SUPPLEMENTARY FUNDS (SF) (₹)	-									Award Plus Suppl ₹	3,51,78,100
Interest Earned on Grant Received from IA	7,14,087	3,28,351	1,44,859	1,52,304	33,096	55,477				Total Grant Amt. ₹	3,58,92,187

ADJ: REVISION / (PERMANENT REDUCTION - (PR))

Revision / (PR) in Fellow Salary (FS)	(46,54,080)	-	-				(46,54,080)				
Revision / (PR) in Overseas Allowance (OA)	(14,10,000)						(14,10,000)				
Revision / (PR) in Transferrable Funds (TF)	59,15,541						59,15,541				
Institutional O.H. @ 10% on above (FS+OA+TF)	(7,28,941)	-	(3,28,351)	(1,44,859)	(1,52,304)	(33,096)	(70,331)	-			
TOTAL - REVISION / (PR) (₹)	(8,77,480)	-	(3,28,351)	(1,44,859)	(1,52,304)	(33,096)	(2,18,870)	-		REVISED AWARD ₹	3,51,78,100
SPENT DETAILS	TOTAL SPENT	1	2	3	4	5	6	7		TOTAL UNSPENT	TOTAL RECEIPT (GT)
Fellow Salary (FS)	22,57,920	13,82,400	8,75,520							-	22,57,920
Overseas All. (Work outside Host Inst.) (OA)	-	-								-	-
Transferable Funds (TF)	2,01,12,101	19,59,352	49,02,301	50,32,411	38,76,345	43,41,692				38,54,583	2,39,66,684
Institutional O.H. @ 10% on above (FS+OA+TF)	22,37,002	3,34,175	5,77,782	5,03,241	3,87,635	4,34,169	-	-		(9,50,615)	12,86,387
TOTAL AMOUNT ₹	2,46,07,023	36,75,927	63,55,603	55,35,652	42,63,980	47,75,861	-	-		29,03,968	2,75,10,991
Unspent Amount (₹)	29,03,968	73,60,989	(8,17,038)	(55,35,652)	23,58,350	(4,62,681)	-	-		29,03,968	36,18,055
Committed Amount Provision ₹ (CP)	-		13,47,326	(5,86,409)	67,35,615	(74,96,532)				-	-
Unspent after Commitment Prov ₹	29,03,968	73,60,989	(21,64,364)	(49,49,243)	(43,77,265)	70,33,851	-	-		29,03,968	36,18,055
UNSPENT / (EXCESS) SPENT - (FS)	5,06,880	-	5,06,880	-	-	-	-	-		5,57,568	
UNSPENT / (EXCESS) SPENT - (OA)	-			0						-	47,97,609
UNSPENT / (EXCESS) SPENT - (TF)	38,54,583	66,91,808	(22,98,467)	(38,07,432)	(38,37,326)	71,06,000	-	-		42,40,041	

Cumulative Total Payment		1,10,36,916	1,65,75,481	1,65,75,481	2,31,97,811	2,75,10,991	3,38,32,467	3,38,32,467	3,51,78,100		3,51,78,100
Current Liability (CL) (Unspent Adjusted Payable)	-	-	-	36,43,849	(36,43,849)		-				
Expenditure (GT+R+CL)	3,51,78,100	1,10,36,916	55,38,565	36,43,849	41,93,972	43,13,180	64,51,618	-	-		
Deferred Liability (DL)		2,50,18,664	1,91,51,748	1,53,63,040	1,10,16,764	66,70,488	-	-	-		

Please Note:

1. Payment of yearly installment will be made subject to submission of (a) Ledger Copy/ R&P/ I&E/ Statement of A/c of Fellows Project, (b)Latest Pay Slip **AND** monthly Salary statement for the previous year, (c) Valid Ethical Approval / Certificate from Sponsor (If appl.), (d) Signed Grant Spend Report for the previous year, (e) Fellows Research Report, (f) Latest Audited & Unaudited Financial Statements **AND** Annual Report of the Institution, (g) WOH Visit & Spent letter from external sponsor, (h) Amount Committed Information for next FY (if any)
2. UNSPENT TF & OA amounts will be adjusted from 3rd installment, it will be released upon submission of Spend Report and Future requirements.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

wellcome trust DBT

(IA) INDIA ALLIANCE

PROVISIONAL GRANT PAYMENT PROFILE

Applicant's Name: Dr. Rohit Antony Sinha

Host Institute Name: SGPIMS, Lucknow

IA Reference No: IA/I/16/2/502691

Grant Award Amt. ₹: 33,934,890

Type of Grant: INTERMEDIATE

Host Institute Ref. No: SGPGIMS, Lucknow

Award Letter Date: 13/10/2017

Grant Start Date: 01/11/2017

Grant End Date: 31/10/2022

Note: *(FS) Fixed till 'MARCH' Only, for current FY

Equipment Cost (E)	Removable Exp.(R)	Inst. Sal Actg Period
9,852,000	-	Apr - Mar

1718 Basic

Work Outside Host. Inst. (OA)		Year (FY)
N/A		
Exchange Rate	No. of Months	
		2017-18
		2018-19
N/A		2019-20
		2020-21
		2021-22
		2022-23
(+) O Travel (₹)		2023-24

IA Fellow Personal Support Details		
Estimated FIXED Personal Support (FS)* p.m. (will be revised every year at beginning of FY)		
IA Salary Cap	Institute Salary	Top-up / IA PS
115200	0	115,200
115200	0	115,200
115200	0	115,200
115200	0	115,200
115200	0	115,200
115200	0	115,200
115200	0	115,200

Particulars	No. of Months	60	5	12	12	12	12	7	0			
		AWARD AMT.	2017-18	2018-19	2019-20	2020-21	2021-22	2022-23	2023-24	RETENTION (R)	Adjustment ±	Net
Ring-fenced Funds (R-f												
Revised Fellow Salary (FS)		6,912,000	576,000	1,382,400	1,382,400	1,382,400	1,382,400	806,400	0		0	6,912,000
Adj. of Unspent/DISALLOWED / Reduction in Top-up of			0	0	0	0	0	0	0		0	0
Net Release of (FS)	(a)	6,912,000	576,000	1,382,400	1,382,400	1,382,400	1,382,400	806,400	0	0	0	6,912,000
Overseas All. (Work outside Host Inst.) (OA)		0	0		0	0		0	0		0	0
Adj. of Unspent / Reduction in (OA)		0	0	0	0	0	0	0	0		0	0
Net Release of (OA)	(b)	0	0	0	0	0	0	0	0	0	0	0
Net R-f Fund (C) = (a+b)		6,912,000	576,000	1,382,400	1,382,400	1,382,400	1,382,400	806,400	0	0	0	6,912,000
Add: Institutional O.H. Cont. @10%												
OH on R-f Fund (c)		691,200	57,600	138,240	138,240	138,240	138,240	80,640	0	0	0	691,200
OH on T-Fund (g)		2,393,790	1,102,583	281,718	281,718	281,718	233,842	164,335	0	47,876	0	2,393,790
Adjustment of Interest Earned on IA Funds				0	0	0	0	0	0		0	0
Total Institutional O.H. Cont. (d)		3,084,990	1,160,183	419,958	419,958	419,958	372,082	244,975	0	47,876	0	3,084,990
Total - Ring-fenced Funds (RF)	(e) = (c+d)	9,996,990	1,736,183	1,802,358	1,802,358	1,802,358	1,754,482	1,051,376	0	47,876	0	9,996,990
Transferable Funds (TF)		23,937,900	11,025,825	2,817,180	2,817,180	2,817,180	2,817,180	1,643,355	0		0	23,937,900
Adj: Other Adjustments +/(-)											0	0
Adj. of Ecess/Un Spent TF Funds +/(-)		0									0	0
Net Transferable Funds		23,937,900	11,025,825	2,817,180	2,817,180	2,817,180	2,817,180	1,643,355	0	0	0	23,937,900
Less: Retention Amt. @2% on TF	(R)						(478,758)			478,758	0	0
Net Release of (TF)		23,937,900	11,025,825	2,817,180	2,817,180	2,817,180	2,338,422	1,643,355	0	478,758	0	23,937,900
Grand Total (GT)		33,934,890	12,762,008	4,619,538	4,619,538	4,619,538	4,092,904	2,694,730	0	526,634	0	33,934,890

ADD: SUPPLEMENTARY FUNDS:

TOTAL - SUPPLEMENTARY FUNDS (SF) (₹)											Award Plus Suppl ₹	33,934,890
Interest Earned on Grant Received from IA ₹											Total Grant Amt ₹	33,934,890

ADJ: REVISION / (PERMANENT REDUCTION - (PR))

Revision / (PR) in Fellow Salary (FS)	-											
Revision / (PR) in Overseas Allowance (OA)	-											
Revision / (PR) in Transferrable Funds (TF)	-											
Institutional O.H. @ 10% on above (FS+OA+TF)	-	-	-	-	-	-	-	-	-		REVISED AWARD ₹	33,934,890
TOTAL - REVISION / (PR) (₹)	-										TOTAL UNSPENT	TOTAL RECEIPT (GT)

SPENT DETAILS	TOTAL SPENT	1	2	3	4	5	6	7			
Fellow Salary (FS)	-									-	
Overseas All. (Work outside Host Inst.) (OA)	-									-	
Transferable Funds (TF)	-									-	
Institutional O.H. @ 10% on above (FS+OA+TF)	-	-	-	-	-	-	-	-	-		
TOTAL AMOUNT ₹	-										
Unspent Amount (₹)	-									-	-
Committed Amount Provision ₹ (CP)	-										
Unspent after Commitment Prov.₹											
UNSPENT / (EXCESS) SPENT - (FS)											
UNSPENT / (EXCESS) SPENT - (OA)											
UNSPENT / (EXCESS) SPENT - (TF)											

Cumulative Total Payment		12,762,008	17,381,546	22,001,084	26,620,622	30,713,526	33,408,256	33,408,256	33,934,890	33,934,890
Current Liability (CL) (Unspent Adjusted Payable)	-	-	-	-	-	-	-			
Expenditure (GT+R+CL)	33,934,890	12,762,008	4,619,538	4,619,538	4,619,538	4,092,904	2,694,730			
Deferred Liability (DL)		21,172,882	16,553,344	11,933,806	7,314,268	3,221,362	526,634			

Please Note:

1. Payment of yearly installment will be made subject to submission of (a) Ledger Copy/ R&P/ I&E/ Statement of A/c of Fellows Project, (b)Latest Pay Slip AND monthly Salary statement for the previous year, (c) Valid Ethical Approval / Certificate from Sponsor (if appl.), (d) Signed Grant Spend Report for the previous year, (e) Fellows Research Report, (f) Latest Audited & Unaudited Financial Statements AND Annual Report of the Institution, (g) WOH Visit & Spent letter from external sponsor, (h) Amount Committed Information for next FY
2. UNSPENT TF & OA amounts will be adjusted from 3rd installment. It will be released upon submission of Spend Report and Future requirements.
3. India Alliance will adjust the Interest earned on IA grants from Institutional Overheads every following year.

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Treatment:

1. Treatment with immunoglobulin via different routes (e.g., subcutaneous and intravenous)
2. Hematopoietic stem cell transplantation (cord blood and bone marrow)
3. Gene therapy

Research:

Research projects to understand the pathogenesis of PID (Basic and Translational). Both fellowships and individual research projects may be funded.

More information on FPID is available at www.fpid.org

Terms and conditions:

Purpose: To set up an SGPGI-FPID Center for diagnosis of PID that will provide free of cost tests for patients with suspected PID

Support: Rs. 5,00,000/annually will be provided to run the laboratory for consumables and manpower . This amount may be increased based upon the need and satisfactory progress report.

Reports: The Recipient will provide 6 monthly report on the progress made

Confidentiality: FPID will protect the confidentiality of information and data provided by the recipient.

Payments: The payments will be made by electronic wire-transfer to SGPGI in the name of **Director, SGPGI (research account).**

Return of unused funds: Any grant that remains unutilized may be carried over for following year and adjusted into following year budget.

Compliance: The FPID reserves the right, in its sole discretion to discontinue the project grant program if the foundation is not satisfied with the progress of the grant or the information reported by the recipient.

Prohibited activities: The money provided by FPID will be used for the sole purpose for which it is to be used and in no circumstances will it be used for any other purpose.

Dispute Resolution: All disputes will be resolved by mutualdiscussion.

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SGPGIMS,Lucknow

Duration of MOU: 5 years

Project commencement:
This MOU will become effective on the date that it is fully executed by both **FPID** and the **Recipient**. The FPID reserves the right, in its sole discretion to discontinue the project grant program if the foundation is not satisfied with the progress of the grant or the information reported by the recipient. In the event of such termination the FPID will provide recipient with written notice of termination documenting the reason for termination.

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SGPGIMS,Lucknow

Other elements of this agreement

Any notice required by the MOU shall be sent in writing by certified mail addressed in the case of FPID to:
Dr Sudhir Gupta
2 Geneve, Newport Beach, CA 92660, USA

And in the case of recipient by courier mail to the address below:
The Director, SGPGI, Lucknow 226014, India

This MOU represents the complete agreement between the parties regarding its subject matter and supersedes all prior written or oral communications, representations and agreements regarding the same subject matter. This MOU may be amended or modified only in a written document signed by duly authorized representatives of FPID and recipient. This MOU may be executed in two or three counterparts, each of which will be deemed an original. If any provision of this MOU is held unenforceable for any reason, than unenforceability shall not affect the enforceability of any other provision of this MOU and the parties will negotiate in good faith to substitute an enforceable provision with similar aims.
Executed by the parties hereto as of the date set forth

FPID

Prof Sudhir Gupta
Co-founder and Chairman, Board of Directors
Date_____

Recipient

DIRECTOR
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW 226 014, INDIA

Date_____

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SGPGIMS,Lucknow

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Executive Registrar
SGPGIMS,Lucknow

(17)

(11)

Title of the Project: A study of seizures in tuberculous meningitis with emphasis on the role of glutamate excitotoxicity .

PI: UK Misra

Professor, Department of Neurology, SGPGIMS, Lucknow

Co PI: J Kalita

Professor, department of Neurology, SGPGIMS, Lucknow

Introduction: Tuberculous meningitis (TBM) is the commonest central nervous system (CNS) infection in the developing countries. Seizures in TBM occur in a large number of patients which ranges between 17% -93%.[1] Seizures in TBM may occur as a presenting feature, in beginning, early or late stage of TBM. The etiology of seizures in TBM is multifactorial. The majority of studies on seizures in TBM have evaluated the frequency, and clinico-radiological correlation. Seizures in TBM may be attributed to meningeal irritation, cerebral oedema, tuberculoma, infarction, hydrocephalus, or metabolic alteration in isolations or in combinations. Seizures may be related to the severity of TBM.

Glutamate is an important excitotoxin having important role in brain function in health and disease. Excess of glutamate in stroke has been associated with poor outcome.[2] Amongst the N-methyl D- aspartate (NMDA) receptors, NR1, NR2A and NR2B are the main component of heteromeric NMDA receptor which are mainly distributed in frontal and hippocampal cortex.[3] In CNS infections, because of oxidative stress, ER stress and up regulation of proinflammatory cytokines, glutamate release may be increased. Excess of glutamate may result in increased excitability and neuronal damage resulting in seizures and cell death. The is no study evaluating the role of excitotoxic injury in the pathogenesis of seizures and outcome of TBM.

Hypothesis: It is assumed that in the patients with TBM having seizures are likely to have grater excitotoxicity (glutamate level and receptors) which may result in poor outcome of TBM patients compared to those without seizures

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Aim:

1. To evaluate the frequency, type and burden of seizures in TBM and their effect on the outcome.

2. To compare the serum glutamate levels and its receptors in the patients with and without seizures and their relation with severity and outcome of TBM patients.

Subject and methods:

Setting: This study will be conducted at Department of neurology, Sanjay Gandhi PGIMS.

Inclusion criteria: All the patients diagnosed with TBM will be included prospectively.

Diagnosis of TBM: The diagnosis of TBM will be based on clinical, MRI and CSF criteria.[4]

1. **Essential criteria:** Features suggestive of meningitis (one or more of the following: headache, irritability, vomiting, fever, weight loss, neck stiffness, convulsions, focal neurological deficits, or altered consciousness) for more than 5 days.

2. Supportive criteria:

(a) CSF cells of 10–500/μL, with predominant lymphocytes (>50%), protein 1 g/L and sterile bacterial and fungal culture.

(b) CT or MRI imaging showing evidence of exudates, infarction, hydrocephalus or tuberculoma in isolation or in combinations.

(c) Evidence of extra CNS tuberculosis(chest radiograph suggestive of active tuberculosis or CT/ MRI/ ultrasound evidence for tuberculosis outside the CNS or Acid Fast Bacillus (AFB) identified or *Mycobacterium tuberculosis* cultured from another source.i.e. sputum, lymph node, gastric washing, urine, blood culture).

(d) Exclusion of alternative diagnoses.

Criteria for definite and highly probable TBM: Essential criteria with two supportive criteria were defined as highly probable TBM; and presence of acid fast bacilli in CSF smear, positive CSF culture or polymerase chain reaction (PCR) for *M. tuberculosis* was considered definite TBM.[5]

Classification of seizures: The seizures will categorise according to the recent ILAE classification of Seizures.[6] The frequency and duration of seizure including status epilepticus will be noted.

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To circumvent the variability of the time to admission (i.e. duration of symptoms), seizures were also classified as Presenting, early onset (within 1 month) and late onset (after 1 month) based on the relationship to the onset of meningitis symptoms.

Seizures will also be classified based on their "most probable aetiology" as follows: related to meningeal irritation, tuberculomas, infarction, metabolic (hyponatremia), and hydrocephalus. Patients with multiple possible causes not attributable to any of the above were classified as "multiple aetiologies".

Clinical evaluation: The patients will be subjected to a detailed medical history and physical examination. History of vomiting, diarrhoea and drug intake (carbamazepine, mannitol and acetazolamide) was noted. Consciousness will be assessed by Glasgow Coma Scale (GCS). The severity of TBM was categorized as stage I (meningitis only), stage II (meningitis with focal neurological deficit or GCS score between 11 and 14) and stage III (meningitis with GCS score < 11) using British Medical Research Council criteria.[7]

Investigations: The laboratory investigations will include haemoglobin, erythrocyte sedimentation rate, serum bilirubin, alkaline phosphatase, transaminases, creatinine, fasting and postprandial blood sugar, HIV serology, radiograph of chest, and abdominal ultrasonography. Cerebrospinal fluid (CSF) will be examined for protein, cells, glucose, bacteria, fungi, malignant cells and smear (using Ziehl – Neelsen method), culture (Lowenstein-Jensen medium, LJ) or polymerase chain reaction (PCR) for *M.tuberculosis*. Hyponatremia will be diagnosed if serum sodium < 135 mEq/L in 2 consecutive reports 24 hours apart. Cranial computerized axial tomography (CT, Siemens, West Germany) scan and/or MRI (Signa GE Medical System, Wisconsin, USA) will be done in all the patients at admission and will be repeated as needed.

Management: The patients with TBM will be treated with four drug anti-tubercular treatment (ATT) (rifampicin, isoniazid, pyrazinamide and ethambutol) for 6 months followed by two drugs (rifampicin, isoniazid) for next 12 months. Prednisolone 0.5 mg/kg/day will be prescribed for 1 month followed by taper in the next month. Aspirin 150 mg/day will also be prescribed for prevention of stroke. The seizures will be treated with nonenzyme inducing antiepileptic drugs such as levetiracetam or lacosamide; clobazamin uncontrolled patients. Status epilepticus will be treated with intravenous lorazepam followed by levetiracetam.

Sample collection and plasma glutamate and its receptor assay: Plasma glutamate level will be measured in TBM patients and 30 healthy age and gender matched controls. Five ml

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venous blood samples will be collected in a EDTA vial. Plasma separation will be performed at 1000 g over 15 min at 4°C and stored at -20°C until use.Plasma glutamate level will be measured using the Amplex Red Glutamic Acid/Glutamate Oxidase Assay kit (cat no. A12221, Invitrogen, U.S). For glutamate measurement, L-glutamic acid is oxidized by glutamate oxidase to produce α-ketoglutarate, NH_3 and H_2O_2. L-Alanine and L-glutamate - pyruvate transaminase will be included in the reaction to regenerate L-glutamic acid by transamination of α-ketoglutarate, resulting in multiple cycles of the initial reaction and a significant amplification of the H_2O_2produced. The hydrogen peroxide reacts with 10-acetyl-3,7- dihydroxyphenoxazine (Amplex® Red reagent) in a 1:1 stoichiometry in the reaction catalysed by horseradish peroxidase (HRP) to generate the highly fluorescent product, resorufin and was determined by a fluorescence micro plate reader (BioTek synergy HT, software Gen5) using excitation at 530 ± 12.5 nm and fluorescence detection at 590 ± 17.5 nm.

B) **RT-PCR study for Glutamate receptors:** RNA will be isolated from the blood samples by kit method (Nucleo-Pore GRNA blood kit) and the concentration and integrity of the RNA will be determined by measuring the absorbance at 260 and 280 nm by spectrophotometer. Total RNA will be reversely transcribed to c-DNA using a high-capacity c-DNA reverse transcription kit (Thermo Scientific Revert Aid First Strand cDNA Synthesis Kit). Equal amount of mRNA will be taken from all samples to convert c-DNA and amplified by RT-PCR. **Receptor expression by reverse transcriptase polymerase chain reaction (RT-PCR):**

Amplified cDNA will be analysed in Real time machine after optimising the primer conditionsand the PCR cycle will be carried out by following steps:

1. Denaturation 94°C for 10 min.
2. Amplification for 45 cycles (95°C for 10 s; 56°C for 10 s and 72°C for 20 s).

Expression of all genes will be normalized to the expression of GAPDH (housekeeping gene). The Cp value of gene will be used for calculation of fold expression of gene.

The 10 µl of sybergreen (Applied biosystem), 0.5 micromolar Forward and Reverse primer, 5µl cDNA and 4 µl of water are used for amplification of 20 µl one well reaction. RT-PCR was performed on Roche system (Light cycler 480). For -

NMDA NR1 - Forward AGGAACCCCTCGGACAAGTT

Reverse CTCTCCAGTCGTCACCAGGT

NR-2A -Forward TGGACGTGAACGTGGTAGC

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Reverse CCCCCATGAATGCCCAAGAT

NR-2B- Forward TTCCGTAATGCTCAACATCATGG

Reverse TGCTGCGGATCTTGTTTACAAA

Follow up and outcome: Death and its possible cause will be noted. The patients will be followed up at 1, 3 and 6 months or earlier if indicated. Occurrence of breakthrough seizure and new onset seizure during follow up and its possible cause will be noted. Outcome will be defined at 6months based on modified Rankin Scale (mRS) as good (mRS<3) and poor (mRS≥3). At follow up, neurological status including cognitive functions will be recorded.

Number of patients: 100 patients with TBM will be recruited and will be followed up till 6 months

Statistical analysis: The relation of glutamate and its receptors with death, disability and cognitive function will be evaluated by using appropriate statistical tests. The glutamate and its receptor levels will be compared between patients and controls as well patients with and without seizures. Statistical analysis will be done using SPSS 16 version software. A two railed P value of <0.05 will be considered significant.

RNA will be isolated from the blood samples using kit method (NUCLEO-PORE GRNA blood kit) and the concentration and integrity of the RNA will be determined by measuring the absorbance at 260 and 280 nm by spectrophotometer. Total RNA will be reversely transcribed to c-DNA using a high-capacity c-DNA reverse transcription kit (Thermo Scientific Revert Aid First Strand cDNA Synthesis Kit). Equal amount of mRNA will be taken from all samples to convert c-DNA and amplified by RT-PCR.

NR1, NR2A and NR2B Receptor expression will be quantified using reverse transcriptase polymerase chain reaction (RT-PCR).

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References:

1. Patwari AK, Aneja S, Ravi RN, Singhal PK, Arora SK. Convulsions in tuberculousmeningitis. J Trop Pediatr. 1996 Apr;42(2):91-7.
2. Arundine M, Tymianski M. Molecular mechanisms of glutamate-dependent Neurodegeneration in ischemia and traumatic brain injury. Cell Mol Life Sci. 2004;61(6):657-68.
3. Marie L. Blanke and Antonius M.J. VanDongen. Activation Mechanisms of the NMDA Receptor. Van Dongen AM, editor.Boca Raton (FL): CRC Press/Taylor & Francis; 2009.
4. Marais S, Thwaites G, Schoeman JF, et al. Tuberculous meningitis: a uniform case definition for use in clinical research. Lancet Infect Dis 2010; 10(11): 803-12.
5. Kalita J, Misra UK, Prasad S, Bhoi SK. Safety and efficacy of levofloxacin versus rifampicin in tuberculous meningitis: an open-label randomized controlled trial. J Antimicrob Chemother. 2014 Aug;69(8):2246-51.
6. Robert S. Fisher, Maslah Saul .The 2017 ILAE Classification of Seizures .ILAE; 2017.
7. British Medical Research Council. Streptomycin in tuberculosis trials committee: streptomycin treatment of tuberculous meningitis, Lancet 1948; 1(6503): 582–596.

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Budget:

5

First Year				
S.NO.	**Items**	**Rate/Units**	**No. of Units**	**Total**
1	Glutamate oxidase assay kit	18000	1	18,000.00
2	C DNA kit	29000	2	58,000.00
3	RNA isolation kit	30000	2	60,000.00
4	ROS syber green	15000	3	45,000.00
5	Fellowship	15000	12 months	1,80,000.00
6	Consumable/ Contingency	30000		30,000.00
	Total			**3,91,000.00**

Second Year				
S.NO.	**Items**	**Rate/Units**	**No. of Units**	**Total**
1	Glutamate oxidase assay kit	18000	1	18,000
2	C DNA kit	29000	1	29,000
3	RNA isolation kit	30000	1	30,000
4	ROS syber green	15000	2	30,000
5	Fellowship	15000	12 months	1,80,000
6	Consumable/ Contingency	30000		30,000
	Total			**3,17,000.00**
	Total Budgets (1st & 2nd year)			**7,08,000.00**

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Title of the Project: A study of seizures in tuberculous meningitis with emphasis on the role of glutamate excitotoxicity

PI: UK Misra

Professor, Department of Neurology, SGPGIMS, Lucknow

Co PI: J Kalita

Professor, department of Neurology, SGPGIMS, Lucknow

Introduction: Tuberculous meningitis (TBM) is the commonest central nervous system (CNS) infection in the developing countries. Seizures in TBM occur in a large number of patients which ranges between 17% -93% [1]. Seizures in TBM may occur as a presenting feature, in beginning, early or late stage of TBM. The etiology of seizures in TBM is multifactorial. The majority of studies on seizures in TBM have evaluated the frequency, and clinico-radiological correlation. Seizures in TBM may be attributed to meningeal irritation, cerebral oedema, tuberculoma, infarction, hydrocephalus, or metabolic alteration in isolations or in combinations. Seizures may be related to the severity of TBM.

Glutamate is an important excitotoxin having important role in brain function in health and disease. Excess of glutamate in stroke has been associated with poor outcome.[2] Amongst the N-methyl D- aspartate (NMDA) receptors, NR1, NR2A and NR2B are the main component of heteromeric NMDA receptor which are mainly distributed in frontal and hippocampal cortex.[3] In CNS infections, because of oxidative stress, ER stress and up regulation of proinflammatory cytokines, glutamate release may be increased. Excess of glutamate may result in increased excitability and neuronal damage resulting in seizures and cell death. The is no study evaluating the role of excitotoxic injury in the pathogenesis of seizures and outcome of TBM.

Hypothesis: It is assumed that in the patients with TBM having seizures are likely to have grater excitotoxicity (glutamate level and receptors) which may result in poor outcome of TBM patients compared to those without seizures

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Aim:

1. To evaluate the frequency, type and burden of seizures in TBM and their effect on the outcome.

Co-PI

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SGPGIMS,Lucknow

55

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SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES,
LUCKNOW.

REF. No. PGI/DIR/RC/ 85 /2019 Dated: 13.02.2019

Subject : Sanction of Intramural Research Grant

To,

Prof. Gaurav Agarwal
Principal Investigator
Dept. of Endocrine Surgery, SGPGI.

It is my pleasure to inform you that your research proposal entitled **"Prognostic and Predictive Value of Tumor Infiltrating Lymphocytes (TILs) and Programmed cell Death – Ligand 1 (PD-L1) in Breast Cancer"**, has been accepted for Intramural funding by the Research Committee of the Institute. A sum of **Rs. 5,00,000=00**, has been sanctioned as per following details:

1st Installment	2nd Installment (Subject to Review of Annual Progress Report by the Research Committee Meeting)
Rs. 2,50,000=00 (Financial Year – 2018-2019)	Rs. 2,50,000=00 (Financial Year – 2019-2020)

The complete grant will be utilized within the period from 01.03.2019 – 28.02.2021.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the Intramural project.**
- **Stationary (office and computer), photocopying, postage and permanent equipments are NOT allowed.**
- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

CHAIRMAN RESEARCH COMMITTEE
&
DIRECTOR, SGPGIMS, LUCKNOW

Copy to:

1. Jr. Accounts Officer (Research), SGPGI.
2. Executive Registrar, SGPGI.

FACULTY INCHARGE RESEARCH
SGPGIMS, LUCKNOW

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Executive Registrar
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16

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

For Intramural Grant submission

PART – 1: GENERAL INFORMATION

Project Title:

Prognostic and Predictive value of Tumor Infiltrating Lymphocytes (TILs) and Programmed cell Death – Ligand 1 (PD-L1) in Breast cancer

Investigators:

NAME	DEPARTMENT	SIGNATURE
PRINCIPAL INVESTIGATOR		
Prof. Gaurav Agarwal	Professor, Endocrine and Breast Surgery	
CO-INVESTIGATORS		
Prof. Niraj Kumari	Professor, Dept of Pathology	
Prof. N. Krishnani	Professor, Dept of Pathology	
Prof. Punita Lal	Professor, Dept of Radiotherapy	
Dr.M. Sabaretnam	Assistant Professor, Dept of Endocrine and Breast Surgery	
Dr.K.M.M.Vishvak Chanthar	Senior Resident, Dept of Endocrine and Breast Surgery	

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Total Cost : Rs. 5,30,000/- (Rupees Five Lakhs thirty thousand only)

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Executive Registrar
SGPGIMS,Lucknow

34

PGI/DIR/RC/105/2019
Dated: 30.01.2019

To,

Dr. Ankur Mandelia
Principal Investigator
Department of Pediatric Surgical Super Specialties, SGPGI.

Sir,

Kindly refer to the intramural project entitled: **A-09-PGI/IMP/79/2018** "Pelvic Diameter to Cortical Thickness Ratio in Antenatally Detected Unilateral Pelvi-Ureteric Junction Obstruction". **The 79th Research Committee in its meeting held on 20.12.2018, has taken the following decision:**

The committee has approved the above project.

This is for your information & necessary action please.

Yours sincerely,

(Prof. Girish Gupta)
Faculty I/c Research

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Executive Registrar
SGPGIMS,Lucknow

31/1/19

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SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

Format for submission of Intramural project

PART – 1: GENERAL INFORMATION

Project Title: Pelvic diameter to cortical thickness ratio in antenatally detected unilateral pelvi-ureteric junction obstruction

Investigators	Name	Department	Signature
Principal Investigator	Dr. Ankur Mandelia	Dept. of Pediatric Surgical Super Specialities	
Co-investigator	Dr. Richa Lal	Dept. of Pediatric Surgical Super Specialities	
Co-investigator	Dr. Mandakini Pradhan	Dept. of Maternal and Reproductive Health	
Co-investigator	Dr. Rajnikant Yadav	Dept. of Radiodiagnosis	

Total Cost (Rs.): Nil

Project summary including clearly state objectives (Not Exceed 250 words):

Pelvi-ureteric junction obstruction (PUJO) is a common cause of hydronephrosis detected during antenatal ultrasound. The sonographic criteria for pyeloplasty have not been uniformly defined in the literature. Previous studies have shown that pelvic diameter to cortical thickness ratio (P/C ratio) on sonography could be a useful, noninvasive, and simple criterion in addition to renographic parameters to select patients with significant obstruction for pyeloplasty.

The aim of this study is to analyse the role of antero-posterior pelvic diameter (APPD) to maximum polar cortical thickness (CT) ratio (P/C ratio) in the follow-up of children with unilateral pelvi-ureteric junction obstruction (PUJO) and assess its usefulness in selection of patients who require surgery.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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Executive Registrar
SGPGIMS,Lucknow

SANJAY GANDHI POSTGRADUATE INSTIT ...ICAL SCIENCE...
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REF. No. PGI/DIR/RC/569 /2019 Dated: 14.03.2019

Subject : Sanction of Intramural Research Grant

To,

Prof. Vikas Agarwal
Principal Investigator
Dept. of Clinical Immunology, SGPGI.

It is my pleasure to inform you that your research proposal entitled "**To Evaluate the Role of CXCR2 Ligands (IL-8 and Gro-ά) and Cytokines (IL-1β, TNF-α) on A1k1 and A1k5 Imbalance in Chondrocytes Derived from OA cartilage**", has been accepted for Intramural funding by the Research Committee of the Institute. **A sum of Rs. 5,00,000=00**, has been sanctioned as per following details:

1st Installment	2nd Installment (Subject to Review of Annual Progress Report by the Research Committee Meeting)
Rs. 2,50,000=00 (Financial Year – 2018-2019)	Rs. 2,50,000=00 (Financial Year – 2019-2020)

The complete grant will be utilized within the period from 01.03.2019 – 28.02.2021.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the Intramural project.**
- **Stationary (office and computer), photocopying, postage and permanent equipments are NOT allowed.**
- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

CHAIRMAN RESEARCH COMMITTEE
&
DIRECTOR, SGPGIMS, LUCKNOW

Copy to:

1. Jr. Accounts Officer (Research), SGPGI.
2. Executive Registrar, SGPGI.

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Executive Registrar
SGPGIMS,Lucknow

A-(8)

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

Format for submission of Intramural project PART – 1: GENERAL INFORMATION

Project Title: To evaluate the role of CXCR2 ligands (IL-8 and Gro-α) and cytokines (IL-1β, TNF-α) on Alk1 and Alk5 imbalance in Chondrocytes derived from OA cartilage

Investigators:	Name	Department	Signature
Principal Investigator	Vikas Agarwal	Clinical Immunology	
Co-investigator			
Co-investigator 1	Durga P Misra	Clinical Immunology	

Total Cost (Rs.):

Five lakhs twenty one thousand only

Project summary including clearly state objectives (Not Exceed 250 words):

TGF-β is a large family of growth factors, which plays a critical role in health of chondrocytes.. In young, healthy cartilage, transforming growth factor-β (TGFβ) signals mainly via ALK5, which stimulates SMAD2–SMAD3 phosphorylation; during ageing, a decrease in expression of ALK5, in combination with stable expression of ALK1, shifts the balance to a higher ALK1:ALK5 ratio. This shift leads to induction of chondrocyte hypertrophy and results in articular cartilage that is prone to development of osteoarthritis (OA). Previous studies had confirmed that Alk1/ALk5 is key factor responsible for OA pathology such as Osteophyte formation, Synovial fibrosis, Subchondrial sclerosis, Chondrocyte hypertrophy, Cartilage damage. Factors responsible for expression of ALK1 are still not clear in aged chondrocytes. Thus we aim to explore certain cytokines (IL-1β, TNF-α) and chemokines (CXCR2) mediated pathways that may cause this imbalance in ALK1:ALK5 ratio in senescent chondrocytes and predispose towards OA.

Lt Col Varun Bajpai VSM
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Key words (at least 5):

osteo arthritis, senescent chondrocytes, hypertrophy, TGF-β, Smad-1,-2,-3,-4,-5,-6,-8.

Copy of the Departmental Research Committee Recommendation Copy of the Ethics committee submission certificate

(Head of Department will be responsible for periodic monitoring of the project)

PART – 2: TECHNICAL DETAILS

Lt Col Varun Bajpai VSM
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SGPGIMS,Lucknow

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES,
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REF. No. PGI/DIR/RC/265/2019 Dated: 14.02.2019

Subject : Sanction of Intramural Research Grant

To,

Dr. Amit Goel
Principal Investigator
Dept. of Gastroenterology, SGPGI.

It is my pleasure to inform you that your research proposal entitled "**Pharmacokinetics of Low-Dose Sofosbuvir in Dialysis-Dependent Patients With Hepatitis C Virus Infection**", has been accepted for Intramural funding by the Research Committee of the Institute. **A sum of Rs. 4,50,000=00,** has been sanctioned as per following details:

1st Installment	2nd Installment (Subject to Review of Annual Progress Report by the Research Committee Meeting)
Rs. 2,50,000=00 (Financial Year – 2018-2019)	Rs. 2,00,000=00 (Financial Year – 2019-2020)

The complete grant will be utilized within the period from 01.03.2019 – 28.02.2021.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the Intramural project.**
- **Stationary (office and computer), photocopying, postage and permanent equipments are NOT allowed.**
- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

CHAIRMAN RESEARCH COMMITTEE
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Lt Col Varun Bajpai VSM
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SGPGIMS,Lucknow

1. Jr. Accounts Officer (Research), SGPGI.
2. Executive Registrar, SGPGI. – 15/3/19

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Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow (SGPGI)

Proposal for Intramural Research Funding

Part-1: General information

1.1 Project title: Pharmacokinetics of low-dose sofosbuvir in dialysis-dependent patients with hepatitis C virus infection

1.2 Investigators

Status	Name	Designation	Signature
PI	Rakesh Aggarwal	Professor, Gastroenterology, SGPGI	
Co-I	Amit Goel	Associate Professor, Gastroenterology, SGPGI	
Co-I	Praveer Rai	Professor, Gastroenterology, SGPGI	
Co-I	Dharmaendra S Bhadauria	Associate Professor, Nephrology, SGPGI	
Co-I	Wahajuddin	Senior Scientist, Division of Pharmaceutics & Pharmacokinetics CSIR-Central Drug Research Institute, Lucknow	He is not in the country at present
Co-I	Amit Gupta	Professor & HOD, Nephrology, SGPGI	

1.3 Total cost (Rs): 6.5 Lakhs only

1.4 Project summary:

Infection with hepatitis C virus (HCV), a hepatotropic RNA virus, is often chronic, and causes liver cirrhosis and liver cancer. The virus is transmitted through parenteral exposure. This infection is particularly common in patients with kidney disease who are on maintenance hemodialysis [1].

Sofosbuvir, an inhibitor of HCV RNA-dependent RNA polymerase, forms the backbone of DAA-based anti-HCV treatment regimens. In preclinical pharmacokinetic studies, administration of the usual 400 mg daily dose to patients with severe renal dysfunction (estimated glomerular filtration rate (eGFR) of <30 ml/min) showed that serum levels of the sofosbuvir and GS331007 were elevated by several folds [2, 3]. Hence, sofosbuvir is not approved for use in patients on maintenance hemodialysis [4,5].

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RESEARCH CELL Received Date: Sign.

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SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES
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REF. No. PGI/DIR/RC/686/2021 Dated: 23.09.2021

Subject : Sanction of 2nd and Final Installment of Intramural Research Grant

To,

Dr. Alok Nath – 29.09.2021
Principal Investigator
Dept. of Pulmonary Medicine, SGPGI.

It is my pleasure to inform you that the second installment of **Rs. 2,50,000=00** for your research proposal entitled "**T-cell Profile and Metabolomic Signatures in Patients with Pulmonary Sarcoidosis and Lymph Node Tuberculosis**", has been approved by the 83rd Research Sub-Committee Meeting of the Institute on 06.09.2021 found that the above project was found satisfactory.

Accordingly, the Chairman Research Committee accord approval for release of 2nd Installment of grant of **Rs. 2,50,000=00**.

The 2nd Installment of grant will be utilized before 28.02.2022.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the Intramural project.**
- **Stationary (office and computer), photocopying, postage and permanent equipments are NOT allowed.**
- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

CHAIRMAN RESEARCH COMMITTEE
&
DIRECTOR, SGPGIMS, LUCKNOW

Prof. R.K. DHIMAN
Director
Sanjay Gandhi Postgraduate Institute of Medical Sciences
LUCKNOW-226014, INDIA

14/9/21

Copy to:

1. Jr. Accounts Officer (Research), SGPGI.
2. Executive Registrar, SGPGI.

Received
Registrar's Office
Date 29/09/2021

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A-3

(34)

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

Format for submission of Intramural project

PART – 1: GENERAL INFORMATION

Project Title: T-cell profile and metabolomic signatures in patients with pulmonary sarcoidosis and lymph node tuberculosis.

Investigators:

	Name	Department	Signature
Principal Investigator	**Dr Alok Nath**	**Department of Pulmonary medicine**	
Co-PI	**Prof. Vikas Agarwal**	**Department of Clinical Immunology**	
Co-investigator:	**Dr Zia Hashim**	**Department of Pulmonary medicine.**	
	Dr Ajmal Khan	**Department of Pulmonary medicine.**	

Total Cost (Rs.): **5,00,000/- (Five Lakhs only)**

Project Summary clearly stating objectives:

Sarcoidosis is a systemic granulomatous disorder of unidentified etiology, with a heterogeneous clinical presentation and is characterized by the presence of noncaseating granulomas in a variety of organs, most commonly the lung. CD4+ and CD8+ T lymphocytes, as well as a few B lymphocytes, form a characteristic ring at granuloma periphery. Despite advances in our knowledge of the immunopathogenesis of sarcoidosis, it is still not clear what determines the varied presentations of this disease. Other issue is close resemblance of the disease with tuberculosis which is endemic in this country. It often becomes a challenge for physician to differentiate between the two disease entities. Both being granulomatous diseases, have many common clinical features and often pose a diagnostic dilemma. TB is characterized by caseating granulomas, whereas sarcoidosis is characterized by non-caseating granulomas. Metabolic profiling is an emerging exploratory tool in rheumatic and infectious diseases. Studies have identified differing metabolic profiles in plasma of patients differentiating latent TB from active

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(21)

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES,
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REF. No. PGI/DIR/RC/606/2020 Dated: 28.10.2020

Subject : Sanction of 2nd and Final Installment of Intramural Research Grant

To,

Prof. Shubha Phadke,
Principal Investigator
Dept. of Medical Genetics, SGPGI.

It is my pleasure to inform you that your research proposal entitled **"To Study Sequence Variations in Genes Involved in Chromosome/Chromatid Separation Including Cohesin – Condensing Complex, Kinetocore Complex and Centromeric Proteins in Mothers of Individuals with Trisomy 21"**, has been approved by the Research Committee of the Institute on 20.12.2018 and after review of the annual progress report by the Research committee on 24.09.2020 and the progress is found satisfactory.

Accordingly, the Chairman Research Committee accord approval for release of 2nd Installment of grant of **Rs. 2,50,000=00**.

The 2nd Installment of grant will be utilized within the financial year 2020-2021.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the Intramural project.**
- **Stationary (office and computer), photocopying, postage and permanent equipments are NOT allowed.**
- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

Lt Col Varun Bajpai VSM
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SGPGIMS,Lucknow

CHAIRMAN RESEARCH COMMITTEE
&
DIRECTOR, SGPGIMS, LUCKNOW

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2. Executive Registrar, SGPGI.

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SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

Format for submission of Intramural project

PART – 1: GENERAL INFORMATION

Project Title: To study sequence variations in genes involved in chromosome / chromatid separation including cohesin – condensing complex, kinetocore complex and centromeric proteins in mothers of individuals with trisomy 21.

Investigators:

	Name	Department	Signature
Principal Investigator	Dr. Shubha R Phadke	Medical Genetics	
Co-investigator	Dr. Moirangthem Amita	Medical Genetics	

Total Cost (Rs.): 5,00,000 (Five lacs)

Project summary including clearly state objectives (Not Exceed 250 words):

Trisomy 21, also known as Down syndrome is the commonest chromosomal disorder and a cause of one third of children with intellectual disability. Despite knowing the chromosomal etiology and non-disjunction in meiosis of mother as the cause of trisomy for more than last 50 years, the pathogenesis of which factors predispose to non-disjunction are totally unknown. In one percent of the families with one offspring with trisomy 21, there is recurrence of trisomy 21. The cause of recurrence is attributed to the germ line mosaicism in mother, though there is no evidence for it. The cause of increased recurrence (8 times that of the population based incidence) may be genetic predisposition due to sequence variations in groups of genes may be responsible for non-disjunction. Structural maintenance of chromosome (SMC) protein complexes, including cohesin and condensin, are increasingly being recognized for their important role in cancer where chromosomal aneuploidy is a norm. This suggests that the possibility of looking for sequence variations in genes in cohesion and condensing pathway and proteins of kinetochore, which is a molecular machine that directs chromosome segregation during cell division, in mothers with an offspring with trisomy 21 may find some clues. With this hypothesis, the study has the following objective.

- To study sequence variations in genes in cohesion and condensing pathway and genes for centromeric proteins in mothers of cases with trisomy 21 due to non-disjunction in mother by whole exome sequencing.

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LUCKNOW.

REF. No. PGI/DIR/RC/ 684 /2020 Dated: 26.10.2020

Subject : **Sanction of 2nd and Final Installment of Intramural Research Grant**

To,

Dr. Gaurav Pande,
Principal Investigator
Dept. of Gastroenterology, SGPGI.

It is my pleasure to inform you that your research proposal entitled "**Assessment of Endotoxins and Cytokines in Acute on Chronic Liver Failure (ACLF) Patients with Large Ascites and Acute Kidney Injury with Slow Albumin, Furosemide and Vasoconstrictors Therapy Versus Albumin and Vasoconstrictors and Oral Dirutics**", has been approved by the Research Committee of the Institute on 20.12.2018 and after review of the annual progress report by the Research committee on 24.09.2020 and the progress is found satisfactory.

Accordingly, the Chairman Research Committee accord approval for release of 2nd Installment of grant of **Rs. 2,50,000=00**.

The 2nd Installment of grant will be utilized within the financial year 2020-2021.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the Intramural project.**
- **Stationary (office and computer), photocopying, postage and permanent equipments are NOT allowed.**
- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

Lt Col Varun Bajpai VSM
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CHAIRMAN RESEARCH COMMITTEE
&
DIRECTOR, SGPGIMS, LUCKNOW

Copy to:

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Executive Registrar
SGPGIMS,Lucknow

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12

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

PART – 1: GENERAL INFORMATION

Project Title:

Assessment of Endotoxins and cytokines in Acute on chronic liver failure (ACLF) patients with large ascites and acute kidney injury with slow albumin ,furosemide and vasoconstrictors therapy versus albumin and vasoconstrictors and oral dirutics

Randomised Control Trial

Investigators:

	Name	Department	Signature
Principal Investigator	DrGauravPande	Gastroenterology	Gaurav
Co Investigator 1	Dr V A Saraswat	Gastroenterology	
Co Investigator 2	DrVikasAggarwal	Immunology	
Co Investigator 3	Dr. Durga P. Misra	Immunology	
Co Investigator 4	Dr Vinod Kumar	Gastroenterology	

Total Cost (Rs.): Rs. Rs/-5,15,000 (Five lakh fifteenthousand only)

Project summary:

Acute-on-chronic liver failure (ACLF) is a newly recognised syndrome characterized by acute deterioration of a compensated or decompensated chronic liver disease, and a mortality rate > 15 % at 28-days. Rapid worsening of underlying chronic liver disease due to an acute insult often culminate in organ failure and high mortality. This study may help in better understanding of pathophysiology, and overall outcome of ACLF patients. That might lead to better treatment protocol, and may potentially help in formulating better treatment protocols thereby reducing the morbidity and mortality associated with it.

PROTOCOL SUMMARY

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Title: Slow infusions of Albumin,Furosemide ± Vasoconstrictors (Terlipressin)(SAFI±T/Na) vs. Standard Medical Therapy (SMT)- Albumin ± Vasoconstrictors and oral dirutics for Acute on chronic liver failure(ACLF) patients with large ascites and Acute kidney injury. A randomized, controlled study.

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Lt Col Varun Bajpai VSM
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SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES,
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REF. No. PGI/DIR/RC/6877/2020 Dated: 26.10.2020

Subject : **Sanction of 2nd and Final Installment of Intramural Research Grant**

To,

Dr. Latika Gupta
Principal Investigator
Dept. of Clinical Immunology, SGPGI.

It is my pleasure to inform you that your research proposal entitled "**Determination of Myositis Specific and Myositis Associated Antibody Profiles of Indian Myositis Patients Using the Immunoprecipitation Assay**", has been approved by the Research Committee of the Institute on 20.12.2018 and after review of the annual progress report by the Research committee on 24.09.2020 and the progress is found satisfactory.

Accordingly, the Chairman Research Committee accord approval for release of 2nd Installment of grant of **Rs. 2,50,000=00**.

The 2nd Installment of grant will be utilized within the financial year 2020-2021.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the Intramural project.**
- **Stationary (office and computer), photocopying, postage and permanent equipments are NOT allowed.**
- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

CHAIRMAN RESEARCH COMMITTEE
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DIRECTOR, SGPGIMS, LUCKNOW

Copy to:

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2. Executive Registrar, SGPGI.

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SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

PART – 1: GENERAL INFORMATION

Project Title:	Determination of Myositis specific and Myositis Associated antibody profiles of Indian Myositis patients using the Immunoprecipitation assay		
Investigators:	Name	Department	Signature
Principal Investigator	Latika Gupta	Clinical Immunology	
Co-investigator	Ramnath Misra	Clinical Immunology	
Co-investigator	Swasti Tiwari	Molecular Medicine	
Co-investigator	Amita Aggarwal	Clinical Immunology	
Co-investigator	Vikas Agarwal	Clinical Immunology	

Project summary including clearly state objectives:

Cost (Rs): 6,00,000 INR

Project summary including clearly state objectives:

Objective

- To assess Myositis Specific Antibodies (MSA) and Myositis Associated Antibodies (MAA) in Indian patients with inflammatory myositis using the Immunoprecipitation assay.
- Compare these with results of MSA and MAA using the Line Immunoblot assay

Inflammatory myositis is a heterogenous group of diseases, with varied organ involvement as well as clinical phenotypes. The profiles as well as phenotypes associated have been seen to remarkably vary across different ethnic groups. Myositis antibodies are often predictive of clinical phenotypes. Certain antibody types are also predictive of responsiveness to therapy , and clinical outcomes in the long term. These antibodies can be assessed by Line immunoblot assay which is widely available. However, this test is marred by ginormous costs, essentially ruling out regular use for clinical practice in a country as ours. In addition, the technique is such that antibodies to linear epitopes are assessable, which those to complex structural epitopes are not, incurring significant loss of sensitivity.

Immunoprecipitation assay is the gold standard for myositis antibody testing. Apart from being sensitive and specific, it has minimal running costs. It also brings in the potential for describing antibodies to novel antigens, which is often seen in different ethnic groups. However, the test is available at very few centres worldwide. With this grant, we intend to set up this assay in our laboratory, in an effort to bring in this technique for clinical use.

Over the last year, we have engaged ourselves with setting up a Pan India collaborative network (called myoIN) on inflammatory myositis. As part of this initiative, six centres across the country are collecting data in a unified manner on a common detailed proforma, and forming a biorepository for later use. We have already collected 170 sera from patients at our centre, as part of this and other ongoing research studies on the disease. SGPGIMS is the reference laboratory for MyoIN, where all sera from these centres would be shipped and stored. With the successful setting up of this assay, we intend to describe the antibody profile of myositis patients from India, and the clinical patterns associated with those.

Lt Col Varun Bajpai VSM
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SGPGIMS,Lucknow

RESEARCH CELL Received Date 15/11/18 S.G.P.G.I.M.S., LUCKNOW

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Executive Registrar
SGPGIMS,Lucknow

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REF. No. PGI/DIR/RC/2[illegible]6 /2019 Dated: 14.03.2019

Subject : Sanction of Intramural Research Grant

To,

Dr. Vinod Kumar
Principal Investigator
Dept. of Gastroenterology, SGPGI.

It is my pleasure to inform you that your research proposal entitled **"To Study the Role of Road of Food Supplementations, Including Probiotic Preparation VSL#3® in Reduction of Intetinal Permeability and Blood Endotoxins Level in Child B Cirrhosis"**, has been accepted for Intramural funding by the Research Committee of the Institute. **A sum of Rs. 5,00,000=00,** has been sanctioned as per following details:

1st Installment	2nd Installment (Subject to Review of Annual Progress Report by the Research Committee Meeting)
Rs. 2,50,000=00 (Financial Year – 2018-2019)	Rs. 2,50,000=00 (Financial Year – 2019-2020)

The complete grant will be utilized within the period from 01.03.2019 – 28.02.2021.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the Intramural project.**
- **Stationary (office and computer), photocopying, postage and permanent equipments are NOT allowed.**
- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

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CHAIRMAN RESEARCH COMMITTEE
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DIRECTOR, SGPGIMS, LUCKNOW

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SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

PART – 1: GENERAL INFORMATION

Project Title:

To Study the role of food supplementations, including probiotic preparation VSL#3® in reduction of intestinal permeability and blood endotoxins level in child B cirrhosis

Observational study

Investigators:

	Name	Department	Signature
Principal Investigator	Dr Vinod Kumar	Gastroenterology	
Co Investigator 1	Dr V A Saraswat	Gastroenterology	
Co Investigator 2	Dr Gaurav Pande	Gastroenterology	
Co Investigator 3	Dr Vikas Aggarwal	Immunology	
Co Investigator 4	Dr Durga P Misra	Immunology	

Total Cost (Rs.): Rs. 5,15,000 (five lakhs fifteen thousand only)

Project summary:

Brief proposal summary; - Cirrhosis is the major cause of liver related morbidity and mortality. The intestinal mucosal layer forming a physical barrier against microbial invaders and toxins. Translocation of bacteria and their products across the intestinal barrier is a commonplace in patients with liver disease. Three factors have been implicated in the development of bacterial translocation: inadequate response of the gut immune system, intestinal bacterial overgrowth (dysbiosis) and increased intestinal permeability.

Factors contribute to mucosal disintegrity leading to increased IP and blood endotoxins level in cirrhotics are decreased level of insulin-like growth factor 1, disturbances in the bile flow and composition, elevated nitric oxide levels, altered gut microbiota and dysbiosis. Plasma levels of inflammatory cytokines and nitrosothiols were significantly higher in patients with altered intestinal permeability.

The deterioration of intestinal barrier integrity and the consulting increased intestinal permeability in cirrhotic patients play a pivotal pathophysiological role in the development of severe complications such as High rate of infections, Spontaneous bacterial peritonitis, Hepatic

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LUCKNOW.

REF. No. PGI/DIR/RC/685/2020 Dated: 26.10.2020

Subject : Sanction of 2nd and Final Installment of Intramural Research Grant

To,

Dr. Moirangthem Amita,
Principal Investigator
Dept. of Medical Genetics, SGPGI.

It is my pleasure to inform you that your research proposal entitled **"Clinical and Genotypic Profile of Arthrogryposis"**, has been approved by the Research Committee of the Institute on 20.12.2018 and after review of the annual progress report by the Research committee on 24.09.2020 and the progress is found satisfactory.

Accordingly, the Chairman Research Committee accorded approval for release of 2nd Installment of grant of **Rs. 2,40,000=00**.

The 2nd Installment of grant will be utilized within the financial year 2020-2021.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the Intramural project.**
- **Stationary (office and computer), photocopying, postage and permanent equipments are NOT allowed.**
- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

CHAIRMAN RESEARCH COMMITTEE
&
DIRECTOR, SGPGIMS, LUCKNOW

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Copy to:

1. Jr. Accounts Officer (Research), SGPGI.
2. Executive Registrar, SGPGI.

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Executive Registrar
SGPGIMS,Lucknow

A-1

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

Format for submission of Intramural project

PART – 1: GENERAL INFORMATION

Project Title: Clinical and genotypic profile of arthrogryposis

Investigators:

	Name	Department	Signature
Principal Investigator	Dr. Moirangthem Amita	Medical Genetics	
Co-investigators			
Co-investigator 1	Dr. Shubha R Phadke	Medical Genetics	
Co-investigator 2	Dr. KausikMandal	Medical Genetics	
Co-investigator 3	Dr. DeeptiSaxena	Medical Genetics	

Total Cost (Rs.): 4,90,000 (Four lacs and ninety thousand)

Project summary including clearly state objectives (Not Exceed 250 words):

Arthrogryposis multiplex congenita or, simply "arthrogryposis"is a symptom complex characterized by multiple congenital joint contractures. This condition is clinically and genetically heterogeneous. Definite clinical diagnosis is mostly impossible and molecular tests are needed. The causative genetic defect has been identified in around 320 conditions associated with arthrogryposis. Many of these have been achieved during the last decade with the widespread use of genomic techniques like exome sequencing. Identification of molecular etiologies has led to recognition of various overlapping functional pathways. This is expected to lead to a better diagnostic approach and potential for development of targeted therapies in future.However, etiology still remains elusive in almost half of the arthrogryposis cases. In addition, there is a paucity of large studies / case series from India. Our center deals with a wide spectrum of patients across all age groups, including evaluation of antenatal cases and fetal autopsy. Hence it provides an optimal opportunity to study the clinical and mutational spectrum of arthrogryposis. With this background , we propose the present study with the objectives of :

- Compilation of clinical data of patients with arthrogryposis multiplex congenita and define the spectrum of presentation, severity and variability
- To identify the underlying genetic etiology by sequencing (Exome/ Sanger)
- To identify any particular hotspot/ founder mutation in the cohort
- Elucidation of genotype-phenotype correlation, if any

Establishing a definite diagnosis will lead to better management and appropriate genetic counseling of the affected families. Moreover, this study is expected to add to the phenotypes of already described disorders and also identify novel variants/ genes.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS Lucknow

Key words (at least 5):

Arthrogryposis, joint contractures, pterygium, fetal hydrops, exome sequencing

Copy of the Departmental Research Committee Recommendation

Copy of the Ethics committee submission certificate

(Head of Department will be responsible for periodic monitoring of the project)

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25

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SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICA
LUCKNOW.

REF. No. PGI/DIR/RC/ 109 /2019 Dated : 16.02.2019

Subject : Sanction of Intramural Research Grant

To,

Prof. Roopali Khanna
Principal Investigator
Dept. of Cardiology, SGPGI.

It is my pleasure to inform you that your research proposal entitled **"Prospective Case Control Study of Objective Cardiac and Vascular Changes in Pheochromocytoma and Paraganglioma and Their Reversal Following Curative Surgery"**, has been accepted for Intramural funding by the Research Committee of the Institute. **A sum of Rs. 4,36,000=00,** has been sanctioned as per following details:

Consumables and Contingencies:	**Rs.**	**4,36,000=00**
Travel:	**Rs.**	**NIL**
Total:	**Rs.**	**4,36,000=00**

The grant will be utilized for the period from 15.02.2019 to 14.02.2021.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the Intramural project.**
- **Stationary (office and computer), photocopying, postage and permanent equipments are NOT allowed.**
- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

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SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

For Intramural Grant submission

PART – 1: GENERAL INFORMATION

Project Title:

Prospective case control study of objective cardiac and vascular changes in Pheochromocytoma and Paraganglioma and their reversal following curative surgery

Investigators:

NAME	DEPARTMENT	SIGNATURE
PRINCIPAL INVESTIGATOR		
Dr.Roopali Khanna	Assoc. Professor, Dept of Cardiology	
CO- PRINCIPAL INVESTIGATOR		
Prof. Gaurav Agarwal	Professor, Endocrine and Breast Surgery	
CO-INVESTIGATORS		
Prof. Aditya Kapoor	Professor, Dept of Cardiology	
Dr.M. Sabaretnam	Assistant Professor, Dept of Endocrine and Breast Surgery	M. Sabaretnam
Dr.K.M.M.Vishvak Chanthar	Senior Resident, Dept of Endocrine and Breast Surgery	

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Total Cost : Rs. 4,36,000/- (Rupees Four lakhs thirty six thousand only)

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SANJAY GANDHI POSTG' ,TITUTE OF MEDICAL SCIENCES,
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REF. No. PGI/DIR/RC/168/2019

Dated : 18.02.2019

Subject : Sanction of Intramural Research Grant

To,

Prof. Amita Aggarwal
Principal Investigator
Dept. of Clinical Immunology, SGPGI.

20/2/19

It is my pleasure to inform you that your research proposal entitled "**Outcome in Adulthood of Children with Enthesitis Related Arthritis (ERA) category of Juvenile Idiopathic Arthritis (JIA) and its Predictors**", has been accepted for Intramural funding by the Research Committee of the Institute. A sum of Rs. 5,00,000=00, has been sanctioned as per following details:

Consumables and Contingencies:	Rs.	5,00,000=00
Travel:	Rs.	NIL
Total:	Rs.	5,00,000=00

The grant will be utilized for the period from 15.02.2019 to 14.02.2021.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned above observing necessary formalities.

- The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the Intramural project.
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- The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.

CHAIRMAN RESEARCH COMMITTEE
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21/2/19

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Executive Registrar
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20

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

Format for submission of Intramural project

PART – 1: GENERAL INFORMATION

Project title: Outcome in adulthood of children with Enthesitis related arthritis (ERA) category of juvenile idiopathic arthritis and its predictors

Investigators

	Name	Designation	Signature
PI	Amita Aggarwal	Professor	
Co-PI	Namita Mohindra	Professor (ASSOCIATE)	
Student	Naveen R	DM student	

Total Cost: Rs 4,10,000

Project summary

Enthesitis related arthritis (ERA) is the commonest category of JIA seen in India and constitutes 30-40% of all JIA patients in contrast to 5% among Caucasians. ERA has a strong association with HLA B27 and is characterized by lower limb arthritis and enthesitis. It resembles adult HLA B27 related spondyloarthropathies (SpA) and is considered by some as its juvenile counterpart. However, children have more of peripheral arthritis and enthesitis while adults usually present with inflammatory low backpain. Though there are many studies on long term outcome in adult SpA but data in children with ERA is scant. In view of difference in clinical features it is likely that the outcome is likely to be different. Further HLA B27 may impact the outcome in children during adulthood as in adult it is thought to be a severity marker

Thus, we want to evaluate all children from our cohort who have reached adulthood and see what is there outcome as regards development of radiological sacroiliitis, physical disability, need for hip replacement and fulfillment of adult Ankylosing spondylitis criteria. In addition, impact of clinical variables and HLA B27 on outcome will be studied.

Nearly 200 children with ERA who are more than 18 years of age and have disease for more than 5 years will be enrolled. Detailed clinical examination including BASDAI, BASMI, BASFI, HAQ-S will be filled. X-ray pelvis will be done to look for radiological sacroiliitis, If X-ray is normal then MRI of SI joint will be done (maximum of 50 patients). HLA B27 typing will be done using PCR method.

Key words: Juvenile spondyloarthropathy, HLA B27, sacroiliitis

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LUCKNO

REF. No. PGI/DIR/RC/190 /2019

Dated : 18.02.2019

Subject : Sanction of Intramural Research Grant

To,

Prof. Soniya Nityanand 20/2/19
Principal Investigator
Dept. of Hematology, SGPGI.

It is my pleasure to inform you that your research proposal entitled "**Evaluation of the Prevalence of Invasive Aspergillosis and Optimal Duration of Anti-fungal Therapy in Acute Leukemia Patiients Using Quantitative Galactomannan Antigen and Aspergillus DNA Assays**", has been accepted for Intramural funding by the Research Committee of the Institute. **A sum of Rs. 5,00,000=00**, has been sanctioned as per following details:

Consumables and Contingencies:	**Rs.**	**5,00,000=00**
Travel:	**Rs.**	**NIL**
Total:	**Rs.**	**5,00,000=00**

The grant will be utilized for the period from 15.02.2019 to 14.02.2021.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the Intramural project.**
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- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

CHAIRMAN RESEARCH COMMITTEE
&
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PART-1: GENERAL INFORMATION

1. Project Title:

"Evaluation of the prevalence of Invasive Aspergillosis and optimal duration of Anti-fungal Therapy in Acute Leukemia patients using Quantitative Galactomannan Antigen and *Aspergillus* DNA Assays"

2. Investigators:

Investigators	Name	Designation	Signature
Principal Investigator	Prof. Soniya Nityanand	Head, Dept of Hematology	S. Nityanand
Co-Investigator	Dr Anshul Gupta	Asstt Prof, Dept of Hematology	Anshul Gupta
Co-Investigator	Dr CP Chaturvedi	Assoc. Prof, Stem Cell Research Centre, Dept of Hematology	

3. Total Budget (Rs): 6.0 Lakhs

4. Project Summary including clearly stated objectives (<250 words):

The advent of effective chemotherapy and better supportive care has improved the survival of acute leukemia (AL) patients including acute myeloid leukemia (AML) and acute lymphocytic leukemia (ALL). But the invasive fungal infections particularly invasive aspergillosis (IA) remains a major cause of mortality in a country like India posing a serious challenge for hemato-oncology clinicians in the management of the disease. The traditional diagnostic methods of IA like culture and microscopy are either time consuming that leads to delay in therapy or not sensitive enough to detect early fungal infection that may lead to

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92

18

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW.

REF. NO. PGI/DIR/RC/ 836 /2018 Dated : 28-09-2018

Subject: **Sanction of Intramural Research Grant**

To,

Dr. Latika Gupta
Principal Investigator
Dept. of Clinical Immunology, SGPGI.

28/9/18

It is my pleasure to inform you that your research proposal entitled – A-08-PGI/IMP/78/2018 **"MRI as Determinant of outcomes in inception cohort of reactive Arthritis"**, has been accepted for intramural funding by the Research Committee of the Institute. **A sum of Rs. 5, 00,000=00,** has been sanctioned as per following details:

Consumables and Contingencies:	**Rs.**	**5, 00,000=00**
Travel	**Rs.**	**NIL**
Total	**Rs.**	**5, 00,000=00**

The grant will be utilized for the period from 11.10.2018 to 10.10.2020.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned as above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the intramural project.**
- **Stationary (office and computer), photocopying, postage and permanent equipments are NOT allowed.**
- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

CHAIRMAN RESEARCH COMMITTEE
&
DIRECTOR, SGPGIMS, LUCKNOW

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SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

Format for submission of Intramural project

PART – 1: GENERAL INFORMATION

Project Title:	MRI as determinant of outcomes in inception cohort of Reactive Arthritis		
Investigators:	Name	Department	Signature
Principal Investigator	Latika Gupta	Clinical Immunology	
Co-investigator	Ramnath Misra	Clinical Immunology	
Co-investigator	Vikas Agarwal	Clinical Immunology	
Co-investigator	Durga P Misra	Clinical Immunology	
Co-investigator	Namita Mohindra	Radiodiagnosis	
Co-investigator	Neeraj Jain	Radiodiagnosis	

Project summary including clearly state objectives:

Objective

- To establish an inception cohort of reA
- Identify chronic and axial spA at the end of one year
  Establish clinical, biochemical and imaging variables predictive of chronicity

Reactive arthritis is a post infectious, non-septic arthritis in the presence or absence of extra-articular features. ReA is fairly common, seen in 6-10% individuals after Salmonella Typhimurium gastroenteritis, and similarly so in various other forms of infections.

Contrary to popular notion that it is a benign arthritis, up to 50% of cases have been seen to have persistent symptoms beyond 6 months with more than one thirds reporting work debility. Although it remains a significant problem in India, the outcomes of reA in the Indian population have never been explored.

The development of imaging as a complementary tool to clinical decision making has opened new avenues in medical science. Unfortunately, in parallel with the declining research on reA worldwide, the findings of extremity MRI in reA remain largely unexplored.

With this study, we aim at setting up the first inception cohort of reA, where clinical features will be recorded at onset. We would also like to describe imaging findings (Xray of the sacroiliac joint and MRI and USG of the extremities) in the patients at onset, and biobank sera, DNA and synovial fluid (if any) for measurement of acute phase reactants (ESR and CRP), HLA B 27 and future research. These patients would then be followed up at 6 and 12 months to explore outcome, and look for predictive factors at onset for the development of chronicity.

Clinical, laboratory and imaging variables predictive of chronic Reactive Arthritis and progression to Axial Spondyloarthritis will be studied.

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Key words (at least 5): Reactive, MRI, ultrasound, Chronicity, inception,

Copy of the Departmental Research Committee Recommendation: Yes

Copy of the Ethics committee submission certificate: yes

PART – 2: TECHNICAL DETAILS

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SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW.

REF. NO. PGI/DIR/RC/ 913 /2018 Dated : 25.10.18

Subject: Sanction of Intramural Research Grant

To,

Dr. Saroj K Sahoo
Principal Investigator
Dept. of Endocrinology, SGPGI.

It is my pleasure to inform you that your research proposal entitled – **A-07-PGI/IMP/78/2018 "Comprehensive evaluation of genetic basis of idiopathic hypoparathyroidism using next-generation sequencing"**, has been accepted for intramural funding by the Research Committee of the Institute. **A sum of Rs. 5, 00,000=00**, has been sanctioned as per following details:

Consumables and Contingencies:	Rs.	5, 00,000=00
Travel	Rs.	NIL
Total	Rs.	5, 00,000=00

The grant will be utilized for the period from 11.10.2018 to 10.10.2020.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned as above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the intramural project.**
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- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

CHAIRMAN RESEARCH COMMITTEE
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A-7

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Application for intramural grant

Title of the study

Genetic and immunological characteristics and skeletal muscle dysfunction in patients with hypoparathyroidism

Investigators

	Name	*Department*	*Signature*
Principle investigator:	Dr Saroj K Sahoo	Endocrinology	Saroj Kumar Sahoo
Co-investigator: 1	Dr Eesh Bhatia	Endocrinology	
Co-investigator 1:	Dr Kaushik Mandal	Medical Genetics	
Co-investigator 3:	Dr Anjali Mishra	Endocrine surgery	Anjali.
Co-investigator 4:	Dr Zia Hashim	Pulmonary Medicine	

Total cost = 5,00,000 INR

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REF. NO. PGI/DIR/RC/ 045 /2018 Dated : 29.09.18

Subject: **Sanction of Intramural Research Grant**

To,

Dr. Anup Kumar
Principal Investigator
Dept. of Biostatistics & Health Informatics, SGPGI.

It is my pleasure to inform you that your research proposal entitled – A-06-PGI/IMP/78/2018 "Work-Life Balance (WLB) among employees in Health Care Sector: A study of Hospitals in Lucknow", has been accepted for intramural funding by the Research Committee of the Institute. **A sum of Rs. 2, 68,650=00,** has been sanctioned as per following details:

Consumables and Contingencies:	Rs.	2, 68,650=00
Travel	Rs.	NIL
Total	Rs.	2, 68,650=00

The grant will be utilized for the period from 11.10.2018 to 10.10.2020.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned as above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the intramural project.**
- **Stationary (office and computer), photocopying, postage and permanent equipments are NOT allowed.**
- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

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29

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

Format for submission of Intramural project

PART – 1: GENERAL INFORMATION

Project Title: Work-Life Balance (WLB) among Employees in Health Care Sector: A Study of Hospitals in Lucknow

Investigators:

	Name, Designation & Qualifications	Departmental Tel Nos. & Email ID	Signature
Principal investigator	Dr. Anup Kumar Assistant Professor, Dept of Biostatistics and Health Informatics, SGPGIMS	8004221413 anup.stats@gmail.com anup@sgpgi.ac.in	Dr. Anup Kumar Assistant Professor Dept. of Biostatistics Health Informatics SGPGIMS, Lucknow
1. Co-PI/Co-Guide /Collaborators	Prof. C. M. Pandey Head, Dept of Biostatistics and Health Informatics, SGPGIMS	8004904476 cmpandeylko@yahoo.com	
2.Co-PI/ Collaborator	Prof. Uttam Singh Dept. of Biostatistics and Health Informatics SGPGIMS	8004904477 uttam@sgpgi.ac.in	

Total Cost (Rs.):Rs 268650

Project summary including clearly state objectives (Not Exceed 250 words):

Due to recent developments in society, work-life balance is an issue for many institutes and its workers. Research on this topic is very recent and many different terms are used to describe and measure this complex phenomenon. Some researcher considers a balance as a certain state or moment in time which can be measured in terms of time, energy, and satisfaction with work and family roles. The aim of this study, however, is not to measure a work-life balance but to understand how doctors and nurses and paramedical staff experience this process. Based on review of literature, empirical study and analysis of reports of news papers and articles, it has been observed there is an increasing trend for organizations to implement more family friendly policies such as five day work week, flextime, family leave, and employee assistance programs to improve employee morale and

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REF. NO. PGI/DIR/RC/ 091 /2018 Dated : 12.10.18

Subject: **Sanction of Intramural Research Grant**

To,

Dr. Siddhnath Sudhanshu
Principal Investigator
Dept. of Endocrinology, SGPGI.

It is my pleasure to inform you that your research proposal entitled – **A-05-PGI/IMP/78/2018 "Vitamin D Deficiency and its Replenishment in children receiving Antiepileptic Drugs"**, has been accepted for intramural funding by the Research Committee of the Institute. **A sum of Rs. 5, 00,000=00**, has been sanctioned as per following details:

Consumables and Contingencies:	**Rs.**	**5, 00,000=00**
Travel	**Rs.**	**NIL**
Total	**Rs.**	**5, 00,000=00**

The grant will be utilized for the period from 11.10.2018 to 10.10.2020.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned as above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the intramural project.**
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CHAIRMAN RESEARCH COMMITTEE
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Executive Registrar
SGPGIMS,Lucknow

Part 1: General Details:

Title: Vitamin D deficiency and its replenishment in children receiving antiepileptic drugs.

Principal investigator: Dr Siddhnath Sudhanshu, Dept of Endocrinology Siddhnath Sudhanshu

Co investigators: Dr Vijayalakshmi Bhatia, Dept of Endocrinology V Bhatia
Dr Vimal Kumar Paliwal, Dept of Neurology

Duration: 2 years

Budget: 5,64,000

Study title: Vitamin D deficiency and its replenishment in children receiving antiepileptic drugs.

Total cost: Rs 5, 64,000

Project summary:

Antiepileptic drugs (AEDs) are well known to affect bone health adversely and the most important clinically proven associated factor is vitamin D deficiency (VDD). Serious effects of vitamin D deficiency include hypocalcemia, seizures, dilated cardiomyopathy and heart failure, and fractures. Other debilitating consequences are bone pains, muscle weakness, softening and bending of bones with deformity.

Currently there is no consensus regarding the recommended dose of vitamin D supplementation in children receiving AEDs. The Endocrine Society (USA) guidelines 2011 recommend 2 to 3 times of RDA (1200 to 1800 IU); however, they do not include any supporting literature for these doses. In contrast, the Eastern Pediatric Epilepsy Network of the UK NHS (EPEN 2015) recommends routine 400 IU per day supplementation; the Global Consensus Recommendations on Prevention and Management of Nutritional Rickets 2016 refrains from making recommendations for children on AEDs. All these authors have

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SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES,
LUCKNOW.

Ref. No. PGI/DIR/RC/ 871 /2018 Dated : 08.10.2018

Subject: **Sanction of Intramural Research Grant**

To,

Dr. Anita Saxena
Principal Investigator
Dept. of Nephrology, SGPGI.

It is my pleasure to inform you that your research proposal entitled – A-03-PGI/IMP/78/2018 **"Enhanced Expression of beta-D-Galactosidase in Probiotic Strains of Lactic Acid Bacteria against Lactose Intolerance"**, has been accepted for intramural funding by the Research Committee of the Institute. **A sum of Rs. 3, 80,000=00,** has been sanctioned as per following details:

Consumables and Contingencies:	Rs.	3, 80,000=00
Travel	Rs.	NIL
Total	Rs.	3, 80,000=00

The grant will be utilized for the period from 11.10.2018 to 10.10.2020.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned as above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the intramural project.**
- **Stationary (office and computer), photocopying, postage and permanent equipments are NOT allowed.**
- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

CHAIRMAN RESEARCH COMMITTEE
&
DIRECTOR, SGPGIMS, LUCKNOW

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SGPGIMS,Lucknow

A-4

(9)

Sanjay Gandhi Postgraduate Institute of Medical Sciences

Part I: General information

Adrenal histoplasmosis: longitudinal study of cortisol reserve and possible role of immune deficiency in susceptibility

Principal Investigator:

Dr Eesh Bhatia — Professor and Head, Department of Endocrinology

Co-investigators:

Dr Amita Agarwal — Professor, Department of Clinical Immunology

Dr Subhash Yadav — Professor, Department of Endocrinology

Dr RungmeiMarak — Professor, Department of Microbiology

Duration: 2 years

DM project: Yes

Total cost: Rs 5,16,000/-

Summary

Infection with the dimorphic fungus *Histoplasma capsulatum* can lead to a wide range of clinical presentations. While the infection is mainly asymptomatic, or mild and self-limiting, it can also result in progressive disseminated disease and severe involvement of many organs, including the adrenal glands. Progressive disseminated histoplasmosis (PDH) is more common in immuno-compromised individuals. The infection is endemic in certain regions of the world such as parts of United States, Central and South America. In India it is endemic in West Bengal and Assam. Hematogenous infection with *Histoplasma* can result in destruction of the adrenal tissue. In clinicalreports, adrenal involvement occurs in 15-80% of patients.

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18

SANJAY GANDHI POSTGRADUATE INST... DICAL SCIENCES, LUCKNOW.

REF. NO. PGI/DIR/RC/842/2018 Dated : 29.09.18

Subject: **Sanction of Intramural Research Grant**

To,

Prof. Eesh Bhatia
Principal Investigator
Dept. of Endocrinology, SGPGI.

It is my pleasure to inform you that your research proposal entitled – **A-04-PGI/IMP/78/2018 "Adrenal Histoplasmosis: Longitudinal Study of Cortisol Reserve and Possible Role of Immue Deficiency in Susceptibility"**, has been accepted for intramural funding by the Research Committee of the Institute. **A sum of Rs. 5, 00,000=00,** has been sanctioned as per following details:

Consumables and Contingencies:	Rs.	5, 00,000=00
Travel	Rs.	NIL
Total	Rs.	5, 00,000=00

The grant will be utilized for the period from 11.10.2018 to 10.10.2020.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned as above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the intramural project.**
- **Stationary (office and computer), photocopying, postage and permanent equipments are NOT allowed.**
- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

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SGPGIMS,Lucknow

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Executive Registrar
SGPGIMS,Lucknow

PART-1: GENERAL INFORMATION

❖ **Project Title: Enhanced expression of *β-D-galactosidase* in probiotic strains of Lactic Acid Bacteria against Lactose Intolerance.**

❖ **Investigators:**

	Name	Designation	Signature
(a) Principal Investigator	Dr. Anita Saxena	Additional Professor, Department of Nephrology	
(b) Co-investigator(s)	1. Dr. Amit Gupta	Professor, Department of Nephrology	
	2. Dr. Rajan Saxena	Professor, Head, Department of Gastro Surgery	
	3. Dr. K.N. Prasad	Professor, Department of Microbiology	
(c) Head of the Institution	Dr. Rakesh Kapoor	Head of the Institution	

❖ **Total Budget (Rs): 3.80 Lakhs**

❖ **Project Summary:**

L. plantarum, a non-pathogenic, gram-positive bacterium has shown the potential to be used as therapeutic agent to treat lactose intolerance (**Markowiak, 2017 and Hertzler, 2003**). The (*LacLM*) *β-D-galactosidase* gene present in this species helps in catabolism of lactose. The key concept of this research includes isolation and cloning of *LacLM* from *Lactobacillus plantarum* into preferable candidate strains of Lactic Acid Bacteria. Preliminary characterizations of the enzymes are taken into consideration for construction of potential cloning vectors **(Otieno *et al.*, 2005).**

The expression of *LacLM* will be enhanced using pSIP expression system **(Sorvig *et al.*, 2003)** which has a promoter and regulatory genes involved in the production of class-II bacteriocins sakacin A **(Axelsson *et al.*, 1995)** and sakacin P **(Brurberg *et al.*, 1997; Huhne *et al.*, 1996)**. Production of these two bacteriocins is regulated via quorum sensing mechanism which is induced in the presence of peptide pheromones **(Eijsink *et al.*, 2002).**

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SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES,
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Ref. No. PGI/DIR/RC/844 /2018 Dated : 29.09.18

Subject: **Sanction of Intramural Research Grant**

To,

Abstract 29-9-18

Dr. Swasti Tiwari
Principal Investigator
Dept. of Molecular Medicine & Biotechnology, SGPGI.

It is my pleasure to inform you that your research proposal entitled – **A-02-PGI/IMP/78/2018 "To examine the immunomodulatory effect of umbilical cord blood Mesenchymal Stem Cell on HLA matched imm8une cell interactions in the Context of Type 1 Diabetes"**, has been accepted for intramural funding by the Research Committee of the Institute. **A sum of Rs. 5, 00,000=00**, has been sanctioned as per following details:

Consumables and Contingencies:	**Rs.**	**5, 00,000=00**
Travel	**Rs.**	**NIL**
Total	**Rs.**	**5, 00,000=00**

The grant will be utilized for the period from 11.10.2018 to 10.10.2020.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned as above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the intramural project.**
- **Stationary (office and computer), photocopying, postage and permanent equipments are NOT allowed.**
- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

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SGPGIMS,Lucknow

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29/9/18

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A-2

PART – 1: GENERAL INFORMATION

Project Title: "To examine the immunomodulatory effect of Umbilical cord blood Mesenchymal stem cells on HLA matched immune cell interactions in the context of Type 1 Diabetes."

Investigators:	Name	Department	Signatures
Principal Investigator	Dr Swasti Tiwari Additional Professor	Molecular Medicine and Biotechnology	Dr. SWASTI TIWARI Additional Professor & Head Dept. Molecular Medicine & Biotechnology SGPGIMS, LUCKNOW
Co-investigator			
Co-investigator 1	Prof Eesh Bhatia Professor	Endocrinology	Dr. Eesh Bhatia MD, DNB (Endocrinology) Professor & Head Dept. of Endocrinol S.G.P.G.I.M.S., Luck
C o-investigator 2	Dr Deepa Kapoor	Gynaecologist, General Hospital	GYNAECOLOGIST
Co-investigator 3	Dr Amrit Gupta Additional Professor	Department of Maternal & Reproductive Health	Dr. Amrit Gupta Additional Professor Maternal & Reproductive Health S.G.P.G.I.M.S., Lucknow-226014

Total Cost (Rs.): 5,00,000.00

Project summary including clearly state objectives (Not Exceed 250 words): Key words (at least 5)

MSCs are adult stem cells residing in bone marrow, adipose tissue, umbilical cord blood, and many other tissues. MSCs have well-characterized hypoimmunogenicity and immunomodulatory effects which could be used as a new approach to overcome the autoimmunity of diseases such as Type1 diabetes (T1DM). MSCs mainly work on inhibiting the antigen-presenting stage and subsequent T-cell-activation stage by secreting soluble factors. Therefore, MSCs offer more selectivity and specificity on hyperreactive T cells instead of compromising the whole-body immunity.

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Type 1 diabetes (T1DM) is an autoimmune disease involving the destruction of insulin-producing pancreatic β -cells by autoreactive β-cell specific CD4+ and CD8+ T lymphocytes. To enhance our knowledge about immunopathogenesis of T1DM we have tried to create an in vitro

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(32)

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW.

Ref. No. PGI/DIR/RC/ 043 /2018 Dated : 29.09.18

Subject: **Sanction of Intramural Research Grant**

To,

Dr. Gyan Chand
Principal Investigator
Dept. of Endocrine Surgery, SGPGI.

It is my pleasure to inform you that your research proposal entitled – A-01-PGI/IMP/78/2018 "**A prospective study to compare the results of intraoperative turbo thyroglobulin estimation vs frozen section in Suspected Cervical Lymphnodes During Differentiated Thyroid Carcinoma Surgery**", has been accepted for intramural funding by the Research Committee of the Institute. **A sum of Rs. 1, 58,400=00,** has been sanctioned as per following details:

Consumables and Contingencies:	Rs.	1, 58,400=00
Travel	Rs.	NIL
Total	Rs.	1, 58,400=00

The grant will be utilized for the period from 11.10.2018 to 10.10.2020.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned as above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the intramural project.**
- **Stationary (office and computer), photocopying, postage and permanent equipments are NOT allowed.**
- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

CHAIRMAN RESEARCH COMMITTEE
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Junior Accounts Officer (Research), SGPGI.
Executive Registrar, SGPGI.

29/9/18

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A-1

30

SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

PART 1: General Information

Project Title: **"A Prospective Study To Compare The Results of Intraoperative Turbo Thyroglobulin estimation vs Frozen Section in suspected cervical Lymphnodes during Differentiated Thyroid Carcinoma Surgery"**

Investigators-

	Name and Designation	Department, phone no and email address	Signature
PRINCIPAL INVESTIGATOR	**Dr GYAN CHAND ADDITIONAL PROFESSOR**	ENDOCRINE SURGERY 4359 Gyan133@sgpgi.ac.in	
CO INVESTIGATOR 1	Prof. Anjali Mishra professor	ENDOCRINE SURGERY 8004904647 anjali@sgpgi.ac.in	
CO INVESTIGATOR 2	Dr Sushila jaiswal Additional Professor	Pathology 8004904563 sushilaj@sgpgi.ac.in	

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33

SANJAY GANDHI POSTGRADUATE I[illegible] F MEDICAL SCIENCES,
LUCKNOW.

Dated : 19.06.18

Ref. No. PGI/DIR/RC/577 /2018

Subject: **Sanction of Intramural Research Grant**

To,

Prof. Soniya Nityanand 21/6/18
Principal Investigator
Dept. of Hematology, SGPGI.

It is my pleasure to inform you that your research proposal entitled "Effect of aPlastic Anemia Bone **Marrow Mesenchymal Stem Cell Derived Extra-cellular Vesicles on Hematopoietic Stem Cells"**, has been accepted for intramural funding by the Research Committee of the Institute. A **sum of Rs. 5, 00,000=00,** has been sanctioned as per following details:

Consumables and Contingencies:	**Rs.**	**5, 00,000=00**
Travel	**Rs.**	**NIL**
Total	**Rs.**	**5, 00,000=00**

The grant will be utilized for the period from 01.07.2018 to 30.06.2020.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned as above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the intramural project.**
- **Stationary (office and computer), photocopying, postage and permanent equipments are NOT allowed.**
- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

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SGPGIMS,Lucknow

INTRAMURAL PROJECT

❖ **Project Title:**

"Effect of aplastic anemia bone marrow mesenchymal stem cells derived extra-cellular vesicles on hematopoietic stem cells"

".

❖ **Investigators:**

Level	Name	Designation	Signature
Principal Investigator	SoniyaNityanand	Prof & Head Dept. of Hematology	S. Nityanand
Co-Investigator	Anshul Gupta	Assistant Professor Dept. of Hematology	
Co-Investigator	C.P Chaturvedi	Wellcome Trust-DBT Fellow Dept. of Hematology	

❖ **Total Budget (Rs): 5.00 Lakhs**

❖ **Project Summary including clearly stated objectives (<250 words):**

Aplastic anemia (AA) is a state of bone marrow failure syndrome, characterized by fatty bone marrow (BM) and defective hematopoiesis. The mesenchymal stem cells (MSCs) and other stromal cells present in the BM microenvironment play a pivotal role in maintaining hematopoietic stem cell (HSC) fate through the expression of multiple adhesion molecules that are necessary for homing and mobilization of HSCs, as well as by production of paracrine factors such as cytokines, chemokines, and extracellular vesicles (EVs) that affect the expansion, and differentiation of HSCs. In AA the BM-MSCs have abnormal gene profile and impaired immunological properties, indicating that defective BM-MSCs may contribute to the pathobiology of AA, but the actual mechanism is not clearly understood.Recently, the effect of MSC-EVs on the expansion, differentiation, and clinical applications of HSCs has been demonstrated. The EVs consist mainly of exosomes and microvesicles, which are crucial in regulating cell-to-cell communication by delivering their cargo molecules including protein, mRNA and miRNA to the nearby cells, thereby affecting the phenotype of target cells. However, the molecular and cellular mechanisms depicting the role of MSC-EVs in

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SAŃJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

Ref. No. PGI/DIR/RC/ 575 /2018 Dated : 19.06.18

Subject: **Sanction of Intramural Research Grant**

To,

Dr. Manish Ora
Principal Investigator
Dept. of Nuclear Medicine, SGPGI.

It is my pleasure to inform you that your research proposal entitled "**To determine the prevalence of osteopenia and its determinants in Thyroid cancer patients**", has been accepted for intramural funding by the Research Committee of the Institute. **A sum of Rs. 4, 47,000=00,** has been sanctioned as per following details:

Consumables and Contingencies:	**Rs.**	**4, 47,000=00**
Travel	**Rs.**	**NIL**
Total	**Rs.**	**4, 47,000=00**

The grant will be utilized for the period from 01.07.2018 to 30.06.2020.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned as above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the intramural project.**
- **Stationary (office and computer), photocopying, postage and permanent equipments are NOT allowed.**
- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

CHAIRMAN RESEARCH COMMITTEE
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Format for submission of Intramural project

PART -1: GENERAL INFORMATION

Project title:

To determine the prevalence of osteopenia and its determinants in Thyroid cancer patients

Objectives of study

- To determine prevalence of osteopenia/ osteoporosis in patient suffering from thyroid cancer
- To know the prevalence of surgical hypoparathyroidism and vitamin D deficiency in the thyroid cancer patient.
- To compare osteopenia between postmenopausal thyroid cancer patients with age matched control.
- To determine the effect of level of Thyrotropin suppression therapy on bone health (S TSH and dosage of LT4 hormone).

Investigators:

	Name	Department	Signature
Principal Investigator	Dr Manish Ora	Nuclear Medicine	
Co- investigator	Prof Sanjay Gambhir	Nuclear Medicine	
Co-investigator	Prof Sushil Gupta	Endocrinology	
Co-investigator	Prof Amit Agarwal	Endocrine Surgery	
Co-investigator	Dr Saba Retnam	Endocrine Surgery	

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Total Cost (Rs): ~447750/- rps

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(29)

SANJAY GANDHI POSTGRADUATE INSTITUTE O. MEDICAL SCIENCES, LUCKNOW.

Ref. No. PGI/DIR/RC/568 /2018 Dated : 19.06.18

Subject: Sanction of Intramural Research Grant

To,

Dr. Anupma Kaul
Principal Investigator
Dept. of Nephrology, SGPGI.

It is my pleasure to inform you that your research proposal entitled **"To evaluate the role of T cell Profile (Th1/Th2/Th17/Treg) and Prodocyturia in the Peripheral Blood of Patients with preeclampsia vs Normal Pregnancy"**, has been accepted for intramural funding by the Research Committee of the Institute. **A sum of Rs. 5, 00,000=00**, has been sanctioned as per following details:

Consumables and Contingencies:	**Rs.**	**5, 00,000=00**
Travel	**Rs.**	**NIL**
Total	**Rs.**	**5, 00,000=00**

The grant will be utilized for the period from 01.07.2018 to 30.06.2020.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned as above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the intramural project.**
- **Stationary (office and computer), photocopying, postage and permanent equipments are NOT allowed.**
- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

CHAIRMAN RESEARCH COMMITTEE
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SGPGIMS,Lucknow

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2. Executive Registrar, SGPGI.

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A-12

(27)

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

Format for submission of Intramural project

PART – 1: GENERAL INFORMATION

Project Title: To evaluate the role of T cell profile (Th1/Th2 /Th17/Treg) and podocyturia in the peripheral blood of patients with preclampsia vs normal pregnancy.

Investigators	Name	Department	Signature
Principal Investigator	Dr Anupma Kaul	Nephrology	
Co-investigator 1	Prof RK Sharma	Nephrology	
Co-investigator 2	Dr Deepa Kapoor	General Hospital	
Co-investigator 3	Prof Mandakini Pradhan	Maternal and Reproductive Health	
Co-investigator-4	Prof Vikas Agrawal	Immunology	
Co-investigator-5	Dr Niraj Kumari	Pathology	
Co-investigator 6	Dr Dharmendra Bhadauria	Nephrology	

Total Cost (Rs.): 5 LACS 11 THOUSAND ONLY

Project summary including clearly state objectives (Not Exceed 250 words):

Key words (at least 5): Tregulatory cells, TH-17 cells , podocytouria, preeclampsia, pregnancy, fetal outcome

Copy of the Departmental Research Committee Recommendation: Attached

Copy of the Ethics committee submission certificate: Attached

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Executive Registrar
SGPGIMS,Lucknow

RESEARCH CELL
Received
Date :- 31/3/18
Sign.
S.G.P.G.I.M.S., LUCKNOW

(Head of Department will be responsible for periodic monitoring of the project

5 June 2018

5/6/2018

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Executive Registrar
SGPGIMS,Lucknow

(29)

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW.

Ref. No. PGI/DIR/RC/567 /2018 Dated : 19.06.18

Subject: Sanction of Intramural Research Grant

To,

Prof. R.N. Misra
Principal Investigator
Dept. of Clinical Immunology, SGPGI.

It is my pleasure to inform you that your research proposal entitled **"Do Serum and Urinary C3d and C4d Level Reflect Disease Activity in Patients with Lupus Nephritis"**, has been accepted for intramural funding by the Research Committee of the Institute. **A sum of Rs. 3, 70,000=00,** has been sanctioned as per following details:

Consumables and Contingencies:	Rs.	3, 70,000=00
Travel	Rs.	NIL
Total	Rs.	3, 70,000=00

The grant will be utilized for the period from 01.07.2018 to 30.06.2019.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned as above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the intramural project.**
- **Stationary (office and computer), photocopying, postage and permanent equipments are NOT allowed.**
- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

CHAIRMAN RESEARCH COMMITTEE
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Lt Col Varun Bajpai VSM
Executive Registrar
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A-11

27

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

Format for submission of Intramural project

PART – 1: GENERAL INFORMATION

Project title: Do serum and urinary C3d and C4d level reflect disease activity in patients with Lupus Nephritis

Investigators:

	Name	Designation	Signature
PI	Ramnath Misra	Professor and HOD Clinical Immunology	
Co-PI	Amita Aggarwal	Professor Clinical Immunology	
Student	Sujata Ganguly	DM student Clinical Immunology	

Total Cost: Rs 3, 70 ,000

Project summary

Lupus nephritis is a serious manifestations of SLE and is responsible for significant morbidity and even mortality. Assessing renal disease activity is a challenge . Though renal biopsy is the gold standard, being invasive repeat biopsies are not practical . Search for urinary biomarkers , which are non invasive has been a major thrust. Though several biomarkers have been described , no single one has been sensitive and specific to be used in clinical practice. We propose to study urinary C4d and C3d as a biomarker to assess disease activity in Lupus nephritis. Earlier , we have shown in cross sectional studies that urinary C3d correlates with disease activity in LN , and recently a study have shown that plasma C4d correlates with active LN both cross-sectionally as well as longitudinally. Therefore, we hypothesize that urine C4d could serve as potential biomarker

Key words: Lupus nephritis Complement split products C3d C4d urine

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RESEARCH CELL
Received
Date :- 31/3/16
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(21)

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW.

Ref. No. PGI/DIR/RC/573 /2018 Dated : 19.06.18

Subject: **Sanction of Intramural Research Grant**

To,

Dr. Sushila Jaiswal
Principal Investigator
Dept. of Pathology, SGPGI.

It is my pleasure to inform you that your research proposal entitled **"Evaluation of 1p and 19q Chromosome Status in Oligodendroglial Tumors"**, has been accepted for intramural funding by the Research Committee of the Institute. **A sum of Rs. 5, 00,000=00,** has been sanctioned as per following details:

Consumables and Contingencies:	**Rs.**	**5, 00,000=00**
Travel	**Rs.**	**NIL**
Total	**Rs.**	**5, 00,000=00**

The grant will be utilized for the period from 01.07.2018 to 30.06.2020.

Juniort Accounts Officer (Research) has been requested to release the amount as per details mentioned as above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the intramural project.**
- **Stationary (office and computer), photocopying, postage and permanent equipments are NOT allowed.**
- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

CHAIRMAN RESEARCH COMMITTEE
&
DIRECTOR, SGPGIMS, LUCKNOW

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Copy to:
1. Junior Accounts Officer (Research), SGPGI
2. Executive Registrar, SGPGI.

21/6/18

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Abhay 20.6.18

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

PART – 1: GENERAL INFORMATION

Title of the Research Project:

- Evaluation of 1p and 19q chromosome status in oligodendroglial tumors

Investigators	Name	Designation	Signature
Principal Investigator	Sushila Jaiswal	Additional Professor, Deptt. of Pathology SGPGIMS, Lucknow	
Co-Investigator	Sarita Agrawal	Professor, Deptt. of Genetics SGPGIMS, Lucknow	
Co-investigator	Arun Srivastava	Associate Professor, Deptt. of Neurosurgery, SGPGIMS, Lucknow	
Co-investigator	Vinita Agrawal	Professor, Deptt. of Pathology, SGPGIMS, Lucknow	Vinita Agrawal
Co-investigator	Shalini Singh	Professor, Deptt. of Radiotherapy, SGPGIMS, Lucknow	
Co-investigator	Awadhesh Kumar Jaiswal	Professor, Deptt. of Neurosurgery, SGPGIMS, Lucknow	

Total cost (Rs.): Five lakh fifteen thousand only

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Executive Registrar
SGPGIMS,Lucknow

Forwarded by HOD:

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Executive Registrar
SGPGIMS,Lucknow

9

51

SANJAY GANDHI POSTGRADUATE INSTITUTE OF ME_ ICES, LUCKNOW.

REF. NO. PGI/DIR/RC/576 /2018 Dated : 19.06.18

Subject: **Sanction of Intramural Research Grant**

To,

Prof. Subhash Yadav
Principal Investigator
Dept. of Endocrinology, SGPGI.

It is my pleasure to inform you that your research proposal entitled **"Evaluation of Cardiovascular Risk Factors in Sheehan's Syndrome"**, has been accepted for intramural funding by the Research Committee of the Institute. **A sum of Rs. 1, 59,000=00,** has been sanctioned as per following details:

Consumables and Contingencies:	**Rs.**	**1, 59,000=00**
Travel	**Rs.**	**NIL**
Total	**Rs.**	**1, 59,000=00**

The grant will be utilized for the period from 01.07.2018 to 30.06.2020.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned as above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the intramural project.**
- **Stationary (office and computer), photocopying, postage and permanent equipments are NOT allowed.**
- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

CHAIRMAN RESEARCH COMMITTEE
&
DIRECTOR, SGPGIMS, LUCKNOW

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SGPGIMS,Lucknow

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

Intramural Project

PART – 1: GENERAL INFORMATION

Project Title: Evaluation of cardiovascular risk factors in Sheehan's syndrome

Investigators:

Name		Department	Signature
Principal Investigator:	Dr. Subhash Yadav	Endocrinology	
Co-investigator:	Prof. Eesh Bhatia	Endocrinology	
Co-investigator 1:	Dr. Sheo Kumar	Radiology	
Co-investigator 2:	Dr. Naveen Garg	Cardiology	

Total Cost (Rs.): Rs 1,59,009

Duration: 2 year

5/6/18

5/6/2018

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Department of Endocrinology,
Sanjay Gandhi Post Graduate Institute of Medical Sciences,
Lucknow, UP

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Executive Registrar
SGPGIMS,Lucknow

(18)

SANJAY GANDHI POSTGRADUATE I F MEDICAL SCIENCES,
LUCKNOW.

Ref. No. PGI/DIR/RC/ 569 /2018 Dated : 19.06.18

Subject: **Sanction of Intramural Research Grant**

To,

Prof. Amita Aggarwal
Principal Investigator
Dept. of Clinical Immunology, SGPGI.

It is my pleasure to inform you that your research proposal entitled **"Prediction of Response to Methotrexate in Rheumatoid Arthritis: Using Genes Involved in Adenosine Pathway"**, has been accepted for intramural funding by the Research Committee of the Institute. **A sum of Rs. 4, 90,000=00,** has been sanctioned as per following details:

Consumables and Contingencies:	**Rs.**	**4, 90,000=00**
Travel	**Rs.**	**NIL**
Total	**Rs.**	**4, 90,000=00**

The grant will be utilized for the period from 01.07.2018 to 30.06.2020.

Juniort Accounts Officer (Research) has been requested to release the amount as per details mentioned as above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the intramural project.**
- **Stationary (office and computer), photocopying, postage and permanent equipments are NOT allowed.**
- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

CHAIRMAN RESEARCH COMMITTEE
&
DIRECTOR, SGPGIMS, LUCKNOW

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Executive Registrar
SGPGIMS,Lucknow

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SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

Format for submission of Intramural project

PART – 1: GENERAL INFORMATION

Project title: Prediction of response to Methotrexate in Rheumatoid arthritis: Using genes involved in adenosine pathway

Investigators:

	Name	Designation	Signature
PI	Amita Aggarwal	Professor	
Co-PI	Ramnath Misra	Professor	
Student	Ankita Singh	PhD student	

Total Cost: Rs 4,90,000

Project summary

Methotrexate (MTX) is the first line therapy of rheumatoid arthritis (RA) and has high efficacy toxicity ratio with almost 65-70% patients having good response. As one third do not respond well to MTX we need a marker that can predict response to MTX so that alternative drugs can be used in them at first instance.

Clinical variables like age, gender, smoking status, baseline disease activity and disability have been suggested as predictors. Genetic polymorphism in enzymes linked to MTX pathway has shown some promise as predictors of response. In recent years increased production of adenosine by MTX has been found to be the major mechanism of action of MTX. This pathway has multiple enzymes including CD39 that leads to conversion of ATP to adenosine. We have recently shown that individuals with low CD39+Tregs have poor response to MTX and CC genotype at SNP rs11188513 of CD39 was associated with a lower frequency of $CD39^+$ Tregs. Since genotypes and clinical variable at baseline are robust markers as they are not labile to change like cytokines, T cell subsets etc we would like to study SNPs in enzymes involved in adenosine pathway and clinical variables at baseline as predictors of MTX response.

Genotyping for key enzymes involved in adenosine pathway as well as 2 other SNPs will be done in 250 patients with RA who will be treated with MTX monotherapy and a composite model including clinical variables and SNPs in these enzymes will be generated for prediction of response and a 4 gene composite model used in earlier studies will also be validated in Indian cohort.

Key words: Rheumatoid arthritis, drug response, Methotrexate

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Executive Registrar
SGPGIMS Lucknow

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Executive Registrar
SGPGIMS,Lucknow

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDIC.. , LUCKNOW.

REF. NO. PGI/DIR/RC/570 /2018 Dated : 19.06.18

Subject: Sanction of in addition Intramural Research Grant

To,

Dr. Moinak Sen Sarma
Principal Investigator
Dept. of Pediatric Gastroenterology, SGPGI.

It is my pleasure to inform you that your research proposal entitled "Assessment of selenium deficiency in gluten-free diet in patients with celiac disease", has been accepted for intramural funding by the Research Committee of the Institute. A sum of Rs. 4, 50,000=00, has been sanctioned as per following details:

Consumables and Contingencies:	Rs.	4, 50,000=00
Travel	Rs.	NIL
Total	Rs.	4, 50,000=00

The grant will be utilized for the period from 01.07.2018 to 30.06.2020.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned as above observing necessary formalities.

- The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the intramural project.
- Stationary (office and computer), photocopying, postage and permanent equipments are NOT allowed.
- The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.

CHAIRMAN RESEARCH COMMITTEE
&
DIRECTOR, SGPGIMS, LUCKNOW

Copy to :
1. Junior Accounts Officer (Research), SGPGI.
2. Executive Registrar, SGPGI.

Lt Col Varun Bajpai VSM
Executive Registrar
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SGPGIMS,Lucknow

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SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

Format for submission of Intramural project

PART – 1: GENERAL INFORMATION

Project Title: Assessment of selenium deficiency in gluten-free diet in patients with celiac disease

Investigators:

	Name, Designation & Qualifications	Departmental Tel Nos. & Email ID	Signature
Principal investigator	Dr. Moinak Sen Sarma Assistant Professor, Dept of Pediatric Gastroenterology SGPGIMS	8004904718 moinaksen@yahoo.com	27/3/18
1. Co-PI/Co-Guide /Collaborators	Prof. S.K. Yachha Professor and Head Dept of Pediatric Gastroenterology SGPGIMS	05222494432 skyachha@yahoo.co.in	Skyachha 27/3/18

Copy of the Departmental Research Committee Recommendation : attached

Copy of the Ethics committee submission certificate: attached
(Head of Department will be responsible for periodic monitoring of the patients)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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Executive Registrar
SGPGIMS,Lucknow

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW.

REF. NO. PGI/DIR/RC/583 /2018 Dated : 21.06.18

Subject: **Sanction of Intramural Research Grant**

To,

Prof. Sarita Agarwal
Principal Investigator
Dept. of Medical Genetic SGPGI.

It is my pleasure to inform you that your research proposal entitled **"To study on the Mosaic Loss of Y-Chromosome in Colorectal, Pancreatic and Prostate cancer in Indian Patients"**, has been accepted for intramural funding by the Research Committee of the Institute. **A sum of Rs. 3, 50,000=00,** has been sanctioned as per following details:

Consumables and Contingencies:	**Rs.**	**3, 50,000=00**
Travel	**Rs.**	**NIL**
Total	**Rs.**	**3, 50,000=00**

The grant will be utilized for the period from 01.07.2018 to 30.06.2020.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned as above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the intramural project.**
- **Stationary (office and computer), photocopying, postage and permanent equipments are NOT allowed.**
- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

CHAIRMAN RESEARCH COMMITTEE
&
DIRECTOR, SGPGIMS, LUCKNOW

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SGPGIMS,Lucknow

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENC

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Format for submission of Intramural project

PART – 1: GENERAL INFORMATION

Project Title: To Study on the mosaic Loss of Y-Chromosome in Colorectal, Pancreatic and Prostate Cancer in Indian Patients.

Investigators:

	Name	Department	Signature
PI	Prof. Sarita Agarwal	Medical Genetics	
Co-PI	Prof. Rakesh Kapoor	Dept. of Urology	
Co-PI	Prof. Neeraj Rastogi	Dept. of Radio Therapy	26/2/18
Co-PI	Dr. Samir Mohindra	Dept. of Gastroenterology	

Total Cost (Rs): 3,50,000/-

Project summary including clearly state objectives:

Cancer is a genetic disease because it is primarily caused by the accumulation of genetic alterations. Due to the absence of any specific sign, symptom or sensitive serum marker, cancer is usually diagnosed at advanced stages. The outcome for patients with advanced stage cancer is dismal because neither radiation nor conventional chemotherapy significantly improves survival or quality of life. Early diagnosis can have the significant impact on prognosis of cancer patients. The identification of reliable tumor markers will facilitate early detection of cancer in high-risk individuals. Large geographical differences in the incidence of cancer have been attributed to genetic factors.

Cancer research has been focusing on investigating non-invasive biomarkers to improve the early diagnosis and management of cancer patients. Recently, Loss of Y-chromosome was suggested as a possible biomarker for different cancers in males. Data from large cohorts associated LOY in peripheral blood with high risk of all-cause mortality and non-hematological cancer mortality. Confirmatory case control studies associating mosaic LOY in peripheral blood cells with elevated risk of cancer are needed. To contribute to the clarification of the role of the LOY in peripheral blood as a cancer biomarker in males in Indian population, we will perform case control study in three different types of cancer in male patients.

Key words: Cancer, Loss of Y chromosome, Biomarker, diagnosis, risk-factor.

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Executive Registrar
SGPGIMS,Lucknow

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Executive Registrar
SGPGIMS,Lucknow

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SANJAY GANDHI POSTGRADUATE INSTITUTE O SCIENCES,
LUCKNOW.

Ref. No. PGI/DIR/RC/574 /2018 Dated : 19.06.18

Subject: **Sanction of Intramural Research Grant**

To,

Prof. Gaurav Agarwal
Principal Investigator
Dept. of Endocrine Surgery, SGPGI.

It is my pleasure to inform you that your research proposal entitled **"Correlation of RET Genotype with Clinical, Pathological Attributes and Outcomes in patients with Medullary Thyroid Cancer"**, has been accepted for intramural funding by the Research Committee of the Institute. **A sum of Rs. 5, 00,000=00,** has been sanctioned as per following details:

Consumables and Contingencies:	**Rs.**	**5, 00,000=00**
Travel	**Rs.**	**NIL**
Total	**Rs.**	**5, 00,000=00**

The grant will be utilized for the period from 01.07.2018 to 30.06.2020.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned as above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the intramural project.**
- **Stationary (office and computer), photocopying, postage and permanent equipments are NOT allowed.**
- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

CHAIRMAN RESEARCH COMMITTEE
&
DIRECTOR, SGPGIMS, LUCKNOW

Copy to :
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SGPGIMS,Lucknow

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Executive Registrar
SGPGIMS,Lucknow

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

For Intramural Grant Submission

PART -1: GENERAL INFORMATION

Project Title:

"Correlation of RET genotype with clinical, pathological attributes and outcomes in patients with Medullary thyroid cancer."

Investigators	Name, Designation & Qualifications	Department	Signature
Principal Investigator	Prof. Gaurav Agarwal	Endocrine Surgery	
Co-Investigator	Prof.Eesh Bhatia	Endocrinology	
Co-Investigator	Prof Vinita Agrawal	Pathology	
Co-Investigator	Dr. Sabaretnam. M	Endocrine Surgery	
Co-Investigator	Dr. Saroj K Sahoo	Endocrinology	
Co-Investigator/ Student	Dr. Valiveru Chakrapani Ramya	Endocrine Surgery	

Total Duration of the Project: TWO YEARS

Departments responsible for conducting the research:

Department of Endocrine Surgery

Department of Endocrinology

Department of Pathology

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Executive Registrar
SGPGIMS,Lucknow

Total cost: INR **5,01,700**

RET genotype and Phenotype

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38

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES,
LUCKNOW.

Ref. No. PGI/DIR/RC/571 /2018 Dated : 19.06.18

Subject: **Sanction of Intramural Research Grant**

To,

Prof. Jayantee Kalita
Principal Investigator
Dept. of Neurology, SGPGI.

It is my pleasure to inform you that your research proposal entitled **"Expression of Death and Survival Signals in Tuberculosis Meningitis: Correlation with disease severity and Outcome"**, has been accepted for intramural funding by the Research Committee of the Institute. **A sum of Rs. 5, 00,000=00.** has been sanctioned as per following details:

Consumables and Contingencies:	**Rs.**	**5, 00,000=00**
Travel	**Rs.**	**NIL**
Total	**Rs.**	**5, 00,000=00**

The grant will be utilized for the period from 01.07.2018 to 30.06.2020.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned as above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the intramural project.**
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- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

CHAIRMAN RESEARCH COMMITTEE
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DIRECTOR, SGPGIMS, LUCKNOW

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Executive Registrar
SGPGIMS,Lucknow

Copy to :
Junior Accounts Officer (Research), SGPGI.
Executive Registrar, SGPGI.

21/6/18 25/6/18

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Executive Registrar
SGPGIMS,Lucknow

A-4

36

A project submitted for intramural funding

Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow

PART-I: GENERAL INFORMATION

Project Title: Expression of death and survival signals in tuberculous meningitis: correlation with disease severity and outcome.

Principal Investigator

Name: Prof.Jayantee Kalita

Professor, Department of Neurology

Sanjay Gandhi Post'Graduate Institute of Medical Sciences,

Raebareily Road, Lucknow, India- 226014

Phone: +91 522 2494169;

FAX: 091-0522-2668811

Email:jayanteek@yahoo.com; jkalita@sgpgi.ac.in

Signature –

Dr. J. KALITA
MD. DM. FAMS
Professor
Deptt. of Neurology
SGPGIMS, Lucknow, INDIA

Co-investigators:

Name: Prof. UK Misra

Professor, Department of Neurology
Sanjay Gandhi Post Graduate Institute of Medical Sciences,

Raebareily Road, Lucknow, India- 226014

Email: drukmisra@rediffmail.com

Signature –

Dr. U. K. MISRA
Professor
Department of Neurology
S.G.P.G.I.M.S., Lucknow

Head of Department: Prof. Sunil Pradhan

Department of Neurology
Sanjay Gandhi Post Graduate Institute of Medical Sciences Lucknow

Signature –

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Dr. Sunil Pradhan
MD (Med), DM (Neuro), FNASc, FICP
FRCP (Edin), DSc (HON)
Professor & Head, Deptt. of Neurology
Sanjay Gandhi Post Graduate Institute of Medical Sciences Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

SANJAY GANDHI POSTGRADUATE INSTI[illegible] OF MEDICAL SCIENCES,
LUCKNOW.

Ref. No. PGI/DIR/RC/578 /2018 Dated : 19.06.18

Subject: **Sanction of Intramural Research Grant**

To,

Prof. Amit Agarwal
Principal Investigator
Dept. of Endocrine Surgery, SGPGI.

It is my pleasure to inform you that your research proposal entitled **"Ruling-in Thyroid Malignancy by Molecular Diagnostics of Fine Needle Aspiration Cytology"**, has been accepted for intramural funding by the Research Committee of the Institute. **A sum of Rs. 5, 00,000=00,** has been sanctioned as per following details:

Consumables and Contingencies:	**Rs.**	**5, 00,000=00**
Travel	**Rs.**	**NIL**
Total	**Rs.**	**5, 00,000=00**

The grant will be utilized for the period from 01.07.2018 to 30.06.2020.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned as above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the intramural project.**
- **Stationary (office and computer), photocopying, postage and permanent equipments are NOT allowed.**
- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

CHAIRMAN RESEARCH COMMITTEE
&
DIRECTOR, SGPGIMS, LUCKNOW

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Executive Registrar
SGPGIMS,Lucknow

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A-3

For Intramural Submission

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

PART – 1: GENERAL INFORMATION

Project Title: Ruling-in thyroid malignancy by molecular diagnostics of Fine Needle Aspiration Cytology

Investigators	**Name**	**Department**	**Signature**
Principal Investigator	Prof. Amit Agarwal	Endocrine Surgery	
Co- investigator 1	Dr. Sabaretnam	Endocrine Surgery	
Co-investigator 2	Dr.Niraj Kumari	Pathology	
Co-investigator 3	Prof. Narendra Krishnani	Pathology	
Co- investigator 4	Dr. Suneel Mattoo	Endocrine Surgery	

Total Cost (Rs.): Rs. 5, 21, 500.

Project summary including clearly state objectives (Not Exceed 250 words):

Thyroid cancer is a common malignancy which can present clinically as thyroid nodules, The diagnosis of thyroid cancer usually begins with a fine needle aspiration cytology of nodules which is reported using diagnostic groups outlined in the Bethesda System for Reporting Thyroid Cytopathology which recognizes six categories. These categories are (i) nondiagnostic/ unsatisfactory; (ii) benign; (iii) atypia of undetermined significance/follicular lesion of undetermined significance (AUS/ FLUS); (iv) follicular neoplasm/suspicious for follicular neoplasm (FN/SFN), a category that also encompasses the diagnosis of Hurthle cell neoplasm/suspicious for Hurthle cell neoplasm; (v) suspicious for malignancy (SUSP), and (vi)

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(2)

62

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES

REF. NO. PGI/DIR/RC/572 /2018 Dated : 19.06.18

Subject: **Sanction of Intramural Research Grant**

To,

Dr. Mohan Gurjar
Principal Investigator
Dept. of Critical Care Medicine, SGPGI.

It is my pleasure to inform you that your research proposal entitled **"Renal outcome of acute kidney disease in critically ill patients: a prospective observational study"**, has been accepted for intramural funding by the Research Committee of the Institute. **A sum of Rs. 2, 95,000=00,** has been sanctioned as per following details:

Consumables and Contingencies:	**Rs.**	**2, 95,000=00**
Travel	**Rs.**	**NIL**
Total	**Rs.**	**2, 95,000=00**

The grant will be utilized for the period from 01.07.2018 to 30.06.2020.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned as above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the intramural project.**
- **Stationary (office and computer), photocopying, postage and permanent equipments are NOT allowed.**
- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

19/6/18
CHAIRMAN RESEARCH COMMITTEE
&
DIRECTOR, SGPGIMS, LUCKNOW

Copy to :

1. Junior Accounts Officer (Research), SGPGI.
2. Executive Registrar, SGPGI.

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SGPGIMS,Lucknow

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20/6/2018

a/c

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Executive Registrar
SGPGIMS,Lucknow

S21 - 655

60

Proposal for Intramural research funding

PART – I: GENERAL INFORMATION

Project Title: "Renal outcome of acute kidney disease in critically ill patients: a prospective observational study"

Name and Designation of Principal Investigator:

Mohan Gurjar
Additional Professor, Department of Critical Care Medicine, SGPGIMS, Lucknow
Email: mohan@sgpgi.ac.in

Mohan 19/03/18

Mohan 24/05/18

Name and Designation of Co-investigator 1:

Dharmendra Bhadauria
Associate Professor, Department of Nephrology, SGPGIMS, Lucknow
Email: drdharm1@rediffmail.com

Name and Designation of Co-investigator 2:

Vikas Agarwal
Professor, Department of Clinical Immunology, SGPGIMS, Lucknow
Email: vikasagr@sgpgi.ac.in

Name and Designation of Co-investigator 3:

Narayan Prasad
Professor, Department of Nephrology, SGPGIMS, Lucknow
Email: narayan.nephro@gmail.com

Name and Designation of Co-investigator 4:

Anupama Kaul
Additional Professor, Department of Nephrology, SGPGIMS, Lucknow
Email: Anupmaneph@gmail.com

Name and Designation of Co-investigator 5:

Hira Lal
Additional Professor, Department of Radiodiagnosis, SGPGIMS, Lucknow
Email: hiralal2007@yahoo.co.in

Name and Designation of Co-investigator 6:

Afzal Azim
Professor, Department of Critical Care Medicine, SGPGIMS, Lucknow
Email: drazal@sgpgi.ac.in

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SGPGIMS, Lucknow

Name and Designation of Co-investigator 7:

Arvind K Baronia
Professor, Department of Critical Care Medicine, SGPGIMS, Lucknow
Email: baronia@sgpgi.ac.in

19/3/18

Total Cost (Rs): 2,95,000.00

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67

SANJAY GANDHI POSTGRADUATE INSTITUTE [illegible] DICAL SCIENCES, LUCKNOW.

REF. NO. PGI/DIR/RC/566 /2018 Dated : 19.06.18

Subject: **Sanction of Intramural Research Grant**

To,

Dr. Chinmoy Sahu
Principal Investigator
Dept. of Microbiology, SGPGI.

It is my pleasure to inform you that your research proposal entitled **"Phenotypic and Genotypic Characterization of Fosfomycin Resistance in Bacterial Isolates from Patients with Urinary Tract Infection"**, has been accepted for intramural funding by the Research Committee of the Institute. **A sum of Rs. 3, 00,000=00,** has been sanctioned as per following details:

Consumables and Contingencies:	**Rs.**	**3, 00,000=00**
Travel	**Rs.**	**NIL**
Total	**Rs.**	**3, 00,000=00**

The grant will be utilized for the period from 01.07.2018 to 30.06.2020.

Junior Accounts Officer (Research) has been requested to release the amount as per details mentioned as above observing necessary formalities.

- **The intramural funds should be utilized for purchase of consumables: chemicals/regents/kits/disposables/micropipettes etc. All the items covered under the Learning Resource Allowance will not be allowed in the intramural project.**
- **Stationary (office and computer), photocopying, postage and permanent equipments are NOT allowed.**
- **The work on the project should be started by the PI after the proper ethical clearance by the Institutional Ethics Committee for the above project.**

CHAIRMAN RESEARCH COMMITTEE
&
DIRECTOR, SGPGIMS, LUCKNOW

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Junior Accounts Officer (Research), SGPGI
Executive Registrar, SGPGI.

20/6/18 21/6/18

FACULTY INCHARGE RESEARCH
SGPGIMS, LUCKNOW

a/c

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

SANJAY GANDHI POST GRADUTE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

Submission of Intramural Project

PART 1- GENERAL INFORMATION

Project Title: Phenotypic and Genotypic Characterization of Fosfomycin Resistance in Bacterial Isolates from Patients with Urinary Tract Infection

Investigators:

	Name	Department	Signature
1. Principal Investigator:	Dr Chinmoy Sahu	Microbiology	
2. Co-Investigator 1:	Dr Atul Garg	Microbiology	
3. Co-Investigator 2:	Prof Kashi Nath Prasad	Microbiology	

Total Cost (Rs.):

Rs 300,000 (Rupees three lakhs only)

Project Summary Including Clearly Stated Objectives:

a) Our aim is to study the prevalence, characterization and possible mechanism of fosfomycin resistance among urinary isolates of Gram negative bacteria. It will be conducted in the Microbiology Department of Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow. A total of 60 fosfomycin resistant bacteria isolates recovered from urine samples will be included in the study. The study will include only Gram negative bacterial isolates like *Enterobacteriaceae* and *Pseudomonas aeruginosa* from urinary tract infections. Bacterial isolates having intrinsic resistance to fosfomycin will not be included .The bacterial isolates will first be identified using routine biochemical tests and subsequently confirmed by Automated Identification System (Vitek 2, Biomeriux, France). Antibiotic susceptibility testing of all the isolates will be done by Kirby- Bauer's disk diffusion method. Minimum inhibitory concentration (MIC) of fosfomycin, will be determined by E-test and subsequently confirmed by agar dilution method. Then susceptibility interpretation by both Clinical and Laboratory Standards Institute (CLSI) and European Committee on Antimicrobial Susceptibility Testing

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Government of National Capital Territory of Delhi

e-Stamp

सत्यमेव जयते

Certificate No.	:	IN-DL07431673165790Q
Certificate Issued Date	:	30-Mar-2018 12:28 PM
Account Reference	:	IMPACC (IV)/ dl732103/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL73210318441565745325Q
Purchased by	:	JSS Medical Research India Private Limited
Description of Document	:	Article 5 General Agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	JSS Medical Research India Private Limited
Second Party	:	Not Applicable
Stamp Duty Paid By	:	JSS Medical Research India Private Limited
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

DATED 29 May 2018
JSS MEDICAL RESEARCH INDIA PRIVATE LIMITED
Vatika Mindscapes (Tower B), Plot 12/2, Sector 27D,
Faridabad- 121003 (Haryana) India
(AS THE CRO)
Dr. Sudeep Kumar
Professor
Department of Cardiology
Sanjay Gandhi PGIMS,
Rae Bareli Road, Lucknow
Uttar Pradesh-226014
(AS THE PRINCIPAL INVESTIGATOR)
AND
Sanjay Gandhi PGIMS,
Rae Bareli Road, Lucknow
Uttar Pradesh-226014
(AS THE SITE/INSTITUTION)

CLINICAL TRIAL AGREEMENT

JSS Signatory

PI Signatory

Institution head signatory

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SGPGIMS,Lucknow

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.

(48)

TABLE OF CONTENTS

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

47

This Clinical Trial Agreement (the "**Agreement**") is dated: 29 May 2018.

BETWEEN:

1. **JSS Medical Research India Private Limited.,** a company registered under the provisions of Indian Companies Act, 1956, having its office at 12/2, 6th Floor, Tower-B, Vatika Mindscapes, Sector 27-D, Faridabad-121003, Haryana, India acting through Kishor Kumar, Financial Controller, India being authorized to sign this Clinical Trial Agreement on behalf of Sponsor, Abbott Healthcare Pvt. Ltd. (hereinafter referred to as "**JSS India**" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

   And

2. **Dr Sudeep Kumar**, working as [Professor, Department of Cardiology at [Sanjay Gandhi, PGIMS Hospital] having his residence at SGPGI Campus Raebareli Road Lucknow (hereinafter referred to as the "**PI**" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

   And

3. **Sanjay Gandhi, PGIMS Hospital**, a *hospital/health care centre/company/nature of entity* registered under the provisions of Indian Companies Act, 1956 OR any other relevant law, having its registered office at Rae bareli road, Lucknow-226014 acting through its Dr Rakesh Kapoor, Director being authorized to sign this Agreement (hereinafter referred to as the "**Site**" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

   JSS India, the PI, and the Site shall hereinafter be referred to individually as "*Party*" and collectively as "*Parties*".

Whereas:

A. JSS India is a CRO and is in the business of providing Clinical Trial Site Management Services, Clinical Trial Monitoring Services and Clinical Data Management Services and certain other services related to any clinical study including site and principal investigator identification, regulatory, pharmacy services, identification and management of other agencies related to a clinical study translation of documents.

B. The Site is engaged in Clinical Trials and the PI is a *consultant* at the Site.

C. Abbott Healthcare Pvt. Ltd (hereinafter referred to as "**sponsor**") is Sponsor, desires to conduct a clinical trial in respect of Ivabradine Prolonged Release Tablets in Patients with Stable Chronic Heart Failure with Systolic Dysfunction and JSS India, the PI and the Site have represented willingness to participate in the Clinical Trial.

D. The Parties are now desirous of conducting the Clinical Trial in accordance with the terms and conditions hereof.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

JSS Signatory

PI Signatory

Institution head signatory

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Executive Registrar
SGPGIMS,Lucknow

46

1. **Definitions and Interpretations**

1.1 In this Agreement:

"**Adverse Event**" shall mean adverse event(s) as provided in the Protocol or any Clinical Trial Document, which may occur to a Subject due to administration of the Clinical Trial Drug.

"**Applicable Laws**" shall mean any applicable statute, law ordnance, regulation, rule, guideline, order, bylaw, administrative interpretation, writ, injunction, directive, judgment, or decree or other instrument which has the force of law in India.

"**Budget**" shall mean the budget agreed by the Parties in respect of conducting the Clinical Trial as more specifically described in Schedule B.

"**Case Report Form**" shall mean the case record form for each Subject in the form and manner provided by Sponsor.

"**Clinical Trial**" shall mean a clinical trial "A Prospective, Randomized, Double-blind, Double dummy, Multi Centre, Comparative Phase III Clinical Trial to Evaluate the Efficacy and Safety of Ivabradine Prolonged Release Tablets in Patients with Stable Chronic Heart Failure with Systolic Dysfunction". Conducted as per the Protocol.

"**Clinical Trial Documents**" shall mean and include all documentation received from Sponsor in respect of a Project, including but not limited to (i) Protocol; (ii) Information Brochure, (iii) Informed Consent Form; (iv) Case Record Form; (v) Questionnaires; (vi) Patient Diaries and (vii) any other document as Sponsor may, from time to time, provide.

"**Disability**" shall mean an event where either Party may be delayed or hindered in or prevented from the performance of any act required hereunder by reasons of strike, lockouts, labor troubles, inability to procure materials or services, failure of power or restrictive government or judicial orders, or decrees, riots, insurrection, war, acts of god, inclement weather or other reason or cause beyond that Party's reasonable control.

"**Dispute Notice**" shall mean a written notice issued by an aggrieved Party to the other Party in relation to any controversy, conflict or dispute of any nature arising out of or relating to or in connection with the provisions of this Agreement.

"**Drug**" or "**Clinical Trial Drug**" shall mean the chemical compound invented by Sponsor, excluding a placebo, in respect of which the Clinical Trial is being conducted.

"**Drugs Act**" shall mean the Drugs and Cosmetics Act, 1945 and rules made there under or any other enactment that may be in force in India.

"**Effective Date**" shall mean the date on which this Agreement shall come into effect.

"**Ethics Committee**" or "**Institutional Ethics Committee**" shall mean the ethics committee formed by the Site and the independent ethics committees formed in accordance with the Applicable Laws to review and approve all types of research proposals involving human participants on the Site with a view to safeguard the dignity, rights, safety and wellbeing of all such actual and potential research participants.

"**Feasibility Study**" shall mean shall mean a feasibility study conducted by JSS India to assess the feasibility of conducting clinical study(ies) in respect of a Project prior to commencement of a Project.

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SGPGIMS,Lucknow

45

"Fee" shall mean the fees and expenses, expenses and pass-through costs incurred in performing the Services payable by Sponsor, or if so authorized by JSS India in respect of each Project and/or Clinical Trial as provided in Schedule B, herein.

"ICH GCP Guidelines" shall mean the International Conference on Harmonization-Good Clinical Practice issued by Helsinki Declaration in June 1964 with applicable updates and amendments thereof.

"ICH" shall mean International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

"**Indian GCP**" shall mean Good Clinical Practice guidelines, issued by the Indian Council of Medical Research. "**Information Brochure**" shall mean the information brochure of Sponsor.

"**Informed Consent Form**" or "**ICF**" shall mean a written consent form provided by Sponsor which is duly approved by the appropriate authorities and the Ethics Committee in respect of a Clinical Trial, which is required to be signed and acknowledged by the Subject.

"**Investigational Products**" shall mean the chemical compound invented by Sponsor, including a placebo, in respect of which the Clinical Trial is conducted or any medical device, etc. developed by Sponsor.

"**Invoice**" shall mean an invoice issued in respect of the services performed by the PI and/or the Site, in accordance with this Agreement.

"**Subject**" shall mean the patient upon whom the Clinical Trial is being conducted by the PI and/or the Site.

"**Payment Milestone**" shall mean payment milestones for payment of the Fees as more specifically described in Schedule B.

"**Protocol**" shall mean Protocol Version 1.1 dated 30 June 2017, Protocol No. IVAP3001 as provided by Sponsor.

"**Price**" shall mean the approved payment rates detailed in the budget proposal attached hereto as Schedule 'C' and in accordance with the milestones mentioned therein (the "Price and Payment Schedule"). The Price shall be the total consideration and includes the consideration for purchase of any equipment or hiring of any manpower, required if any, in connection with the Clinical Trial.

"**Screen Failure**" shall mean the screen failure as defined in the Protocol.

"**Serious Adverse Event**" or an "**SAE**" includes all adverse experience(s) which are defined as serious in accordance with the Protocol, ICH guidelines and/or any other Applicable Laws.

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"**Services**" shall mean the services detailed in Schedule 'A'.

"**Site Indemnitee**" shall mean the Site and its employees and its associated staff.

"**Sponsor Property**" shall mean all data and information generated or derived by JSS India arising out of any Services performed by JSS India.

JSS Signatory

Institution head signatory

PI Signatory

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244

"**Standard Operating Procedures**" or "**SOP**" shall mean the written code specifying the standard operating procedures in respect of the Clinical Trial of the relevant Party.

1.2 In this Agreement:

1.2.1 words denoting the plural number include the singular and vice versa;

references to Recitals, Clauses and Schedules are references to recitals, clauses and schedules to or of this Agreement;

references to this Agreement include the Recitals and the Schedules;

the headings and contents page(s) are for the purpose of reference only, have no legal or other significance, and shall be ignored in the interpretation of this Agreement;

references to any document (including, without limitation, to all or any of the Relevant Documents) are, unless the context otherwise requires, references to that document as amended, supplemented, novated or replaced from time to time;

references to statutes or provisions of statutes are references to those statutes, or those provisions, as from time to time amended, replaced or re-enacted; and

references to any Party include its successors, transferees and permitted assignees.

2. Scope of the Agreement

The PI agrees to perform the Clinical Trial for and on behalf of the JSS India/sponsor in accordance with the Protocol and/or any other document specifically provided in this respect by JSS India.

3. Term

3.1 This Agreement shall commence on the Effective Date and shall continue till the Clinical Trial is completed as per the Protocol or till the date it is terminated earlier in accordance with this Agreement (the "**Term**").

4. Clinical Trial

4.1 Clinical Trial Initiation: JSS India shall provide the PI all Clinical Trial Documents. The PI and/or the Site shall obtain the approval of the Ethics Committee in respect of the Clinical Trial. If the PI and/or the Site are unable to obtain the approval of the Ethics Committee within such duration, the Parties shall agree upon an alternative duration within which the PI and/or the Site shall obtain such approval. It is expressly agreed that the JSS India may terminate this Agreement if such approval is not obtained by the PI and/or the Site within the time period prescribed hereunder.

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4.2 Duration: The estimated duration for a Clinical Trial is defined in the Protocol including follow-ups. The Site and the PI acknowledge that a Clinical Trial may be discontinued at any time, upon written instructions from JSS India.

4.3 Completion of Subject related procedures: A Clinical Trial shall be considered to be completed when criteria for completion as specified in the Protocol are met.

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43

5. Responsibilities and Obligations of the Parties

5.1 JSS India shall be responsible for the following:

i. Clinical Trial Documents, Investigational Products: Providing all the Clinical Trial Documents and the Investigational Products in advance or on time to the PI and/or the Site on behalf of sponsor.

ii. Other Duties: Site Monitoring, Medical Monitoring, Clinical Data Management, including electronic data capture Statistical Programming, Clinical Study Report preparation & IMP logistic management

5.2 The PI and/or the Site shall be responsible for the following:

a. The PI shall be responsible that the Trial should be conducted as per the Protocol, GCP Guidelines and Investigator's undertaking. For the tasks performed, Standard Operating procedures are to be documented.

b. PI shall be responsible for the identification and documentation of any and all Adverse Events and/ or Serious Adverse Events.

c. Upon request by JSS India, the PI will provide JSS India all information needed by JSS India and/or sponsor in the clinical sections of regulatory submissions to any regulatory agency including but not limited to, the "Investigational New Drug", annual report and the NDA ("**New Drug Application**") safety update, as well as regulatory submissions to other such agencies, in accordance with the Applicable Laws.

d. The PI agrees that as soon as minimum essential information about an SAE becomes available to PI, it will immediately report such information to JSS India and/or Sponsor, as directed in the Protocol. The PI will act reasonably to provide to the JSS India with at least the minimum essential information about an SAE, as identified in the Clinical Trial Documents at the earliest as per timelines mentioned in the protocol. The PI will not postpone or cause delay in reporting any such information to JSS India and/or Sponsor irrespective of whether more detailed information may become available at a later time, or because the available information is not yet confirmed.

e. The PI is responsible for making available any and all other safety information, as directed by JSS India and/or Sponsor, in accordance with regulatory standards and the Clinical Trial Documents.

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5.3 Regulatory Agency Audit: The PI and the Site will inform JSS India within twenty-four (24) hours of being notified of a regulatory agency audit (if advance notice is given by any applicable regulatory agency) or within twenty-four (24) hours of the beginning of any applicable regulatory agency audit (if no advance notice is given by the applicable regulatory agency). The PI and the Site shall provide JSS India with a copy of all Clinical Trial specific observations made during a regulatory audit at the PI and/or the Site's facilities, immediately upon receipt of such information. The PI shall cooperate fully with JSS India in any such investigation, and in the implementation of appropriate action plans for such observations.

6 Representations, Warranties and Covenants.

6.1 JSS India represents, warrants and covenants to Sponsor as follows:

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Institution head signatory

PI Signatory

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42

(a) Formation/Power and Authority: JSS India is duly formed and validly existing under the laws of India and has all requisite power and authority, to own and operate its business and properties and to carry on its business as such business is now being conducted and to execute and deliver this Agreement and to perform its obligations hereunder.

(b) Compliance with Applicable Law: JSS India represents and warrants that it is in full compliance at all times and shall continue to be in compliance at all times with all Applicable Laws of India.

(c) Permits: JSS India will or it shall cause Sponsor to identify all permits and approvals necessary or helpful in connection with the conduct and successful completion of a Project.

(d) Freedom to Use: JSS India hereby represents and warrants that Sponsor may freely use, practice, reproduce, distribute, make and sell all intellectual property rights and any other advice, data, information, inventions, works of authorship or know-how, including Sponsor Property and any deliverables, that JSS India conveys or provides hereunder without restriction and without infringing or misappropriating any third party's (e.g., a university's or corporation's) intellectual property or other rights.

(e) Debar: JSS India certifies that it has not been debarred under any Applicable Laws and that it will not employ any person or entity that has been so debarred in respect of any Clinical Trial.

JSS India agrees that it will promptly notify the other Parties in the event of any such debarment, conviction, threat or indictment occurring during the Term.

6.2 The Site represents, warrants and covenants to JSS India and Sponsor as follows:

(a) Formation/Power and Authority: The Site is duly formed and validly existing under the laws of India and has all requisite power and authority, to own and operate its business and properties and to carry on its business as such business is now being conducted and to execute and deliver this Agreement and to perform its obligations hereunder.

(b) Compliance with Applicable Law: The Site represents and warrants that it is in full compliance at all times and shall continue to be in compliance at all times with all Applicable Laws of India.

(c) Ethics Committee: The Site represents that it is duly authorized by the Ethics Committee of the Site to do so, agrees to enroll Subjects up to such higher numbers as agreed upon with JSS India in writing from time to time to meet the subject selection criteria described in the Protocol.

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SGPGIMS,Lucknow

(d) Freedom to Use: The Site hereby represents and warrants that the JSS India/Sponsor may freely use, practice, reproduce, distribute, make and sell all intellectual property rights and any other advice, data, information, inventions, works of authorship or know-how, including Sponsor Property and any deliverables, that the Site conveys or provides hereunder without restriction and without infringing or misappropriating any third party's (e.g., a university's or corporation's) intellectual property or other rights.

(e) Debar: The Site represents that it has never been, and its employees, and investigators, who will be rendering their services in respect of the Clinical Trial have never been debarred or convicted of a crime for which a person can be debarred under the provisions of the Drugs Act or any other Applicable Laws.

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Executive Registrar
SGPGIMS,Lucknow

41

i. The Site agrees that it will promptly notify JSS India in the event of any such debarment, conviction, threat or indictment occurring during the Term, or the three (3) year period following the termination or expiration of this Agreement.

ii. The Site agrees not to employ or otherwise engage during the Term any individual who will be rendering services to the PI and/or the Site in respect of the Clinical Trial who has been (i) debarred or (ii) convicted of a crime for which a person can be debarred.

iii. Upon JSS India request from time to time, the Site will certify in writing, the Site's compliance with the foregoing provisions of this paragraph.

6.3 The PI represents, warrants and covenants to JSS India as follows:

(a) Power and Authority: The PI hereby represents that it is duly registered in accordance with the Applicable Laws, and it has all power and authority (legal, corporate or other) to execute and deliver this Agreement and to perform its obligations hereunder.

(b) Ethics Committee: The PI representing that he is duly authorized by the Ethics Committee of the Site to do so, agrees to enroll Subjects up to such higher numbers till the study recruitment target is achieved as agreed upon with JSS India in writing from time to time to meet the subject selection criteria described in the Protocol.

(c) Debar: The PI represents that it has never been debarred or convicted of a crime for which a person can be debarred under the provisions of the Drugs Act or any other Applicable Laws.

i. The PI agrees that it will promptly notify JSS India in the event of any such debarment, conviction, threat or indictment occurring during the Term, or three (3) year period following the termination or expiration of this Agreement.

ii. Upon JSS India request from time to time, PI will certify in writing, the PI compliance with the foregoing provisions of this paragraph.

7 **Use of Name**

No Party shall use the name of another Party either expressly or by implication in any news or publicity release, policy recommendation or commercial fashion without the express written approval of that Party. Nothing herein shall be construed as prohibiting by JSS India and/or Sponsor from reporting on this study to a governmental agency and to other investigators studying the Drug, or of exercising its publication rights in accordance with Clause 10.

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8 **Ownership of Property and Data**

Sponsor shall have sole ownership and rights to any inventions or discoveries relating to the Drug or study, whether patentable or not, made in the performance of this Agreement.

9 Record Retention and Site Audits

a. The Site shall retain all records and documents pertaining to a Clinical Trial for a period of at least fifteen (15) years, following the latest of the following dates: (a) the date on which a marketing application for the particular Clinical Trial Drug is approved by the

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PI Signatory

Institution head signatory

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40

appropriate government body and/or other applicable regulatory authorities and until there are no pending or contemplated marketing applications in an ICH region (*any other applicable regulation*) **(b)** the date of completion of the Clinical Trial, or (c) if the Clinical Trial is discontinued before completion, the date on which the any applicable regulatory authorities are so notified.

b. JSS India / sponsor may monitor and audit the Site and the PI's performance of the Clinical Trial. Such audits may, as JSS India/sponsor so elect, comprise: (a) inspection of the PI's and/or the Site's facilities and records relating to the rendering of services to or for a Clinical Trial; (b) review of the PI and/or the Site's compliance with licensures and certifications as per the Applicable Laws; and (c) the PI's adherence to Applicable Laws, including in particular, but without limitation, Indian GCP and ICH GCP Guidelines.

10 Publications

JSS India and Sponsor shall retain ownership of all original Case Report Forms, data, analyses and reports that result from the Clinical Trial. Notwithstanding the foregoing, the PI and the Site understand and agree that participation in the Clinical Trial may involve a commitment to publish the data from the Clinical Trial in a cooperative publication with other investigators prior to publication or presentation of individual investigator results. The PI and the Site may only publish the results of the Clinical Trial in accordance with Applicable Laws and with prior written information & approval from the Sponsor . The PI and the Site agrees to delete any information that may be confidential or proprietary.

11 Fees

11.1 Budget: The CRO, PI and/or the Site shall provide an estimate of the budget to the other Parties on or before site selection. The Parties shall negotiate and agree on the Budget The Budget shall include Fees, the costs for conducting the Clinical Trial and any other incidental and/or overhead charges.

11.1.1 The Budget may only be modified in exigent circumstances, and only with the prior written consent of JSS India. It is expressly agreed that tests or services not required by the Protocol or performed in excess of Protocol requirements shall not be compensated by the JSS India unless the PI and/or the Site have taken the written consent of JSS India before administration of such tests or services.

11.2 Payment of Fees and Expenses to the PI and/or the Site: The CRO- JSS India shall provide the PI and/or the Site the Fees in accordance with Schedule B.

The PI and/or the Site shall be paid for all patients, including any Screen Failure patients. In case the PI and/or the Site recruits more or less than the number of Subjects provided in the Protocol, the consideration for their services will be prorated according to the actual number of subjects enrolled and the agreed per Subject consideration. The PI and/or the Site will also be paid for Screen Failure patients. This consideration will be paid in addition to patients actually randomized, in accordance with Schedule C.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

11.2.1 Unless otherwise agreed by the Parties, the following shall apply:

(a) the PI and/or the Site will issue its invoice for the Fees to the JSS India, on reaching the Payment Milestone (as defined in Schedule B)] on a monthly basis; and

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

39

(b) the JSS India, if so authorized, shall pay the invoiced amount within sixty (60) business days of the date of the invoice. The payment shall be made through crossed cheque/DD, as applicable:

PAYEE INFORMATION:

The Total study budget will be paid to below payee details (after TDS deduction)

Payee details:

PAYEE NAME	Director SGPGI Research Account
PERMANENT ACCOUNT NUMBER (PAN) OF PAYEE	AAAJS3913N

11.2.2 Taxes: Any service tax, duty, value added tax, or other government instituted tax or levy that may become payable in respect of the services offered in this Agreement shall be to the PI's and/or Sponsor's account. The payment shall be made after deducting all applicable deductions as per Applicable Law, including tax deducted at source.

11.2.3 Final Payment: Upon completion or termination of the study, the PI and/or the Site shall provide a written notice to JSS that all work requested under this Agreement has been completed and all monies due have been received. Acceptance of the payments as "final" constitutes such acknowledgement.

12 Insurance

a. JSS India shall maintain all adequate insurance coverage, including a (i) professional liability insurance, (ii) indemnity insurance covering JSS India, the PI and the Site, (iii) human clinical trial insurance covering JSS India, the PI and the Site during the Term.

b. The JSS shall deliver copies of the certificate evidencing the insurance coverage in accordance with Clause 13.4 to the Site and the PI.

13 Indemnification

13.1 Indemnity: JSS India on behalf of Sponsor shall indemnify, defend and hold harmless the Site, the PI, the Site Indemnitees, the Clinical Trial, and JSS India and any of the associated staff against any liability, loss, damage or expense (including reasonable attorneys' fees and expenses of litigation) ("**Loss**") incurred by or imposed on the Site Indemnitees or the Site, the PI, the Clinical Trial or JSS India or any of the associated staff in connection with any claims, suits, actions, demands or judgments made or instituted against Site, the Clinical Trial and/or JSS India to the extent (i) they are the direct result of the administration of the Study Drug to a Study Subject furnished by or on behalf of Sponsor or by a properly-performed Study procedure, and (ii) such activities were conducted in compliance with the Agreement, the Protocol and Investigator's Brochure

13.2 Exclusions from Indemnification: The JSS India obligation to indemnify in accordance with Clause 13.1, expressly excludes any indemnity obligations to indemnify, defend and hold harmless any Study Subject liability, damage, loss or expense incurred by or imposed on the Site Indemnitees or any one of them in connection with any claim, suit, action, demand or judgment arising:

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38

(i) from malpractice, negligence, recklessness, intentional or willful misconduct or omission of, or the breach of the Agreement and/or the Protocol on the part of any Site Indemnitee;

(ii) from any activities contrary to or outside the scope of the Protocol or to other information provided to any Site Indemnitee in connection with the Study or the Study Drug, including, but not limited to information provided in the Investigator's Brochure;

(iii) from any unauthorized representations and/or warranties made by any Site Indemnitee concerning the Study Drug;

(iv) in any case in which a Study Subject did not sign and agree to an Informed Consent Form;

(v) due to any failure on the part of a Site Indemnitee to comply with any Applicable Laws, regulations or governmental requirements for which the Site shall indemnify, defend and hold harmless Sponsor and its employees, officers, directors, contractors, successors, assign, representatives or agents;

(vi) due to an omission by any Site Indemnitee to inform Study Subjects, to

a. inform PI and/or Site of any new diseases or medical conditions that have arisen during the Study;

b. immediately notify Investigator, PI and/or Site of a personal injury or other damage that may be the consequence of the Study;

c. agree in writing to all reasonable measures (which may include a post-mortem examination) the objective of which is to investigate the cause and the extent of the damage suffered or to mitigate such damage.

13.3 The Site, the PI, the Site Indemnitees, the Clinical Trial and JSS India or the associated staff (each Party referred to as "**Indemnified Party**") seeking indemnification under Clause 3 above, directly or due to a third-party claim shall give written notice to the JSS India, against whom such indemnification rights are claimed. Pursuant to Clause 3 after receiving written notice of any such claim or legal proceeding against it or discovering the liability, obligation, or facts giving rise to such claim for indemnification, describing the claim, the amount thereof (if known and quantifiable), and the basis thereof in reasonable detail; provided, however, that the failure to so notify the JSS India/Sponsor shall not relieve the JSS India/Sponsor of its obligations hereunder except to the extent such failure shall have materially prejudiced the JSS India/Sponsor or its defences. With respect to any claim by a third party with respect to which indemnification is being sought by the Indemnified Party under Clause 3 above, the Indemnified Party shall have the right, at its election and at the sole cost and expense of Sponsor, to proceed with the defense (including settlement or compromise) of such claim or legal proceeding on its own if Sponsor fails to initiate the same within fifteen (15) business days of receipt of the notice in writing of such legal claim or proceeding from Sponsor; provided, however, that: (i) the Indemnified Party shall obtain the prior written consent of the JSS India/Sponsor (which shall not be unreasonably withheld or delayed) before entering into any settlement of a claim if (A) pursuant to or as a result of such settlement, injunctive or other equitable relief will be imposed against Sponsor, (B) such settlement does not expressly unconditionally release the JSS India/Sponsor from all liabilities and obligations with respect to such claim or legal proceeding and all other claims arising out of the same or similar facts and circumstances, with prejudice; or (C) involves criminal or quasi-criminal allegations against the JSS India/Sponsor; provided, however, such consent shall not be required if such settlement provides solely for the payment of monetary damages and an unconditional release of liability of the Indemnified Party with respect to such claim; (ii) no such settlement or compromise shall be conclusive evidence of the amount of Loss incurred by the Indemnified

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37

Party or payable by Sponsor in connection with such claim or legal proceeding; (iii) the JSS India/Sponsor shall be entitled to participate in the defence of such action, lawsuit, proceeding, investigation or other claim giving rise to the Indemnified Party's claim for indemnification, at its own expense; and (iv) if the Indemnified Party abandons or fails to reasonably assume the defence of any such claim or legal proceeding, JSS India/Sponsor may assume control of the defence of such claim or legal proceeding at its own expense; provided, however, that if the JSS India/Sponsor shall control the defence of any such claim or legal proceeding it shall select legal counsel reasonably acceptable to the Indemnified Party, the JSS India/Sponsor shall obtain the prior written consent of the Indemnified Party (which shall not be unreasonably withheld) before entering into any settlement of a claim or ceasing to defend such claim, if (A) pursuant to or as a result of such settlement or cessation, injunctive or other equitable relief will be imposed against the Indemnified Party, (B) such settlement does not expressly unconditionally release the Indemnified Party from all liabilities and obligations with respect to such claim and all other claims arising out of the same or similar facts and circumstances, with prejudice, or (C) involves criminal or quasi-criminal allegations.

13.4 Site and Clinical Trial Insurance: Nothing herein contained shall be deemed to be a waiver of the insurance obligations of the Site, the Clinical Trial and JSS India as contained in the Clinical Trial Agreement.

13.5 Entire Obligation

The foregoing terms constitute the entire indemnification obligation of JSS India/Sponsor in relation to the Study.

13.6 The CRO shall pay the cost of all reasonable and necessary medical diagnoses and treatment of any injury or illness sustained by a Subject arising out of or reasonably attributable to the Clinical Trial Drug, but only to the extent that said Subject's insurance or other third-party insurance is insufficient to cover said costs or as per the regulatory requirement. The CRO shall not be liable for payments for a Subjects' lost wages.

14 **Confidentiality**

a. All of the information disclosed by JSS India or developed hereunder by the PI, the Site or associated staff shall be subject to the following provisions: (a) neither the PI, the Site, nor associated staff or any other person engaged in the Clinical Trial shall disclose the information to any third party (other than JSS India or its representatives) without the prior written permission of by JSS India and (b) neither the PI, the Site nor associated staff or any other person engaged in the Clinical Trial shall use the information for any purpose other than the conduct of the Clinical Trial. However, nothing herein shall be construed as preventing the PI or the Site from publishing the data generated from the study, as provided in Clause 7 above.

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In handling a Subject's medical records, the PI, the Site and associated staff shall hold in strict confidence the identity of the Subject, and shall comply fully with any and all Applicable Laws regarding the confidentiality of such records.

15 Termination

15.1 JSS India may terminate the Clinical Trial by written notice of at least one (1) month in advance.

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15.2 The CRO may terminate for any of following reasons:

a. Notification to any of the Parties from the local regulatory authorities to terminate Clinical Trial.

b. Determination by JSS India that the PI and/or the Site is not performing the Clinical Trial as required in the Protocol or is not meeting any agreed requirements.

c. Failure of the PI and/or the Site or its associated staff or any other person engaged in the Clinical Trial to provide access by JSS India and/or its representatives to any and all original medical records necessary to verify entries on the Case Report Forms.

d. Failure of the PI and/or the Site or its associated staff or any other person engaged in the Clinical Trial (excluding Subjects) to be available, upon reasonable notice by JSS India, to meet with JSS India or its representatives during the course of the Study as necessary to discuss information relevant to the Study.

e. Failure of the PI and/or the Site to comply with any regulatory requirements, under the Applicable Laws of India.

f. Unauthorized replacement of PI

g. Determination by JSS India in writing that business or scientific considerations require termination.

h. Case Report Forms provided to the PI and/or the Site or its associated staff by JSS India or its representatives for use in the Study, are not completed and forwarded to JSS India or its designated representative, within the timelines prescribed by JSS India.

15.2 In case PI is unable to continue as PI, he will propose the name of another investigator in writing to JSS India. However, JSS India shall have the sole right to determine the acceptability of a new PI.

15.3 In the event that JSS India exercise its right to terminate the Study based on any of the enumerated grounds above, written notice of its decision to exercise such right shall be given by registered mail delivered fifteen (15) business days before said termination.

15.4 Immediately upon receipt of any notice of termination, the PI and/or the Site shall stop recruiting patients into the Clinical Trial and shall cease treatment with the Drug, to the extent medically permissible, on the Subjects. In the event of termination, the payments under this Agreement shall be prorated based on actual work performed in accordance with the Protocol. The PI and/or the Site shall cause to return to the JSS India (i) all documentation in respect of the Clinical Trial; and (ii) any funds not due under this calculation but already paid to the PI and/or the Site.

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16 Miscellaneous

16.1 Notices and Deliveries: Any notice required or permitted to be given hereunder by either Party shall be in writing and shall be deemed given on the date received if delivered by hand or by a reputable overnight delivery service, or three (3) business days after the date postmarked if sent by registered or certified mail, return receipt requested, postage prepaid to the following addresses:

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35

If to JSS India:

JSS Medical Research India Private Limited
Vatika Mindscapes (Tower B), 6th Floor,
Plot 12/2, Sector 27D, Faridabad-121003,
Haryana, India
Attention: Dr. Renu Razdan
Designation: Vice President, India Operations
Telephone: +91 129 6613 500
E-mail: renu.razdan@jssresearch.com

If to the PI:

Sanjay Gandhi PGIMS,
Rae Bareli Road, Lucknow
Uttar Pradesh-226014
Attention: Dr. Sudeep Kumar
Designation: Associate Professor
Telephone: 9919002761
Email:sudeepkumar@yahoo.com

If to the Site:

Sanjay Gandhi PGIMS,
Rae Bareli Road, Lucknow
Uttar Pradesh-226014
Attention: Dr. Rakesh kapoor
Designation: Director
Telephone: 9415410130
Email: rkapoor@sgpsi.ac.in

16.2 Amendment: No Party may amend any of the terms of this Agreement except by a written amendment/agreement signed by the Parties. In addition, any amendment to the Protocol must be approved in writing by Sponsor, DCGI and Institutional Ethic Committee.

16.3 Independent Contractor Relationship: The Parties are independent contractors and nothing contained in this Agreement shall be construed to place them in the relationship of partners, principal and agent, employer/employee or joint ventures. The Parties agree that all employees/ consultants of the PI and/or the Site shall remain employees/ consultants of the Site and performance of services under this Agreement shall not be construed as transfer of their employment to JSS India.

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16.4 Assignment: This Agreement may be assigned by JSS India to any of its affiliates or to any third party without prior written confirmation of other parties. The PI and the Site shall not assign this Agreement without the prior written consent of JSS India.

16.5 Force Majeure: In the event either Party shall be delayed or hindered in or prevented from the performance of any act required hereunder by reasons of a Disability, then performance of such act (except for the payment of money owed) shall be excused for the period of such Disability. The Party incurring the Disability shall provide notice to the other of the commencement and termination of the Disability. In case a Disability continues for more

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than three (3) months, the Party(ies) unaffected by the Disability may terminate this Agreement upon prior written notice to the affected Party. Should the Disability affect the performance of both parties, then such termination shall only be by mutual written agreement.

16.6 Survival: Sections 8, 9, 13, 14, 15, 16.2, 16.3 and 16.11 of the agreement shall survive any termination or expiration of this Agreement, as well as any other terms which by their intent or meaning are intended to so survive. No termination hereunder shall constitute a waiver of any rights or causes of action that either Party may have based upon events occurring prior to the termination date.

16.7 Severability: If any provisions herein are found to be unenforceable on the grounds that they are overly broad or in conflict with Applicable Laws, it is the intent of the parties that such provisions be replaced, reformed or narrowed so that their original business purpose can be accomplished to the extent permitted by law, and that the remaining provisions shall not in any way be affected or impaired thereby.

16.8 Counterparts: This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which taken together shall be deemed to constitute one and the same instrument. Delivery of an executed signature page of this Agreement by facsimile transmission shall be as effective as delivery of an original executed counterpart of this Agreement.

16.9 Governing Law. This Agreement shall be governed by the laws of India, and the courts of Delhi alone shall have exclusive jurisdiction in respect thereof.

16.10 Dispute Resolution: The Parties shall endeavor to resolve all disputes amicably by meetings caused between designated officials of each Party, within fifteen (15) days of receipt of a Dispute Notice. If the Parties are unable to resolve any dispute within the above referred fifteen (15) days, then the dispute shall be resolved by arbitration through a sole arbitrator jointly appointed by all Parties as per the provisions of the (Indian) Arbitration and Conciliation Act, 1996, as amended from time to time. If the Parties are not able to agree on a sole arbitrator, within fifteen (15) days of referral of a dispute to arbitration, the dispute shall be resolved by a panel of three (3) arbitrators. The Site and the PI shall appoint one (1) arbitrator, and JSS India and Sponsor shall appoint one arbitrator. The two (2) arbitrators so appointed shall jointly appoint the third arbitrator which shall be the presiding arbitrator. The venue of arbitration will be New Delhi, India. Cost of arbitration including but not limited to fees of arbitrator(s) shall be shared equally by all Parties or as per the award of the arbitrator(s).

16.11 Interim Relief: Nothing shall preclude either Party from seeking an interim, from a court having jurisdiction to grant such relief. The pursuit of interim relief shall not be a waiver of the duty of any of the Parties to pursue any remedy (including for monetary damages) through the arbitration as more specifically described in Clause 16.10 above.

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33

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

JSS India

By:
Print Name: Kishor Kumar

Title: Financial Controller
JSS Medical Research India Private Limited

Date: 28 MAY 2018

The Principal Investigator

By:
Print Name: Dr Sudeep Kumar
Title: Professor
SGPGIMS, Lucknow

Date: 01 June 2018

The Site

By:
Print Name: Dr Rakesh Kapoor
Title: Director
SGPGIMS, Lucknow

Date: 18 JUNE 2018

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32

Schedule A

[List of services to be provided by the PI and/or the Site]

Protocol Title: A Prospective, Randomized, Double-blind, Double dummy, Multi Centre, Comparative Phase III Clinical Trial to Evaluate the Efficacy and Safety of Ivabradine Prolonged Release Tablets in Patients with Stable Chronic Heart Failure with Systolic Dysfunction

Protocol ID: IVAP3001

List of services to be provided by the PI and/or the Site, but not limited to:

1. *Identification of protocol eligible patients for the study*
2. *Administration of informed consent process and AV recording*
3. *Recruiting patients as per protocol inclusion & exclusion criteria*
4. *Administration of patient diaries as per protocol*
5. Treat study participants as per randomization & adequate treatment follow-up
6. *Taking complete medical history of the patients*
7. *Responsibility for adverse events reporting*
8. *Writing the patient study summary-completion of source documentation*
9. Compliance to study subject visits as per Protocol
10. Transcription of data in to electronic case report form & resolution of data queries
11. Allow oversee of the study by CRO or their designee through regular monitoring visits
12. Site readiness for regulatory inspection & external/internal audits
13. IP management as per protocol and Archival of study documents & material
14. Regulatory document submission & management as applicable
15. Coordination with Ethics committee
16. Maintain Study site files

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Schedule B
Budget and Payment Schedules

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Payment shall be made against invoices sent every month according to table mentioned below.

The Parties understand and agree that the currency of the Agreement is and shall remain India Rupee (INR) and shall not be modified notwithstanding any exchange fluctuations that may occur.

All invoices shall be sent to the following address:

JSS Medical Research India Private Limited.
Plot No. 12/2, 6th Floor, Vatika Mindscapes Tower-B,
Near Sarai Khwaja Metro Station,
Sector-27D, Faridabad – 121003 (INDIA)

Each invoice must be an original copy (PDF or fax copies are not acceptable) and contain, as a minimum, the following information:

a) The Research Institution's Name and Address as it is written at the front of this Agreement
b) A description of the deliverable along with supporting attached (e.g. final written report) associated with the invoice
c) The total invoice amount in the currency specified in this Agreement, Payee Name, PAN
d) Signed & date by authorized signatory

Payment Schedule/Milestones per patient:

Visit Type	Amount INR	Approx. Percentage
V1(Including 2D Echo)	7750	25.8%
V2	3250	10.8%
V3	6250	20.8%
V4	3500	11.6%
V5	3500	11.6%
V6	5750	19.1%
Sub Total per subject	30000	NA
IOH @ 25%	7500	25%
Total for per protocol completed patient	37500	NA
Start up Amount	25000	NA

The cost for the trial will be as mentioned below:

a) The cost per protocol-correct and completed subject will be INR 30,000 (excluding Institutional overhead)
Note: Completed patient means once the subject has completed the final follow up and complete data entered and verified in the eCRF by the monitor.

This will include the following fees, as applicable, but not limiting to:

- The PI fees, study team fees, costs for unscheduled visits, site infrastructure maintenance for this study, stationery, courier and other study-related bills

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b) If required/requested by site, A nonrefundable advance amount of INR 25000 would be issued to the site upon receipt of completely executed agreement and unconditional EC approval.

c) The following costs incurred by site, where applicable, would be reimbursed to site upon receipt by CRO of original receipts/ bills:

i. Fees related to local Ethics Committee reviews
ii. SAE management costs: The SAE management costs are applicable to all SAEs only related to the Clinical Trial/ protocol/ Investigational Product. The costs would be reimbursed to the site once the original bills/receipts are made available to CRO i.e. bills pertaining to hospitalization, investigations & procedures, medications for the SAE.
iii. This Clinical Trial will not involve any monetary expenses. Subjects will be reimbursed for all their expenses in connection with this Clinical Trial on actual basis (e.g. travel costs) by CRO. Subject travel re-imbursement will be paid on actuals upto Rs. 500 per visit upon producing the vouchers/ bills for the same to CRO.

d) The fees for a screen failure patient will be INR 5000. This screen failure payment includes all charges. The screen failure cost shall be applicable for every 3rd Screen failure.

e) Institutional overhead 25% of the total budget (if applicable)

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(29)

SCHEDULE C

JSS India on behalf of Abbott Healthcare Pvt.Ltd will make the payments as follows:

(i) Payments will be made once the CRFs for the patient visits have been verified by the CRO/ designee & query has been resolved. Invoices will be raised on monthly basis and sent to CRO for payment. Invoices will be raised on the basis work completed during previous month In the event that a subject withdraws or is withdrawn from the Trial for reasons beyond the Investigator's control (but after commencing the dosing regimen in accordance with the Protocol), payment shall be made pro rata (based on the number of visits completed) in respect of that subject provided all data in respect of that subject up to the time of that subject's withdrawal from the Trial have been completed and sent to and accepted by CRO.

(ii) Invoices will be paid within 60 days of receipts to the payee. Service tax as applicable will be levied on each invoice according to the guidelines of service tax rules of India.

(iii) From each invoice CRO will keep 15% retention money and the same will be paid once all queries are resolved and Clinical trial/Site is closed out in all respects.

(iv) There is no other amount payable to Institute/Investigator for the Clinical Trial (except) mentioned in this agreement.

(v) Above budget does not include any Related Adverse Event or Serious Adverse Event expenses. Any related Adverse Event or Serious Adverse Event expenses will be reimbursed on actual. Reimbursement of Adverse Event or Serious Adverse Event management will include but not limited to Investigations, Hospitalisation, Treatment costs. Site agrees to take approval for any special investigations in case of Adverse Events. Site agrees to give timely update on the plan of management in terms of cost, on the cost incurred in management of the above events.

vi) In case of early termination of Clinical Trial, final payment calculation will be based on actual work completed. In case extra payment has been made, payee will refund the extra money. In case there is any amount payable to payee the same will be paid by CRO.

vii) All payments are subject to TDS (other taxes as applicable) and all payments will be made once payment is received by CRO from Sponsor.

Summary of the items included in payment & items not to be reimbursed:

Items included in payment:

Items included in Professional fees of per patient cost:
• PI fees
• Clinical Trial team fees
• Administrative cost
• Payments for unscheduled visits
• Site infrastructure (including Telephone/ fax/ internet), IMP storage.
• Stationary and Couriers
Pass through costs to be paid on Actuals:
• Ethics Committee fees
• SAE management costs, if any
• Subject Compensation if any
• Travel reimbursements of patients

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Government of National Capital Territory of Delhi

e-Stamp

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Certificate No.	:	IN-DL751133608130 84Q
Certificate Issued Date	:	12-Jan-2018 12:11 PM
Account Reference	:	IMPACC (IV)/ dl982203/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL98220353284573996806Q
Purchased by	:	PHARMAZZ INDIA PRIVATE LIMITED
Description of Document	:	Article 5 General Agreement
Property Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	PHARMAZZ INDIA PRIVATE LIMITED
Second Party	:	SGPGI AND DR U K MISRA
Stamp Duty Paid By	:	PHARMAZZ INDIA PRIVATE LIMITED
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

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Executive Registrar
SGPGIMS,Lucknow

CLINICAL TRIAL AGREEMENT BETWEEN

Pharmazz India Private Limited (Sponsor)

And

Sanjay Gandhi Post Graduate Institute of Medical Sciences (Institution)

And

Dr. U.K. Misra (Principal Investigator)

PHARMAZZ INDIA PVT. LTD. * Saving Lives Through Innovation *

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(27)

FOR THE STUDY

Title of Study:	A Prospective, Multicentric, Randomized, Double Blind, Parallel, Saline Controlled Phase II Clinical Study to Compare the Safety and Efficacy of PMZ-1620 Therapy along with Standard Supportive Care in Subjects of Acute Ischemic Stroke.
Protocol Number:	PMZ-01
Version Number:	02
Date of Protocol:	18 April 2016

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (hereinafter referred to as the "**Agreement**") is made on **23 Mar 2018** ("**Effective Date**") at New Delhi **BY AND BETWEEN**:

PHARMAZZ INDIA PVT LTD, a Company incorporated and existing in accordance under Indian Companies Act, 1956, with its Office at B-4 Sarita Vihar New Delhi 110076, (hereinafter referred to "**Pharmazz**", which expression shall, unless repugnant to the context or meaning thereof, be deemed to include its successors and permitted assigns) **OF THE FIRST PART**;

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences, an Institution having its office at Department of Neurology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow,-226014, (hereinafter referred to as **"Sanjay Gandhi Post Graduate Institute of Medical Sciences"**, which expression shall, unless repugnant to the context or meaning thereof, be deemed to include its successors and permitted assigns) **OF THE SECOND PART**;

AND

Dr. U. K. Misra a registered medical practitioner holding MCI registration number-18599 , is the Professor at Department of Neurology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow,-226014 (hereinafter referred to as **"Principal Investigator"**), which expression shall, unless repugnant to the context be deemed not to include its successors and permitted assigns **OF THE THIRD PART**;

Pharmazz, **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and Principal Investigator shall hereinafter be collectively referred to as the "**Parties**". Each of the Parties shall hereinafter individually be referred to as a "**Party**".

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(26)

RECITALS

1. WHERE **(Sanjay Gandhi Post Graduate Institute of Medical Sciences)** is a pioneering institution of world-class investigator sites in India. It is a chain of investigator sites having an exclusive set up for conducting Phase II to Phase IV clinical trials and has assured the sponsor of its capability and infrastructure and logistics to conduct the desirous clinical trial

2. Pharmazz has rights to Intellectual Property related toPMZ-1620 is a lyophilized IRL-1620 Injection, proposed to act as a Treatment agent in Acute Ischemic Stroke.

3. Principal Investigator **Dr. U.K Misra, DM (Neurology)** is a registered medical practitioner and has been actively involved in many clinical trials both as sub-investigator and as principal investigator.

4. **AND WHEREAS** Pharmazz is desirous of entering into an agreement with **Dr. U.K. Misra** for conducting Clinical Trial Phase II study titled **"A Prospective, Multicentric, Randomized, Double Blind, Parallel, Saline Controlled Phase II Clinical Study to Compare the Safety and Efficacy of PMZ-1620 Therapy along with Standard Supportive Care in Subjects of Acute Ischemic Stroke"."**at Sanjay Gandhi Post Graduate Institute of Medical Sciences Department of Neurology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow,-226014

5. The Principal Investigator has, after careful review of the Protocol provided by Pharmazz and other materials relating to the Clinical Trial conveyed his willingness to **Sanjay Gandhi Post Graduate Institute of Medical Sciences** to conduct the proposed Study. Principal Investigator understands that he is bound under his duty to complete this said trial unless repudiated by law or government order.

NOW THEREFORE, THE PARTIES HEREBY AGREE BY AND BETWEEN AS FOLLOWS:

1. DEFINITIONS AND INTERPRETATION

1.1 **Definitions**

All capitalized terms whenever used in this Agreement, unless repugnant to the meaning or context thereof, the following words and terms shall have the meanings set forth below:

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a) **"AGREEMENT"** shall mean this Clinical Trial Agreement;

b) **"CONFIDENTIAL INFORMATION"** means and includes any non-public information disclosed by either party to the other party either directly or indirectly, in writing, orally, by inspection/observation, in any floppy diskette, photocopy, scan, magnetic tape etc., information pertaining to and without limitation to know-how, technical data, trade secrets, research and product plans, services, prototypes, equipments, samples, services, customer lists,

PHARMAZZ INDIA PVT. LTD. Saving Lives Through Innovation

Dr. U. K. Misra
Professor
Department of Neurology
S.G.P.G.I.M.S., Lucknow

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Executive Registrar
SGPGIMS,Lucknow

marketing strategies, developments, inventions, financial and other business information with regard to this project;

c) "**EFFECTIVE DATE**" shall mean the date of execution of this Agreement;

d) **"INTELLECTUAL PROPERTY"** shall mean and include patents, copyrights, trade names, trademarks, service marks, mask works, trade secrets, inventions, databases, names and logos, trade dress, technology, know-how, and other proprietary information and licenses from third persons granting the right to use any of the foregoing, including all registrations and applications for any of the foregoing that have been issued by or filed with the appropriate authorities, any common-law rights arising from the use of the foregoing, any rights commonly known as "industrial property rights" or the "moral rights" of authors relating to the foregoing, all rights of renewal, continuations, divisions, extensions and the like regarding the foregoing and all claims, causes of action, or other rights arising out of or relating to any actual or threatened infringement by any person relating to the foregoing; all computer applications, programs and other software, including without limitation operating software, network software, firmware, middleware, and design software, all design tools, systems documentation and instructions, databases, and related items; and all cost information, sales and pricing data, customer prospect lists, supplier records, customer and supplier lists, customer and vendor data, correspondence and lists, product literature, artwork, design, development and manufacturing files, vendor and customer drawings, formulations and specifications, quality records and reports and other books, records, studies, surveys, reports, plans and documents. The term shall include all present and future Intellectual Properties, particularly with respect to the present study;

e) **"INTELLECTUAL PROPERTY RIGHTS"** shall mean and include, but shall not be limited to, all foreign and domestic rights, contained in the Intellectual Property defined herein above;

f) **"STUDY" or "CLINICAL TRIAL"** shall mean study entitled **"A Prospective, Multicentric, Randomized, Double Blind, Parallel, Saline Controlled Phase II Clinical Study to Compare the Safety and Efficacy of PMZ-1620 Therapy along with Standard Supportive Care in Subjects of Acute Ischemic Stroke"**As defined in the Protocol.

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g) "**PROTOCOL**" shall mean: The description of the Study contained in the Study protocol number **PMZ 01** (a copy of which is attached as Exhibit A) and all amendments thereto as the Parties may from time to time agree in writing.

h) "**STUDY DRUG**" or "**Investigational Drug**" shall mean: IRL-1620 For Injection 30 µg/vial

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i) **"ETHICS COMMITTEE"** shall mean: An independent body, including but not limited to, independent ethics committee or institutional review board, constituted and registered with the licensing authority under the provisions of Drugs and Cosmetic Act, 1945 and rules amended thereof.

j) **"DCGI"** Drug Controller Government of India.

1.2 **Interpretation**

In construing this Agreement:

a) Unless the context otherwise requires, words importing the singular shall include the plural and vice versa;

b) References to a person includes an individual, body corporate, association or body of persons (whether or not incorporated), trust, firm or any other entity by whatever name called;

c) Clause headings are for reference only and shall not affect the construction or interpretation of this Agreement;

d) References to Recitals, Clauses, Exhibits and Schedules are references to Recitals, Clauses, Exhibits and Schedules of and to this Agreement;

e) All the Exhibits referred to in this Agreement shall be deemed to be a part and parcel of this Agreement.

f) wherever the context so demands the references to a Party to this Agreement includes references to its successors or assigns (immediate or otherwise) of that Party and reference to agreements shall include reference to all the amendments thereto made in writing;

g) unless otherwise specified, time periods within or following which any payment is to be made or act is to be done shall be calculated by excluding the day on which the period commences and including the day on which the period ends and by extending the period to the following Business Day if the last day of such period is not a Business Day;

h) unless otherwise specified, whenever any payment is to be made or action taken under this Agreement is required to be made or taken on a day other than a Business Day such payment shall be made or action taken on the next Business Day;

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i) the terms "herein", "hereof", "hereto", "hereunder" and words of similar purport refer to this Agreement as a whole; and

j) Unless otherwise specified, any reference to "consent" or "approval" of a Party under this Agreement shall mean the consent or approval of such Party at its sole discretion.

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Dr. U. K. Misra
Professor

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Executive Registrar
SGPGIMS,Lucknow

(23)

2. ROLE &RESPOSIBILITIES

The Scope of Services (hereinafter referred to as '**Services**'), under this Agreement includes **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and Principal Investigator to complete the following -

Responsibility of the Sanjay Gandhi Post Graduate Institute of Medical Sciences & Principal Investigator

The **Sanjay Gandhi Post Graduate Institute of Medical Sciences** agrees to provide full support to the Principal Investigator **at Sanjay Gandhi Post Graduate Institute of Medical Sciences Department of Neurology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow-226014** to conduct the Clinical Trial in **Sanjay Gandhi Post Graduate Institute of Medical Sciences** premises and to make all reasonable endeavors to retain the P.I. and utilize reasonably the facilities available in the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and the said hospital for the Study and shall allot qualified co-investigators, sub investigators, if any, and other persons, with prior consent of concerned authorities for proper conduct of the Study in accordance with the terms of this Agreement and the Protocol.

2.1 The Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall be jointly and severally responsible

a) to conduct and complete the Clinical Trial of the Pharmazz strictly in accordance with the applicable regulatory requirements and the Protocol as approved by the Ethics Committee; Guidelines/ Standard Operating Procedure/ Protocol will be provided by the sponsor to conduct clinical trial which has to be adhered to in consonance with Hospital's protocol and the same is annexed hereto as Exhibit A, which also forms part of this agreement.

b) to comply with all applicable rules, regulations and guidelines, both national and international, including but not limited to, ICH Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95), Good Clinical Practice Guidelines issued by CDSCO, Directorate General of Health Services, Govt. of India; Drugs and Cosmetics Act 1945 and Rules, gazette, notifications made thereunder (as amended from time to time), ethical principles contained in the current revision of Declaration of Helsinki, Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research ("**Applicable Laws & Guidelines**");

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c) to fulfill all other terms and conditions stipulated herein and in the Exhibits hereto, during the period of, and also after the completion of, the Clinical Trial as agreed upon; and

d) to provide Pharmazz a copy of registration certificate issued by the licensing authority to Ethics Committee before initiation of the Clinical Trial.

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(12)

2.2 The Principal Investigator shall personally review all case report forms including Electronic Case Report Forms to assure its completeness and accuracy. A case report form/eCRF is deemed complete when:

a) the case report form has been completed by the Principal Investigator in accordance with Study requirements;

b) it relates to a properly qualified subject who participated in and completed the Study in accordance with all Study requirements and directions from the Pharmazz; and

c) it can be used in all analyses of the Study results.

The Principal Investigator undertakes that all data shall be submitted in a timely manner to Pharmazz.

Principal Investigator shall at all-time exercise independent medical judgment as to the compatibility of each subject with the Study as per Sponsor's Protocol requirements. Principal Investigator shall notify the Pharmazz, Chairman of Ethics Committee and licensing authority i.e. DCGI within twenty four (24) hours in writing of any serious adverse events related to or unrelated to the Study Drugs and of overdoses and any other event as set forth in detail in the Protocol and as required by the Drugs & Cosmetic Act with latest amendments.

The Principal Investigator and Pharmazz shall provide report of serious adverse events of death after due analysis to the Head of Institution, Chairman of the Ethics Committee, IEC and Chairman of the expert committee constituted by licensing authority with a copy to the licensing authority of any deviations in the Protocol or serious adverse events within fourteen (14) calendar days from the date of occurrence of such deviation and/or serious adverse events of death, as the case may be.

The Principal Investigator and Pharmazz shall provide report of serious adverse events other than death after due analysis to the Head of Institution, Chairman of Ethics Committee, licensing authority within fourteen (14) calendar days of occurrence of such serious adverse events other than death.

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In the event the Principal Investigator becomes unwilling or unable to perform the Study at any latter stage, the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall provide notice promptly to the Study subjects, Ethics Committee and Pharmazz before Principal Investigator intends to withdraw from Clinical Trial. The Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall endeavour to promptly recommend a replacement of Principal Investigator, from among the consultants of the **Sanjay Gandhi Post Graduate Institute of Medical Sciences.** The Pharmazz shall have the exclusive right to approve or reject any such replacement of Principal Investigator. The new

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principal investigator which is approved by the Pharmazz shall be required to agree to the terms and conditions of this Agreement.

2.3 If there is a change in the Principal Investigator, the Organizational Official selects and appoints a new Investigator for the study. The outgoing Investigator notifies the Sponsor and the EC that he or she has relinquished the responsibilities of the Principal Investigator to the person named. The newly appointed Principal Investigator notifies the EC that he or she has read the protocol and agrees to accept the responsibility of the Principal Investigator for that research study. This new Investigator starts research work only after completion of required applicable training.

2.4 Principal Investigator shall ensure that the informed consent form signed by or on behalf of the Study subjects have been reviewed and approved by Ethics Committee prior to initiation of the Study. Upon approval of the informed consent form by the Ethics Committee, a copy of the approval letter shall be provided to the Pharmazz by the Principal Investigator, who shall further obtain informed consent form duly signed by each of the subjects or on behalf of the Study subjects enrolled in the Study in accordance with Applicable Laws and Guidelines. The Principal Investigator shall ensure to maintain for record an audio – video recording of the informed consent process of individual subjects including procedure of providing information to the subjects and their understanding on such consent. However, the audio-video recording shall be shared with the Ethical committee or the regulatory agency if required. The Study of the Pharmazz is being entrusted to the Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** as a technical assignment, based on the skill, knowledge and experience of the Principal Investigator in the specialty areas related to the Clinical Trial and **Sanjay Gandhi Post Graduate Institute of Medical Sciences's** experience in conducting Clinical Trial and requisite infrastructure and logistics. The Principal Investigator shall be personally obligated to conduct and complete the Clinical Trial in accordance with the Protocol as well as other terms and conditions specified by the Pharmazz herein. All items received from the Pharmazz, from time to time, (including, but not limited to, Study Drug, documents, Confidential Information, communications, instructions etc.), records and registers required to be maintained and all data generated hereunder by the Principal Investigator, shall be under the exclusive care, custody and responsibility of the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences** throughout the period of the Clinical Trial and **with third party vendor or sponsor** for a period of fifteen (15) years after the Study completion or such longer period as required by Applicable Laws & Guidelines. At the end of such period mentioned above, the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall obtain written approval from Pharmazz before destruction of such data.

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2.5 Principal Investigator agrees to follow Sponsor's requirement for the Study related duties and functions under this Agreement and the Protocol.

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Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall ensure that all the individuals involved in the conduct of the Study shall strictly adhere to the terms and conditions of this Agreement. **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and Principal Investigator represents and warrants that it shall not use in any capacity, in connection with the Study, any individual who is not duly qualified or has been debarred pursuant to any Applicable Laws & Guidelines or against whom any action, suit, claim, investigation or legal or administrative proceeding is pending.

2.6 Principal Investigator represents and warrants that no action, suit, claim investigation or legal or administrative proceeding is pending or threatened relating to Principal Investigator's debarment and/or debarment of the persons engaged by Principal Investigator to assist for the Study.

2.7 Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences** represents and warrants that all the necessary approvals, permissions and sanctions from Ethics Committee and all the government and regulatory authorities to conduct the Clinical Trial have been obtained **Sanjay Gandhi Post Graduate Institute of Medical Sciences.** The Pharmazz will provide the Study Drug to the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences** free of cost/charge and in such quantities sufficient to complete the Study, together with guidelines and descriptions for the safe and proper use, administration, storage and disposal of the Study Drug. Principal Investigator shall use Study Drug and other items provided by the Pharmazz only to conduct the Study in accordance with the Protocol and Applicable Laws & Guidelines and instructions of the Pharmazz and shall not chemically, physically or otherwise modify the Study Drug, unless specifically required to do so by the Pharmazz in writing to the Principal Investigator. Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** jointly and severally agrees that they shall administer, handle, use, store, and or dispose the Study Drug and other items provided by the Pharmazz in compliance with Pharmazz's instructions and all Applicable Laws & Guidelines.

The Parties hereby clearly understand that the subject matter of the Agreement is to clinically evaluate the Safety and Efficacy of PMZ-1620 therapy along with standard supportive care in subjects of acute ischemic stroke.

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VISIT AND INSEPECTION

3.1 The Pharmazz or its authorized representatives, and regulatory authorities to the extent permitted by law, shall have the absolute right to:

a. examine and inspect the **Sanjay Gandhi Post Graduate Institute of Medical Sciences's** facilities whenever Principal Investigator is conducting Study;

b. Inspect and copy all data and work products relating to the Study, and audit all

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reports and data from Principal Investigator to ensure compliance with the terms of this Agreement and Protocol.

c. Sponsor will provide the Investigator with the monitoring reports timely for review and consideration.

4 RECORDS AND REPORTING

The sponsor agrees to promptly report any new findings to the Institution/Investigator that could affect the safety of participants or influence the conduct of the study. The sponsor agrees to promptly report Data and safety monitoring reports to the Institution/Investigator.

The sponsor agrees to communicate findings from a completed study to the Investigator and Institution when those findings directly affect participant safety. These findings would be communicated within (03 months) after completion of the study.

5 PAYMENT, PRICING TERMS

5.1 Pharmazz agrees that in consideration of the Principal Investigator's and Sanjay Gandhi Post Graduate Institute of Medical Sciences carrying out the Clinical Trial in accordance with the terms of this Agreement, the Pharmazz shall make the payment of the amount as set forth in Exhibit B, to the **Director SGPGI, Research Account** in accordance with the payment schedule set forth therein which shall include the remuneration and all other related cost.

5.2 The Parties agree that the payment of the amount set forth in Exhibit B will be paid by the Pharmazz to the **Director SGPGI, Research Account** to compensate all the expenses incurred by them in execution and conducting the Clinical Trial so that, neither the Study subject, nor the insurance program nor the public assistance agency nor the Sponsor shall be liable for the same. The payment of the amount set forth in Exhibit B is also meant to compensate Principal Investigator for the professional and clerical allowances for all the activities as per the Protocol including but not limited to, preparation of the subject records, medication accountability records and other trial related documentation.

5.3 The Parties agree that the amount of payment as mentioned in Exhibit B to be paid to **Director SGPGI, Research Account** shall be paid by Pharmazz. This amount is based on the estimated number of subjects in the time duration as agreed by Principal Investigator as per site feasibility report Exhibit D. Any change in the estimated number of subjects will proportionally affect the amount of payment.

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5.4 Pharmazz shall be entitled to deduct tax at source i.e TDS (if applicable) while making payment to **Director SGPGI, Research Account** under this Agreement. The Budget as reflected in Exhibit B is exclusive of taxes.

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5.5 Site will raise GST invoices visit wise as mentioned in Exhibit B. All payments under this Agreement will be made within 15 days from the date of receipt of Invoice.

6 REPRESENTATION AND WARRANTIES

6.1 Each Party represents that it is authorized to enter into this Agreement and that the terms of this Agreement are not inconsistent with or a violation of any contracted or other legal obligation to which it is subject.

6.2 Each Party represents that in performing under this Agreement it shall (a) conduct business in conformance with sound ethical standards of integrity and honesty; b) conduct business in such a way as to not give the appearance of impropriety, even when the behavior or activity is in compliance with the law; and (c) not achieve business results by illegal act or unethical conduct, corrupt and fraudulent practice.

6.3 Sponsor represent that it has all necessary or appropriate qualifications, authorizations, licenses or permits as the sponsor to conduct the study.

6.4 The Parties understand and agree that neither Principal Investigator / Institution's provision of the Services nor its receipt of consideration under this Agreement, shall require, induce, or in any way influence the Principal Investigator / Institution or any of its Affiliates to promote, recommend, require the use of, or list on any formulary, any pharmaceutical product reviewed or involved in the provision of the Services, or any pharmaceutical product manufactured, produced or distributed by Sponsor, or to not list any other pharmaceutical product on any formulary.

7. COMPLIANCE OF LAW

In performing its obligations and exercising its rights under the agreement, **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and PI shall fully comply with all applicable law of India (including without limitation all statutes, Labour Law legislation, decrees, all relevant testifying certificates, ordinances, administrative orders, rules, regulations, and other mandatory directives, policies, and instructions with binding legal effect)

The Second Party i.e. **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall be solely liable to pay all costs of such compliance. In addition, the Second Party shall be solely responsible to obtain in a timely and effective manner all licenses, permits, and other approvals, if any, necessary for Second Party's successful implementation of its objective under the agreement.

Sanjay Gandhi Post Graduate Institute of Medical Sciences and PI are jointly and severally responsible for all costs, risks, damages, and other liability incurred by it as a result of its failure to comply with the applicable law.

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The Second Party and PI will provide the Sponsor with all necessary documentation to support Sponsor's regulatory filings, as and when required.

8. TERMS AND TERMINATION

8.1. This Agreement shall come into effect on the Effective Date and shall remain in effect for a period of one year from the Effective date of this Agreement. This agreement can be extended with mutual understanding, if the trial is not complete.

8.2 Both Parties have the right to terminate this Agreement with or without cause by giving the other Party 90 day written notice.

8.3 On termination or expiry of this Agreement in accordance with the terms hereof, **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and the Principal Investigator shall be discharged from all its obligations and duties under this Agreement.

9 VALIDITY & TERMINATION

9.1 Pharmazz may unilaterally terminate this agreement at any time, in whole or in part, for any of the following reasons by giving thirty (30) days written notice: -

a) Material breach of trust by **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and PI

b) **Sanjay Gandhi Post Graduate Institute of Medical Sciences** financial insolvency, bankruptcy, assignment in favor of creditors or similar or comparable status

c) Determination by the Pharmazz that the Principal Investigator is not performing the Study as required in the Protocol and/or is not meeting the agreed parameters upon enrollment and as per his undertaking and site feasibility report provided **(Exhibit D);**

d) Failure of the Principal Investigator's or its associated staff or any other person engaged in the Study (excluding subjects) to be available, upon reasonable prior notice by the Pharmazz, to meet at mutually convenient time with the Pharmazz enabling it to monitor the course of the Study as necessary and to discuss information relevant to the Study;

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e) Determination by the Pharmazz that business or safety reasons relating to the use of the Study Drug or scientific considerations require termination;

f) At the request of either DCGI or Ethics Committee;

g) Notification to the Pharmazz from central or state regulatory authorities to terminate the Study;

h) Failure of the Principal Investigator **Sanjay Gandhi Post Graduate Institute of Medical Sciences** to provide access by the Pharmazz's representatives all

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original medical records necessary to verify entries on the Study case report forms/ electronic case report forms;

10 SUSPENSION

The agreement may be suspended in whole or in part, at any time or from time to time: (1) by mutual agreement; (2) for Second Party's and PI's default or substantial non-compliance with the requirements of the agreement. In each case, written notice will be issued stating the effective date of the action.

The cure period shall be effected by written notice to the Second Party and PI, which notice shall identify the basis for suspension and/or possible termination, the reason(s), therefore, the effective date of the action, a statement identifying which part (or all) of the remainder of the agreement Term or the program activities are subject to possible termination, and procedures and standards, as appropriate, for phase down costs and submission of final invoices. The notice shall be effective on the date stated in the notice, or the date the notice is delivered to Second Party and PI, whichever is later. The Second Party and PI shall be given reasonable opportunity to present to the Pharmazz a plan of corrective action and shall have (thirty) 30 days to cure all issues as identified in the notice. If Pharmazz and Second Party mutually agree on the plan in writing, Second Party and PI will be provided an additional period of time, specified and agreed to in writing by the parties, to remedy the delay in meeting its obligations. If Pharmazz is dissatisfied with the corrective action plan or failure of Second Party and PI to meet the deadline of (30) days for corrective measures then Pharmazz may terminate the agreement in whole or part effective on such date.

11 EFFECT OF TERMINATION

11.1 Upon receipt of notice of termination, the Principal Investigator shall immediately stop enrolling subjects into the Study and to the extent medically permissible, cease administering the Study Drug and conducting Clinical Trial on subjects already entered into the Study. In case of early termination of this Agreement, due to any reason the Principal Investigator shall request all Study subjects within one month from the date of termination notice to attend a follow up visit for proper safety assessment of the subjects enrolled. The Principal Investigator shall use all reasonable efforts to check for completion of reports as per protocol and Investigator brochure for all subjects that have been entered into the Study prior to the date of termination of this Agreement.

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11.2 Upon termination or completion of the Study, the Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall return or certify in writing to the Pharmazz all unused Study drugs, case report forms, whether completed or not and other related materials including but not limited to materials that were

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furnished to the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** by or on behalf of the Pharmazz. In case, the Pharmazz desires destruction of aforementioned material, the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall return such material to Pharmazz.

12 INDEMNIFICATION; LIMITATION ON LIABILITY; INSURANCE

12.1 The Pharmazz irrevocably agrees that it shall indemnify, defend and hold harmless the Principal Investigator, **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and all its directors, staff and agents from and against any and all, damages, suits, actions, claims, costs and expenses including reasonable attorney's fees related to the clinical trial or arising as a result of (i) either breach of any representation/warranty made by the Pharmazz herein and or (ii) of personal injury to (including death of) Study subject, except to the extent such claims are attributable to:

a) the failure of the Principal Investigator, any co-investigator or any other personnel involved in the performance of the Study to adhere to the terms of the Study Protocol or any written instruction relative to the administration, use, handling, storage of any drugs used in the performance of the Study, or comply with any Applicable Laws & Guidelines; or

b) any negligent or wrongful act or omission, or willful malfeasance/misconduct of the Principal Investigator/co-investigator/any other personnel (including employees, agents or independent contractors) involved in the performance of the Study.

The indemnity granted in this Article shall apply separately to each Indemnity in such manner and to the same extent as though a separate indemnity had been given to each. Said indemnity shall survive the completion or early termination of this Agreement.

12.2 It is a condition precedent to the Pharmazz's indemnification obligations under above mentioned clause 12.1 that:

a) Whenever Principal Investigator has information from which it may reasonably conclude an incident of bodily injury or death has occurred, Principal Investigator shall immediately give notice to Pharmazz of all pertinent data surrounding such incident. In addition, Principal Investigator shall comply with all of their obligations with regard to adverse event reporting procedures as set forth in this Agreement and the Protocol; and

b) the Principal Investigator under clause 12.1 above must (i) promptly notify the Pharmazz of the assertion of any such claims (ii) authorize and permit Pharmazz to conduct and exercise sole control of the defense and deposition (including all decisions relative to litigation, appeal or settlement) of such claims and (iii) fully cooperate with Pharmazz regarding any such claims (including access to pertinent records and documents and provision of relevant testimony) and in determining the scope of Pharmazz's obligations hereunder. Subject to the foregoing, Principal

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Executive Registrar
SGPGIMS,Lucknow

Investigator may also participate with prior consent of the Pharmazz in any such claims at his own cost and expense. Principal Investigator agrees to cooperate with and to authorize Pharmazz to carry out sole management and defense of such claim or action. Principal Investigator shall not compromise or settle any claim or action without the prior written approval of Pharmazz.

The Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** hereby irrevocably agree that they shall indemnify and hold harmless the Pharmazz, its present and future directors, officers and or employees against any and all, damages, suits, actions, claims, costs and expenses including reasonable attorney's fees and any cost of medical treatment of any illness or injury sustained by a Study subject, (collectively the "**Claims**") arising out of or in relation to (i) any breach of any of the representations and/or warranties made/held out by the Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** in this Agreement; or (ii) breach of any of the terms of this Agreement by the Principal Investigator, the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** or any individual engaged by Principal Investigator to support him in the conduct of the Study; or (iii) intentional deviation or omission or negligence in conducting the Study by the Principal Investigator, the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** or any individual engaged by Principal Investigator to support him in the conduct of the Study; or (iv) failure to follow the instructions of Pharmazz by the Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences**; or (v) failure of the Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** to conduct the Study in accordance with the Protocol, Applicable Laws & Guidelines. The Institution and the Principal Investigator however shall in no event be liable whether in contract, tort, misrepresentation, negligence or otherwise, for any remote, indirect, incidental or consequential damages arising out of or in connection with this Agreement, or any performance, non-performance or breach of any provision hereof if the same is due to negligence and / or misconduct on the part of Pharmazz.

Sponsor warrant that they shall provide a diligent defense against and/or settlement of, any claims brought or actions filed for the loss which is the subject of the indemnity, whether such claims or actions are rightfully or wrongfully brought or filed. Sponsor shall have the right to settle claims at its sole expense.

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12.3. Sponsor shall provide the cost of medical management and compensation as per Rule 22-DAB-Compensation in case of injury or death due to study drug during the conduct of clinical trial.

a) In case of an injury occurring to the clinical trial subjects, he or she shall be given free medical management as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.

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SGPGIMS,Lucknow

b) In case the injury occurring to the trial subject is related to the clinical trial, such subject shall also be entitled for financial compensation as per order of the Licensing Authority defined under clause (b) of rule 21, and the financial compensation will be over and above any expense incurred on the medical management of such subject.

c) The expense on medical management and financial compensation in the case of clinical trial injury or death of the trial subject shall be borne by the sponsor of the clinical trial.

12.4 **Insurance**

The Pharmazz undertakes that it will secure and maintain in full force and effect throughout the performance of the Study (and following termination or early termination of the Study and to cover any claims arising from the Study) a clinical trial liability insurance policy from an Indian insurance company for an amount appropriate to, and in accordance with, the DCGI rules. This Insurance covers the Clinical Trial to be conducted for the Study at **Sanjay Gandhi Post Graduate Institute of Medical Sciences.** The Insurance policy is attached at Exhibit E.

13. PUBLICATION OF RESULTS

It is the general policy of the Pharmazz to encourage publication of results of Clinical Trial on a case to case basis. However, according to good scientific practice no interim data should be published by the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences** unless agreed by the Parties in writing. It is further agreed that when the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences** request for publications, the manuscript shall be based on final report of the Study and before any publication it shall be sent to the Pharmazz for its perusal, comments and approval. The Pharmazz may at its discretion may either refuse the publication or forward it to the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences** along with its comments or modifications which shall be final and binding on the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences.**

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14. PUBLICITY AND PRODUCT PROMOTING ACTIVITY

It is agreed that no Party shall issue any press release or other third party communication relative to this Agreement without the prior written consent of the other Party except to the extent that the Pharmazz shall have absolute right to issue any press release relating to the Study related data. Principal Investigator shall not use the name of the Pharmazz and/or its employees in any advertising or sales promotional material or in any other way not required by law or regulation without the prior written consent of the Pharmazz.

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15. INTELLECTUAL PROPERTY RIGHTS

Sanjay Gandhi Post Graduate Institute of Medical Sciences agrees that all the Intellectual Property Rights with regard to **PMZ-1620** are and shall remain Pharmazz's exclusive property, and understands that **Sanjay Gandhi Post Graduate Institute of Medical Sciences** acquires no right, title, or interest in the Intellectual Property and the know-how used/created for the purpose of this Agreement. **Sanjay Gandhi Post Graduate Institute of Medical Sciences** agrees that all rights that may be created by the use of the Intellectual Property under this Agreement by **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall inure to the sole benefit of Pharmazz and shall be the exclusive property of Pharmazz. **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall not at any time do or suffer to be done any act which would impair materially Pharmazz's proprietary rights in or to, or infringe, any Intellectual Property Rights of Pharmazz.

Pharmazz will be exclusively responsible if any dispute or claim arises regarding the ownership of the patent rights, copy rights & trade mark rights used by Pharmazz.

16. CONFIDENTIALITY

a) The Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** agree to keep confidential and secret all materials, documents and confidential information that the Pharmazz discloses to the Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** pursuant to this Agreement and also all materials, documents and information's gathered, generated or developed by Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** under the Study including but without limitation to results and discoveries emanated from the Study, regardless of whether such information is marked as "Confidential," "Proprietary" or the like, which is furnished to the Principal Investigator by or on behalf of the Pharmazz whether in written, electronic, oral, visual or other form ("**Confidential Information**").

b) The Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** agree, represent and warrant that any Confidential Information that they receive shall be protected at least, with the same degree of care and protection in the strictest confidence as of its own and shall take all reasonable measures to protect it. The Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall use such Confidential Information only for the purpose of fulfilling their obligations mentioned herein and shall not disclose such Confidential Information without the prior written consent of the Pharmazz to any third party except as required by law provided that the Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall:

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First give prompt notice of such disclosure requirement to the Pharmazz so as to seek any limitations on or exemptions from such disclosure requirement; and

Reasonably co-operate with the Pharmazz in any such efforts of defense in the confidential and proprietary information to be made before appropriate authority.

c) Principal Investigator and/or the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** may disclose Confidential Information to their co-investigator, hospital authorities, Ethics Committee members and others who are required to be involved in the Study on a need-to-know basis provided that: (i) such receiving party shall always remain liable to maintain the confidentiality in terms hereof and (ii) all such receiving party shall be bound by obligations of confidentiality with respect to such Confidential Information at least as stringent as those provided herein. Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall be liable for any breach of this Agreement by its representatives. The obligations of confidentiality hereunder shall continue for a period of fifteen (15) years from the date the Confidential Information is disclosed or developed. The obligation of confidentiality hereunder shall not apply to information that Principal Investigator and/or the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** can prove and produces credible written evidence to establish that such information or material:

i. at the time of disclosure or after disclosure to the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences** becomes part of the public domain by publication or otherwise, except by breach of this Agreement by the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences** or their successors or assigns;

ii. by written records were in the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences**'s possession at the time of disclosure by the Pharmazz were not acquired directly or indirectly from the Pharmazz;

iii. subsequent to disclosure hereunder, the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences** receives from a third party legally in a position to provide with information to the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences,** provided, however, that such was not obtained by said third party directly or indirectly from the Pharmazz under an obligation of confidentiality.

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d) All clinical data, including case report forms and other information and discoveries resulting from the Study ("**Inventions**") shall be the sole property

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of the Pharmazz and will be treated as "Confidential Information" by the Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and may be used by the Pharmazz in any manner. Further, Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall assign to the Pharmazz all of their rights, title, and interest in such Inventions.

e) All Confidential Information disclosed pursuant to this Agreement, together with all copies thereof, summaries and all information, know-how, data and materials generated by the use of the Confidential Information, shall be returned to the Pharmazz by Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** forthwith upon written request or upon termination of this Agreement, whichever is earlier.

f) Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** agree that the Confidential Information is of a special and unique kind, the protection of which is essential to the operation of the Pharmazz, and that if there is a breach (either actual or **threatened) by the Principal Investigator/ Sanjay Gandhi Post Graduate Institute of Medical Sciences** or co-investigator or a party in receipt of Confidential Information under this Agreement, the Pharmazz would have complete remedy at law. Therefore, in addition to any other remedies that may be available at law or equity, Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** agree that the Pharmazz shall be entitled to seek from any court of competent jurisdiction, injunctive relief, specific performance or other equitable relief, for any actual or threatened violation of this Agreement (without the necessity of posting any bond or other security proving special damages) and that the Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall not oppose the granting of such relief. In the event of any litigation relating to this Agreement, if a court of competent jurisdiction determines that this Agreement has been breached by one Party, then that Party shall reimburse the non-breaching Party for all its costs and expenses (including, without limitation, attorney fees and other legal expenses) incurred in connection with all such litigation.

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g) Institution Information. During performance of this Agreement, Sponsor representatives may gain access through site visits or otherwise to information relating to Institution's business or research operations, policies, or procedures that Institution identifies to Sponsor as proprietary and confidential or that is reasonably apparent to Sponsor to be so. Unless Institution provides written consent, Sponsor will not copy or remove such information, use such information for any purpose other than performance of this Agreement, or disclose such information to any third party except as required by law.

17. SEVERABILITY & WAIVER AND ASSIGNMENT

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a) The invalidity or unenforceability of any term or provision of this Agreement, the remaining provisions shall stand to the fullest extent permitted by law. The failure of any Party at any time or times to require performance of any provision hereof shall in no manner affect the right of such Party at a later time to enforce such provision or any other provision of this Agreement. The parties agree that they negotiate in good faith or will permit a court/ Arbitration to replace any provision hereof so held invalid with a valid provision.

b) Waiver by either Party or the failure by either Party to claim a breach of any provision of this Agreement shall not be deemed to constitute a waiver or estoppels with respect to any subsequent breach of any provision hereof but only by an instrument in writing..

c) This Agreement shall not be assigned as a whole or in part by any party without the prior written consent of the other parties except for the following types of general support services: communication, translation, photocopy of documents or similar services, failing which all actions taken will be null and void.

18. MISCELLANEOUS

a) It is agreed by the Parties that the Principal Investigator and Sanjay Gandhi Post Graduate Institute of Medical Sciences shall act in the capacity of independent contractor hereunder and not as employees, agents or joint ventures of or with any Parties including Pharmazz. Neither Principal Investigator nor **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall have any authority to represent, or bind the Pharmazz.

b) Principal Investigator shall comply with all the terms of the undertaking annexed hereto as **Exhibit C** and be read as part of this agreement, he has provided to the Pharmazz under this Agreement.

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c) This Agreement contains the entire understanding of the Parties hereto and supersedes all prior oral and written agreements and understandings of the Parties except confidentiality agreement, if any, pertaining to the subject matter hereof.

d) If the terms contained in any of the Exhibit attached hereto conflict with any provisions contained in this Agreement, the terms contained in this Agreement shall prevail. Unless otherwise provided herein, this Agreement may not be amended, supplemented or otherwise modified except by an instrument in writing signed by the Parties hereto.

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e). The governing (applicable) language of this agreement shall be English, and all notices and other communications relating or pursuant to the provisions of the agreement (including, without limitation, those in connection with issues, disagreements and disputes) shall be in such language. This agreement, its formation and the facts and circumstances surrounding its making and performance, shall be interpreted in accordance with the following, and listed in order of precedence: (1) the express terms and conditions of the agreement; (2) the local laws of India

19. NOTICES

19.1. Unless otherwise provided herein, any communication, notice or notice of conditions interfering the performance of the agreement, report, payment or document to be given by one party to the other shall be in writing and shall be deemed given when received and acknowledged in case of electronic mode: Notifications shall be made to the following addresses:-

Pharmazz	**Sanjay Gandhi Post Graduate Institute of Medical Sciences**	**Principal Investigator**
Mr. Sunil Gulati Chief Operating Officer	Dr. Rakesh Kapoor Director SGPGI	Dr. U.K Misra Principal Investigator
Pharmazz India Pvt. Ltd. B-4 Sarita Vihar New Delhi 110076 **Email**: sunil.gulati@pharmazz.com	Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow- 226014 **Email:** director@sgpgi.ac.in	Department of Neurology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow-226014 **Email:** ukmisra@rediffmail.com

19.2.1. Any dispute or difference whatsoever arising between the Parties out of or relating to the construction, meaning, scope, operation or effect of this Agreement or the validity or the breach thereof shall be exclusively settled by arbitration., which shall be governed by the Arbitration and Conciliation Act, 1996 as amended from time to time. The arbitral tribunal shall comprise of sole arbitrator to be appointed as per provisions of Arbitration and Conciliation Act, 1996 as amended from time to time. The language to be used in the arbitral proceedings shall be English. The award rendered by the arbitrator shall be final and binding upon the Parties hereto. Place of Arbitration shall be Delhi and both the parties shall bear the cost of arbitration in equal excluding counsel cost Parties agree that for claiming injunctive relief and for the enforcement of arbitral award only Delhi courts shall have exclusive jurisdiction

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in all matters arising out of or with this Agreement. This Agreement shall be governed by Laws of India.

20. RENEWAL CLAUSE

The agreement can be renewed by way of mutual consent of the parties in the event of requirement of further study of the protocol to complete the obligations enumerated herein above.

21. FORCE MAJEURE

Any delay or failure by the either party of required obligations shall be excused if and to the extent caused by acts of God, fire, storm, lockout, strike, terrorist act, flood, sabotage, Government Notification/ order, embargo, war (whether declared or not), riot, or other causes beyond the reasonable control of the said Party. If and when either party asserts Force Majeure as an excuse for failure to perform their obligations, then the said Party must notify the other Party in writing and upon the review of the said party's notice, the other Party shall determine whether the term of the agreement shall be extended for a reasonable time period to complete activities interrupted by the delays.

22. FURTHER ASSURANCES

Each party agrees that subsequent to the execution and delivery of this Agreement it will execute and deliver any further legal instruments and perform any acts which are or may become reasonably necessary to effectuate the purposes of this Agreement.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be duly executed as of the date first set forth above in triplicate each being legally authentic and binding.

For **Pharmazz India Pvt. Ltd.**	For **Sanjay Gandhi Post Graduate Institute of Medical Sciences**	**Principal Investigator**
Signature: ..... Name: Mr. Sunil Gulati Title: Chief Operating Officer	Signature: ..... Name: Dr. Rakesh Kapoor Title: Director, SGPGI	Signature: ..... Name: Dr. U.K. Misra Title: Principal Investigator

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DIRECTOR
Sanjay Gandhi Post Graduate Institute of Medical Sciences
LUCKNOW-226014, INDIA

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Exhibit-A

Clinical Trial Protocol

REFERENCE ENCLOSED

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(5)

Exhibit B

(Budget and Payment Schedule)

Budget

Total duration of Study	**9 months**		
Subject enrollment duration	**6 months**		
Total number of subjects	**15**		
Payment heads	**Total per subject**	**No. of Subjects**	**Amount per Head**
Investigator's Fees (In Rupees)	18000	15	270000
Study Coordinator Fees (In Rupees)	10000		150000
Protocol Procedures (Lab expenses) (In Rupees)	4425		66375
CT/ MRI cost (In Rupees)	4800		72000
Subject Travel (In Rupees)	2500		37500
Institutional Overhead on Investigator's & Coordinator's fees (In Rupees)			105000
Total Study Budget (In Rupees)			700875

- Protocol Procedures includes Lab expenses that is composed of cost of all the tests mentioned in protocol excluding Troponin T test, INR 55 shall be added to the Protocol procedures on Visit 1 (Baseline) for UPT if the subject is female.
- Recruitment of estimated number of trial subjects should be completed within 6 months.
- Archival fee will be paid on close out visit and it will be as per the institutional EC SOP.
- In addition to the above fee, Pharmazz shall pay for unscheduled visit (only if required) activities listed in Protocol.
- GST invoices required for release of payments visit wise.

Payee Details-

Payee Name	Director SGPGI, Research Account
Name of the Bank & Branch	State Bank Of India
A/C No:	10095237492
IFSC	SBIN0007789
MICR	226002034
PAN No./TAN No.	AAAJS3913N
GST No. (if applicable)	Not applicable

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Exhibit-C

Principal Investigator's Documents

REFERENCE ENCLOSED

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(3)

Exhibit-D

Site Feasibility Questionnaire Filled and Accepted by PI

REFERENCE ENCLOSED

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Executive Registrar
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Exhibit-E

Insurance Policy for study

REFERENCE ENCLOSED

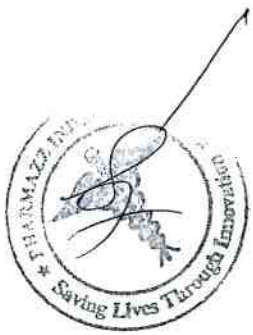

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Exhibit-F

Phase II Clinical Trial NOC

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GOVT. OF KARNATAKA
DEPT. OF STAMP & REGISTRATION
भारत INDIA 20955 195333 SEP 18 2018 कर्नाटक
Rs.0000100 PB6936
STAMP DUTY KARNATAKA
Sub Registrar
Bommanahalli.

CLINICAL TRIAL/STUDY AGREEMENT

This agreement is made on this 18 Sep 2018 by and between "**Norwich Clinical Services**" a company incorporated under Companies Act, 1956 and having its registered office at No.147/F, 8th main, 3rd block, Koramangala, Bangalore-560034, (hereinafter referred to as **CRO/Sponsor Representative**), which expression unless repugnant to the context or meaning thereof shall include its successors and permitted assigns) being of the One Part;

AND

"Dr. Raghunandan Prasad" working at **Sanjay Gandhi Post Graduate Institute of Medical Sciences(SGPGI), Rae Bareli Road, Lucknow-226014** (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 Second Part;

And

Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGI), Rae Bareli Road, Lucknow-226014 of the third part.

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

"**Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization- A Phase IV study.**" in accordance with applicable laws including but limited to Declaration of Helsinki, Schedule Y of Drugs and Cosmetics Act, 1940 and the rules framed there under, Good Clinical Practices (GCP), Good Laboratory Practices (GLP) and ICMR Guideline 2017, on patients as stated in the protocol (hereinafter referred to as the subjects).

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1. The SPONSOR (GUERBET a company registered in France) 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;

1.1. **CRO/Sponsor representative** is a professional clinical research organization in India engaged in the business of undertaking bio studies, Clinical Trial Services and pharmacovigilance services in conformance to international standards.

1.2. The CRO has 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.

1.3. The CRO has 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.

1.4. Whereas the CRO desires to enter into agreement with **Sanjay Gandhi Post Graduate Institute of Medical Sciences** & Dr. Raghunandan Prasad to conduct the study in the Sanjay Gandhi Post Graduate Institute of Medical Sciences.

1.5. The CRO has agreed to engage Dr. **Raghunandan Prasad** who is a Specialist in the therapeutic area required for the study, be a Principal Investigator for the study mentioned above.

1.6. The CRO has agreed to engage Sanjay Gandhi Post Graduate Institute of Medical Sciences & the Principal Investigator for providing the services contemplated under this agreement, subject to the terms and conditions contained herein.

1.7. Whereas during the term of this Agreement, the terms and conditions herein contained shall govern the services to be provided by the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** & Principal Investigator to CRO under any subsequent individual agreement for specific services to be rendered, referred to as a Specific Protocol

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1.8. The Project shall be conducted as per the CRO/sponsor's confidentiality requirements.

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49

1.9. **Sanjay Gandhi Post Graduate Institute of Medical Sciences &** the Principal Investigator agree that the CRO/sponsor shall, subject to prior intimation to the Hospital and the P.I., have the right to enter their facility at reasonable times to inspect the facility, and the performance of the services hereunder. The CRO and the sponsor shall have the right to inspect and audit **Sanjay Gandhi Post Graduate Institute of Medical Sciences** & the Principal Investigator records only to the extent they relate to services performed by **Sanjay Gandhi Post Graduate Institute of Medical Sciences** & the Principal Investigator hereunder for which the CRO is making payment to **Sanjay Gandhi Post Graduate Institute of Medical Sciences &** the Principal Investigator.

1.10. 1.10.1. Such rights shall, however, be only exercised by the CRO and the sponsor during **Sanjay Gandhi Post Graduate Institute of Medical Sciences** & the Principal Investigator's normal business hours at a mutually agreed time and only following reasonable prior notice (48 hours prior notice being presumptively reasonable).

1.11. During the term of this Agreement, Sanjay Gandhi Post Graduate Institute of Medical Sciences & Principal Investigator agrees to diligently and conscientiously use its reasonable efforts to discharge its obligations in the Project as per the terms agreed hereunder, requested from time to time by the CRO/sponsor.

1.12. Responsibilities of **Sanjay Gandhi Post Graduate Institute of Medical Sciences** & Principal Investigator include providing such advice and information relating to the results of the studies subject matter of the Project as CRO/sponsor may reasonably request in writing from time to time to **Sanjay Gandhi Post Graduate Institute of Medical Sciences** & Principal Investigator.

1.13. Notwithstanding the provisions of this clause, nothing in this Agreement shall preclude **Sanjay Gandhi Post Graduate Institute of Medical Sciences &** Principal Investigator from providing services to any other person or entity for such Project which is similar to the one undertaken in this Agreement.

1.14. The CRO expressly will have exclusive ownership interest in information, results; data developed or conceived under this Agreement and the studies covered by this agreement.

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PAN No. - AAAJS3913N

- Limited within 45 days after the receipt of invoice from the Hospital.
- Investigator payments will be made after the receipt of completed CRFs.
- In case of patients not completing the study, payment of investigator fee will be made on prorate basis, up to the stage of study completion for that patient as per the calculation above.
- For SAE's if any, 20% of the fee payable to the Investigator will be withheld and released only on completion of reporting, follow-up and relevant documentation.
- The above payments will be subject to TDS at the applicable rates.

Note:

"In case of an injury occurring to the subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier." It is hereby clarified that the cost of the aforesaid medical management shall 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.

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(10)

For NORWICH CLINICAL SERVICES

Signature:

Name: Dr. Saral Thangam

Title: Chief Executive Officer

Date:

NORWICH CLINICAL SERVICES PVT. LTD. BANGALORE

For Principal Investigator

Signature:

Name: Dr. Raghunandan Prasad

Title: Principal Investigator

Date: 25/09/18

For Sanjay Gandhi Post Graduate Institute of Medical Sciences.

Signature:

Name: PROF. RAKESH KAPOOR

Title: DIRECTOR

Date: 29.09.18

DIRECTOR
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

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Executive Registrar
SGPGIMS,Lucknow

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Executive Registrar
SGPGIMS,Lucknow

Appendix E – Insurance

ICICI Lombard
GENERAL INSURANCE

CERTIFICATE OF INSURANCE [CLINICAL TRIALS LIABILITY INSURANCE]

Certificate Number:	4067/CT/GUERBET/16-17 – 001		Policy number: 4067/101887722/01/002
Insured Company:	GUERBET		
Mailing Address:	15 Rue Des Vanesses, VillepinteSeine-Saint-Denis, 93420 FRANCE		
Policy Period:	June 1, 2016 (00.01 hrs)	to	May 31, 2018 (23.59 hrs)
Coverage for the below mentioned trial is effective from:	March 1, 2017		
Retroactive date:	June 1, 2016		

Coverage

The Policy of Insurance listed herein have been issued to the Insured named above for the Policy period indicated. Notwithstanding any requirement, term or condition of any contract or other document with respect to which this Certificate may be issued or may pertain, the Insurance afforded by this Policy is subject to all the terms, exclusions and conditions of such Policy. Aggregate Limit shown may have been reduced by paid claims.

Territorial Scope / Jurisdiction:	India	
Aggregate Limit of Indemnity*:	₹ 74,389,500	
Any One Accident Limit*:	₹ 74,389,500	
Deductible:	₹ 111,584	any one claim including cost and expenses

* this is the total Limit applicable to the Policy and its shared by all the trials covered under this Policy

Limits and Deductibles if indicated in foreign currency are for the sake of convenience only. The policy will be issued in equivalent INR as on the date of inception of cover/ exchange rate agreed.

Study Protocol Number:	LUF-44-001
Study Title	Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization - A Phase IV study
Clinical phase	as per the respective study protocol
Trial Start Date:	March 1, 2017
Estimated End:	June 30, 2018
Sponsor of the trial	GUERBET Address : 15 Rue Des Vanesses, Villepinte Seine-Saint-Denis, 93420 FRANCE

The Country in which the clinical trial take place: India **Number of Human Test Subjects: 125**

Certificate Holder: (optional)

☑ "To whom it may concern."

☐ If to be named on the certificate, state name and address of person/institution to whom the certificate will be handed out:

Required Language of the Certificate: (tick) **Number of Certificates requested:** one

English: (default) ☑

Other: ☐

Date: February 6, 2017

Place: Mumbai

Authorised Signatory

Important Notes: (A) This Certificate is issued as a matter of information only and confers no rights upon the certificate holder (B) This Certificate does not ammend, extend or alter the coverage afforded by the Policy (C) Should above described Policy be cancelled before the expiration date thereof, the issuing Insurer will endeavor to mail 30days written notice to the Certificate Holder (if any name specified above), but failure to do so shall impose no obligation or liability of any kind upon the Insurer, its agents or representatives (D) Inception of the Policy is subject to full-filment of all subjectivites communicated by us and 100% premium received by us (as per Insurance Act of India - Section 64 VB) and the Policy shall stand cancelled ab initio in the event of non-realization of the premium.

ICICI Lombard General Insurance Company Ltd.
Address: # 414, Veer Savarkar Marg [Near Siddhi Vinayak Temple] Prabhadevi, Mumbai, India- 400 025

Prepared By:

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(8)

ICICI Lombard
GENERAL INSURANCE

CERTIFICATE OF INSURANCE [CLINICAL TRIALS LIABILITY INSURANCE]

Certificate Number:	4067-18-19- Guerbet -1	Policy number:	4067/149576020/00/000
Insured Company:	GUERBET		
Mailing Address:	15 RUE DES VANESSES, VILLEPINTE SEINE-SAINT- DENIS, 93420 FRANCE ILE DE FRANCE PARIS PIN - 92654		
Policy Period:	1-Jun-18 (00.01 hrs)	to	31-Dec-18 (23.59 hrs)
Retroactive date:	June 1, 2016		

Coverage

The Policy of Insurance listed herein have been issued to the Insured named above for the Policy period indicated. Notwithstanding any requirement, term or condition of any contract or other document with respect to which this Certificate may be issued or may pertain, the Insurance afforded by this Policy is subject to all the terms, exclusions and conditions of such Policy. Aggregate Limit shown may have been reduced by paid claims.

Territorial Scope / Jurisdiction:	India	
Aggregate Limit of Indemnity*:	INR 74389500	Aggregate limit
Any One Accident Limit*:	INR 74389500	per occurrence limit
Deductible:	INR 111,584	

* this is the total Limit applicable to the Policy and its shared by all the trials covered under this Policy

Limits and Deductibles if indicated in foreign currency are for the sake of convenience only. The policy will be issued in INR and the exchnage rate noted on the policy will be the prevailing rate as on the date of inception of cover. All claims will be paid to the Insured in India in INR.

Study Project Number:	LUF-44-001
Title of the Study:	Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization, a phase IV study
Trial Start Date:	June 1,2016
Estimated End:	31 Dec 18
Sponsor of the trial:	GUERBET
Additional Insured:	All Sites and Investigators are Insured

The Country in which the clinical trial take place: India **Number of Human Test Subjects: As per protocol**

Certificate Holder: (optional)

■ "To whom it may concern."

☐ if to be named on the certificate, state name and address of person/institution to whom the certificate will be handed out:

Date: June 7, 2018

Place: Mumbai Authorised Signatory Prepared by Shreya

Important Notes:(A) This Certificate is issued as a matter of information only and confers no rights upon the certificate holder (B) This Certificate does not ammend, extend or alter the coverage afforded by the Policy (C) Should above described Policy be cancelled before the expiration date thereof, the issuing insurer will endeavor to mail 30days written notice to the Certificate Holder (if any name specified above), but failure to do so shall impose no obligation or liability of any kind upon the Insurer, its agents or representatives (D) Inception of the Policy is subject to full-fillment of all subjectivities communicated by us and 100% premium received by us (as per Insurance Act of India - Section 64 VB) and the Policy shall stand cancelled ab initio in the event of non-realization of the premium.

ICICI Lombard General Insurance Company Ltd.
Address: # 414, Veer Savarkar Marg [Near Siddhi Vinayak Temple] Prabhadevi, Mumbai, India- 400 025

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Appendix F – Indemnity

Guerbet

Confidential

Guerbet

Boîte postale 57400
95943 Roissy CdG Cedex France
Tél. : 33 (0)1 45 91 50 00
www.guerbet.com

Société Anonyme
au capital de 12 501 148 €
Siège social :
15, rue des Vanesses
93420 Villepinte
308 491 521 RCS Bobigny
Siret 308 491 521 00057

NAF 2120 Z

February 1st, 2018

RE: Protocol No. LUF-44-001 "Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization - A Phase IV study" ("Protocol")

Dr. Raghunandan,

Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGI),
Rae Bareli Road, Lucknow-226014

Dear Dr. Raghunandan,

This letter outlines the indemnification obligations that Guerbet ("Sponsor") agrees to assume as sponsor of the Study. The terms of the Study are set forth in the Clinical Trial Agreement executed between Norwich Clinical Services (CRO) and Institution ("Agreement"). CRO is providing clinical research organization services to Sponsor under a separate contract.

Sponsor shall indemnify, defend, and hold harmless "Institution" involved in the Study and their respective trustees, directors and personnel, including Investigator (collectively, the "Indemnitees") from and against any and all liabilities, damages, losses, claims, and expenses, including court costs and reasonable attorneys' fees ("Losses") resulting from or arising out of any third-party claims, actions or proceedings arising out of (i) personal injury to or death of any Study subject enrolled in the Study, which injury or death is caused by treatment of such Study subject in accordance with the Protocol, or (ii) Sponsor's use or publication of Study Data (as defined in the Agreement), in each case solely to the extent that such Losses do not arise out of or in connection with any Institution Indemnitee's (A) failure to comply with this Agreement, the Protocol, any written instructions of Sponsor or CRO concerning the Study, or any applicable law, regulation or guidance, including good clinical practices, issued by any regulatory authority or (B) negligence or willful misconduct.

An Indemnitee claiming a right of indemnification or defense under this letter shall provide Sponsor prompt written notice (in all events within thirty (30) days) of any such claim, including a copy thereof, served upon it, and shall cooperate fully with Sponsor and its legal representatives in the investigation of any matter regarding the subject of indemnification, at Sponsor's expense; provided, however, that failure by an Indemnitee to provide prompt notice shall not relieve Sponsor of its obligations hereunder except to the extent that Sponsor is prejudiced by such failure. Sponsor shall have the right to exercise sole control over the defense and settlement of any such complaint or claims for which indemnification or defense is sought, including the sole right to select defense counsel and to direct the defense or settlement of any such claim or suit; provided that Sponsor shall not enter into any settlement or admit fault or liability on behalf of any Indemnitee without the prior written consent of such Indemnitee, which consent shall not be unreasonably withheld or delayed. An Indemnitee shall have the right to select and to obtain representation by separate legal counsel at the Indemnitee's sole expense.

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In addition to the above, Sponsor shall reimburse Institution for the direct, reasonable and necessary medical expenses incurred by Institution for the treatment of any adverse event experienced by, illness of or bodily injury to a Study subject that is caused by treatment of the Study subject in accordance with the Protocol, except to the extent that such adverse event, illness or personal injury is caused by (A) failure by Institution, Investigator or any of their respective personnel to comply with the Agreement, the Protocol, any written instructions of Sponsor concerning the Study, or any applicable law, regulation or guidance, including good clinical practices, issued by any regulatory authority, or (B) negligence or willful misconduct by Institution, Investigator or any of their respective personnel.

Under no circumstances shall Sponsor be responsible to the Indemnitees for any lost profits, lost opportunities, or other incidental, consequential or special damages.

The Institution shall promptly notify CRO and Sponsor in writing of any claim of illness or injury actually or allegedly due to an adverse reaction to the Study Product and cooperate with Sponsor in the handling of the adverse event.

Sincerely,

Pierre DESCHE
Senior VP, Development & Regulatory Affairs

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INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA70819968564369R
Certificate Issued Date	:	11-Mar-2019 01:15 PM
Account Reference	:	NONACC (FI)/ kacrsfl08/ VIJAYANAGAR2/ KA-BN
Unique Doc. Reference	:	SUBIN-KAKACRSFL08733275547610 34R
Purchased by	:	MYLIN BIOTECH INDIA PVT LTD
Description of Document	:	Article 12 Bond
Description	:	CTA AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	MYLIN BIOTECH INDIA PVT LTD
Second Party	:	SGPGI LUCKNOW
Stamp Duty Paid By	:	MYLIN BIOTECH INDIA PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

MYLIN BIOTECH INDIA PVT LTD IN-KA70819968564369R RS. 100 11-MAR-2019 01:15 PM

Please write or type below this line

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SGPGIMS,Lucknow

CLINICAL TRIAL AGREEMENT

Protocol # NIZY-BYT-MB-18

This Clinical Trial Agreement ("Agreement") is made as on 07.03.2019 between

Mylin Biotech India Pvt Ltd, incorporated under the laws of India with its registered office located at at #40/11-1 2nd floor, Govindraj Nagar, Magadi Road Bangalore -560040 and having PAN:AAICM3171B, including its successors, assigns and Affiliates (hereinafter "**Mylin**");

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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.

and

PROFESSOR Dr. ANITA SAXENA an Indian citizen/resident, with his address at Department of Nephology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Rae Bareli Road, Lucknow – 226014, Uttar Pradesh and having PAN : AAAJS3913N (hereinafter **"Principal Investigator");**

and

Sanjay Gandhi Post Graduate Institute of Medical Sciences, with its address at Rae Bareli Road, Lucknow 226014, Uttar Pradesh (hereinafter **"Institution").**

Mylin Biotech wishes to support a clinical trial entitled Protocol #**NIZY-BYT-MB-18 "A prospective, double blind, multicentric randomized, placebo controlled Interventional study to evaluate the safety and efficacy of Enzobiotics (Synbiotics and Proteolytic Enzymes)in pre dialysis kidney disease patients.**

The parties agree as follows:

1. Definitions:

1.1.1 **Affiliate:** means with respect to a Person, and other Person which, directly or indirectly through one or more intermediaries, Controls, is Controlled by or is under common Control with the first mentioned Person, "Control" shall mean with respect to any Party, the possession, directly or indirectly, of 50% or more of the voting securities and/or the power to direct or cause the direction of the board and/ or management and/or policies of that Person, whether through ownership of voting securities, contract or otherwise.

1.1.2 **Applicable Laws** means any statute, law, regulation, ordinance, rule, judgment, injunction, order, decree, ruling, license, permit, consent, approval, directive, agreement, guideline, policy or restriction, or any requirement or decision or interpretative, legislative or administrative action of, or determination by, any Authority having jurisdiction over the matter in question, or otherwise applicable to the Parties, whether in effect as of the date of this Agreement or at any time thereafter; and including all data protection, privacy, drug, anti-competitive, anti-corruption, anti-bribery as well as export and re-export laws and regulations, GCP and related United States Food Drug Administration ("FDA"), European Medicines Agency ("EMA") and India Food and Drugs Administration (or any other similar Authority), regulations and guidelines.

1.1.3 **Authority** means any constitutional, judicial, governmental, quasi-governmental, legislative, statutory, quasi-judicial, departmental, regulatory or public body constituted by any statute or ordinance or by a court of competent jurisdiction, or any authority having jurisdiction over the Parties or the subject matter of this Agreement.

1.1.4 **Intellectual Property Rights:** includes patents, trademarks, service marks, logos, trade names, internet domain names, copyright and moral rights, database rights, semi-conductor topography rights, rights in designs, rights in inventions, rights in know-how and other intellectual property rights, in each case whether registered or unregistered, and all rights or

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forms of protection having equivalent or similar effect anywhere in the world and the term "registered" includes registrations and applications for registration, rights to Study Results, economic copyrights and know-how therein conceived, generated or reduced to practice during the Study.

1.1.5 **Invention:** shall be understood in the widest sense of the word, in particular including but not limited to patentable and non-patentable technical inventions, discoveries, improvements, and innovations of any kind.

1.1.6 **Party:** means Mylin Biotech, Institution and Principal Investigator and "Parties" shall mean all of them.

1.1.7 **Person:** means any individual, corporation, company, partnership, trust, limited liability company, association or other entity.

1.1.8 **Study Site:** means the premises on which the Study will be carried out.

1.1.9 **Study:** means the investigation to be conducted at the Study Site in accordance with the Protocol.

1.10 **Study Team:** means the Principal Investigator, Sub-Investigator(s), Institution staff, employees Of Institution's Affiliates or any person involved in the conduct of the Study at the Study Site.

1.11.1 **Regulatory Approval:** means any and all permits, consents, grants, approvals, authorizations, licenses, waivers, exemptions, concessions, sanctions, permissions, registrations, certificates, agreements, orders, declarations, filings, reports or notices of, with or to any Authority pursuant to Applicable Law.

1.11.2 **Research Staff:** Institution staff, employees of Institution's Affiliates or any person involved in the conduct of the Study at the Study Site.

2. **Investigators and Research Staff.**

2.1 **Principal Investigator.** The Principal Investigator is an employee of the Institution who will be responsible for the direction of the Trial in accordance with applicable Institution policies. The Principal Investigator commits himself and his Research Staff to conduct the Trial as per the Protocol and the Applicable Laws, against fair compensation.

2.2 **Sub-investigators and Research Staff.** Principal Investigator will ensure that only individuals who are appropriately trained and qualified assist in the conduct of that Trial as Sub-investigators or Research Staff.

2.3 **Obligations of Principal Investigator.** Principal Investigator shall be solely responsible for strict compliance by all Trial personnel, including the Sub-investigators and the Research Staff, with the terms of this Agreement. Principal Investigator shall 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. Principal Investigator will assume all those responsibilities assigned to all principal investigators under various Applicable Laws, rules, regulations, guidelines and standard including without limitation all relevant International Conference on Harmonization Good Clinical Practice ("ICH GCP") guidelines and standards, and all Applicable Laws including those relating to the confidentiality, privacy and security of patient information.

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2.4 The Principal Investigator shall be solely responsible and liable for performance of the obligations under this Agreement by the Study Team. Any breach committed by the Sub-investigator or any other member of the Study Team shall be deemed to be a breach committed by the Principal Investigator. Nothing Contained herein shall discharge or relieve Principal Investigator from its obligations or liability hereunder.

2.5 **No Substitution.** Principal Investigator may not reassign the conduct of the Trial to a different principal investigator without prior written authorization from Mylin Biotech, In the event Mylin Biotech approves such replacement, such replacement principal investigator will be required to agree to the terms and conditions of this Agreement separately in writing. In the event Mylin Biotech does not approve a replacement principal investigator, Mylin Biotech will have the option to terminate this Agreement in accordance with the termination provisions below.

2.6 **Delegation of duties by Principal Investigator.** Principal Investigator may delegate duties and responsibilities to Sub-investigators or Research Staff only to the extent permitted by Applicable Law governing the Trial Conduct, as described below.

2.7 **Compliance with Institutional Policies.** Principal Investigator will comply with the policies and procedures of the Institution, with which Principal Investigator is affiliated, including any applicable financial policies. Principal Investigator will notify Mylin Biotech promptly of any conflict between the terms of this Agreement and any such policy or procedure, and the Parties will attempt to reach an appropriate accommodation.

3. **Protocol.** The Principal Investigator shall conduct the Trial in accordance with the Protocol.

3.1 **Amendments.** The Protocol may be modified only by a written Amendment, signed by both, Mylin Biotech and the Principal Investigator. The parties acknowledge that Protocol Amendments are also subject to approval by the responsible Institutional Ethics Committee ("IEC").

3.2 **Emergency Amendments.** If it is necessary to change the Protocol on an emergency basis for the safety of the Trial Subjects (hereinafter defined), Principal Investigator will notify Mylin Biotech and the responsible IEC as soon as practicable but, in any event, no later than three working days after the change is implemented. Any emergency change to the Protocol must be followed by a written Amendment duly executed by Mylin Biotech and the Principal Investigator.

3.3 **No Additional Research.** Principal Investigator represents and warrants that no additional research will be conducted on Trial Subjects during the conduct of the Trial, unless it is approved by Mylin Biotech in writing, and documented as a companion protocol or an Amendment to the original Protocol. Such prohibited research activities include analyses of biological samples from Trial Subjects for any non-therapeutic purpose.

4. **Institutional Ethics Committee.** Before the Trial is initiated, Principal Investigator will ensure that both the Trial and the informed consent form are approved by an IEC that complies with all applicable regulations. Principal Investigator will further ensure that the Trial is subject to continuing oversight by the IEC throughout its conduct.

4.1 **Trial Disapproval.** If, through no fault of Principal Investigator, the Trial is disapproved by the IEC, this Agreement will immediately terminate with no penalty to the Principal Investigator, as outlined below.

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5. **Trial Conduct.** Principal Investigator will conduct the Trial in accordance with the Protocol, Mylin's or its designee's written instructions and Applicable Law.

5.1 **Trial Initiation:** Prior to initiation of the Trial, Mylin Biotech shall organize an investigator meeting for all investigators who are taking part in the clinical trial for Mylin Biotech, at such place and time as finalized by Mylin Biotech **("Investigator Meeting").** The purpose of the investigator Meeting will including but not limited to, to make the investigators aware about – (i) scientific aspect of the clinical trial; (ii) standard operating procedures including documentation process and adverse event reporting; (iii) Protocol and various regulatory guidelines within which the investigator needs to conduct clinical trial for Mylin Biotech. The Principal Investigator agrees to attend the said Investigator Meeting along with such member of its Research Staff, as approved by Mylin Biotech **("Attendees").** Mylin Biotech agrees that it shall arrange for the travel and boarding and lodging of the Investigator Meeting Attendees.

6. **Mylin Biotech.** Mylin Biotech will provide the Principal Investigator with sufficient quantities of Mylin Biotech product that is being studied **("Mylin Biotech")** to conduct the Trial. If required by the Protocol and unless otherwise agreed in writing, Mylin Biotech will also provide placebo or comparator drug ("**Comparator Drug").**

6.1 **Custody and Dispensing.** Principal Investigator will adhere to Applicable Law and industry standards requiring careful custody and dispensing of Mylin Biotech or Comparator Drug, as well as appropriate documentation of such activities.

6.2 **Control.** Principal Investigator will maintain appropriate control of supplies of Mylin Biotech or Comparator Drug and will not administer or dispense it to anyone who is not a Trial Subject, or provide access to it to anyone except Principal Investigator, Sub-investigators, or Research Staff.

6.3 **Use.** Principal Investigator will use Mylin Biotech or Comparator Drug only as specified in the Protocol. Any other use of Mylin Biotech or Comparator Drug constitutes a material breach of this Agreement.

6.4 **Ownership of Mylin Biotech.** Mylin Biotech is and remains the sole and exclusive property of Mylin. Mylin Biotech grants or assigns Principal Investigator no express or implied intellectual property rights in Mylin Biotech or in any methods of making or using Mylin Biotech.

6.5 **Payment for Mylin Biotech or Comparator Drug.** Principal Investigator will not charge a Trial Subject or third-party payer for Mylin Biotech or Comparator Drug or for any services reimbursed by Mylin Biotech under this Agreement.

7. **Representation and Warranties:**

7.1 The Principal Investigator and Institution hereby jointly and severally represent and warrant to Mylin Biotech the following:

a. The Principal Investigator is trained and qualified to conduct clinical trials at the Study Site, and the Study Team working on the Study shall be appropriately trained in ICH GCP and the Protocol;

b. The Principal Investigator and the Study Team shall perform the Study in an efficient and professional manner and shall complete the Study within the time period as informed by Mylin Biotech from time to time;

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c. The Principal Investigator and Institution shall duly observe and follow all directives, conditions and restrictions, if any imposed by the respective Authority(ies) under the applicable Regulatory Approval. It shall not in any during the course of its business with any other party, breach directly or indirectly, any Applicable Law which may have an impact on the Study in any manner;

d. The Principal Investigator and the Study Team shall conduct the Study under the review and direct supervision of Mylin Biotech, the EC, or an appropriate independent review committee of scientists or other qualified individuals or any such board, body or committee authorized to co-ordinate, review and safeguard the rights, safety and well-being of the Trial Subject;

e. The representation, warranties set or hereunder may be relied upon in any applications of any Authority(ies);

f. The Principal Investigator and/or the Institution shall not, at all times during the term hereof, neither appoint nor utilize the services nor assign the activities of the Study contemplated under the Protocol to any Sub-investigator(s), who is debarred under any regulatory requirements/ Law or statutes from undertaking or performing the Study or the obligations hereunder;

g. The Principal Investigator shall ensure the safe custody of the Study Drug in accordance with the Protocol and shall not use the Study Drug for any purpose other than the purpose of this Agreement;

h. The Principal Investigator and/or the Institution shall publish any data in connection with the Study only in accordance with the Protocol;

i. The Principal Investigator and the Institution shall promptly notify Mylin Biotech in writing of any change in the truth of any of the aforesaid representations;

j. The Principal Investigator shall take necessary and appropriate steps to inform its Study Team of the terms and conditions of this Agreement and to ensure that such persons comply with the terms and conditions of this Agreement;

k. The Principal Investigator and the Institution shall at all times be accountable to Mylin Biotech for any and all breach, action, inaction or omission, committed by the Study Team, support staff and personnel provided by it for conducting the Study;

l. In the event the Study Site is inspected and the Study data are audited / examined by any Authority(ies) having competent jurisdiction under the regulatory requirements or Applicable Laws, the Principal Investigator and/or the Institution shall forthwith notify Mylin Biotech in writing of such inspection, inquiry, audit or examination conducted by such Authority(ies);

m. The Principal Investigator shall co-ordinate, co-operate with and assist in conducting the Study and shall perform such obligations and duties, as may be assigned or imposed upon him/her, in a timely manner, in accordance with the regulatory requirements and Applicable Law;

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n. The Principal Investigator and/or the Institution shall not in any during the course of its business with any other party, breach directly or indirectly, any Applicable Law which may have an impact on the Study / Study Agreement in any manner;

o. The Principal Investigator and the Institution shall apply for, and obtain, maintain, renew all the applicable approvals including Regulatory Approvals, if any, during the term of the

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Agreement, Further, the Principal Investigator and the Institution shall during the term of this Agreement abide by all Applicable Laws, as amended from time to time;

p. The Principal Investigator and the Institution shall perform such other roles, responsibilities and duties related to the Trial, as may be reasonable required by Mylin Biotech from time to time; and

q. The Principal Investigator shall maintain true and complete financial records relating to the Study performed under this Agreement including costs and expenses incurred in connection with the Study.

7.2 Each Party hereby represents, warrants and undertakes as follows:

a. it has taken all necessary action on its part required to authorize the execution and delivery of this Agreement;

b. this Agreement constitutes a legal, valid and binding obligation of the Parties; and

c. Neither the execution nor the delivery of this Agreement nor its performance would violate any agreement nor constitute a default under any such agreements to which the Parties are a party.

7.3 Mylin Biotech hereby represents and warrants to the Institution that it will, during the term of this Agreement abide by all Applicable Laws Including provisions of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945, as amended from time to time.

8. Intellectual Property Rights

8.1 The Principal Investigator and/or the Institution shall duly notify Mylin Biotech, in a confidential written notification, of any Invention and/or Intellectual Property Rights arising as an incident to and/or during the conduct of the Study.

8.2 Principal Investigator and the Institution acknowledge and agree that any Intellectual Property Rights relating to the Study shall be deemed to be works for hire created for Mylin Biotech, who shall claim such Intellectual Property Rights through Mylin Biotech and shall hold sole title to such Intellectual Property Rights. All such Intellectual Property Rights shall be deemed assigned to Mylin Biotech, and the Principal Investigator and the Institution shall do or cause to be done all such things and deliver or cause to be delivered all such documents as are necessary to give effect to this provision. The Principal Investigator shall ensure that all members of the Study Team assign all Intellectual Property Rights to Mylin Biotech.

8.3 **Principal Investigator and the Institution hereby jointly undertake that:**

a. The Principal Investigator will unequivocally transfer to Mylin Biotech the right to obtain patent on Invention.

b. Principal Investigator shall take all steps necessary to secure Inventions and Intellectual Property Rights for the benefit of Mylin Biotech. To ensure the duties set forth in this Section are carried out, Mylin Biotech may, at its own cost, request that Principal Investigator prepares and signs appropriate documents and authorisations, as well as performs any other actions necessary for the rights to Inventions and Intellectual Property Rights to be vested fully and effectively in Mylin Biotech, Mylin Biotech has the exclusive right to choose the form of protection of intellectual property.

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c. Principal Investigator shall refrain from taking any actions that would prejudice the Intellectual Property Rights of Mylin Biotech in any way. Moreover, Principal Investigator agrees to inform Mylin Biotech of any known infringement of its Intellectual Property Rights, and to support Mylin, at Mylin's expense, in actions intended to protect Mylin's Intellectual Property Rights.

d. Mylin Biotech shall have exclusive and undisputed ownership of anything related to the Study, including without limitation, the Confidential Information, the Study Drug, the CRFs, the Protocol and the Study Results.

8.4 Any and all Intellectual Property Rights in relation to the foregoing in Section 8.3(d) shall vest exclusively in Mylin Biotech.

8.5 The provisions of this Section shall survive the expiration and/or termination of this Agreement indefinitely.

9. **Research Grant.** Funding will be made to the Principal Investigator by way of grant payments in accordance with **Attachment-B.** The grant represents Principal Investigator's costs of conducting the Trial. All amounts are inclusive of all direct, indirect, overhead and other costs, including laboratory and ancillary service charges, and will remain firm for the duration of the Trial, unless otherwise agreed in writing by the parties, The Principal Investigator will not directly or indirectly seek or receive compensation from patient(s) participating in the Trial ("Trial Subject(s)") or third-party payers for any material, treatment or service that is required by the Protocol and provided or paid by Mylin Biotech including, but not limited to, Mylin Biotech, Comparator Drug, Trial Subject screening, infusions, physician and nurse services, diagnostic tests, and Mylin Biotech and/or Comparator Drug administration.

10. **Trial Subject Enrolment.** Principal Investigator has agreed to enrol Trial Subjects in the Trial in accordance with the Protocol. Mylin Biotech reserves the right, on written notice, to limit the number of Subjects to be included in the Study, including, but not limited to instances where the recruitment target has been reached.

10.1 **Multi-Center Studies.** Mylin Biotech may discontinue patient enrolment if the total enrolment needed for a multi-center Trial has been achieved.

11. **Informed Consent.** Principal Investigator undertakes that it will obtain a written Informed Consent Form ("ICF") for each Trial Subject explaining the Trial Subject's rights in connection with its relationship with the Institution and Principal Investigator. Principal Investigator will maintain a signed original of that ICF in the Trial Subject's record. Principal Investigator will provide Mylin Biotech an opportunity to review and approve the content of the ICF, including any revisions made during the course of the Trial, before it is used. Principal Investigator will allow Mylin Biotech or its designee to inspect signed ICF's or photocopies thereof during monitoring visits or audits. Principal Investigator will submit any modifications it may propose to the ICF to Mylin Biotech for review and written approval by Mylin Biotech before submitting the ICF for IEC approval. The Principal Investigator will ensure that every Trial Subject signs and ICF approved by Mylin Biotech and the IEC before the Trial Subject begins participating in the Trial. When required, the approved ICF will be modified to reflect amendments to the Protocol.

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12. **Adverse Events.** Principal Investigator will report adverse events experienced by Trial Subjects in accordance with instructions in the Protocol and applicable regulations. This includes, where required, prompt reporting by telephone. If the Trial Subject is physically

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injured by Mylin Biotech or properly performed Trial procedures and the Institution, Principal Investigator and other individuals participating in the conduct of the Trial have followed the Protocol, all Applicable Laws and regulations and all directions of Mylin Biotech, Mylin Biotech will reimburse the reasonable costs of medical expenses necessary to treat the injury.

13. **Protected Health Information.** The Parties recognize a common goal of securing all individually identifiable health information and holding such information in confidence and protecting if from unauthorized disclosure. Principal Investigator represents and warrants that he/she will comply with the provisions of any Applicable Laws relating to the confidentiality, privacy and security of such information.

13.1 **Authorization to Use and Disclose Health Information.** Principal Investigator will obtain a written privacy authorization, complying with Applicable Law, for each Trial Subject which will enable Principal Investigator to provide Mylin Biotech and other persons and entities designated by Mylin Biotech with completed Case Report Forms **("CRFs"),** source documents and all other information required by the Protocol. Mylin Biotech, though not a covered entity, recognizes that, pursuant to this Agreement, it has the responsibility to protect all individually identifiable patient information and to restrict the use of such information to those persons and entities, including consultants, contractors, subcontractors and agents, who must have access to such information in order to fulfil their assigned duties with respect to the Trial, Such use also will be restricted to those uses permitted in the authorization forms and neither Mylin Biotech nor any party to whom Mylin Biotech may disclose individually identifiable health information may use such information to recruit research subjects to additional studies, to advertise additional studies or products, or to perform marketing or marketing research. Principal Investigator will provide Mylin Biotech an opportunity to review and approve the content of the authorization (including any revisions made during the course of the Trial) before it is used.

14. **Confidential Information.** During the course of the Trial, Principal Investigator and/or the Institution may receive or generate information that is confidential to Mylin Biotech Affiliate.

14.1 **Definition.** Excepts as specified below, Confidential Information includes all information provided by Mylin Biotech, or developed for Mylin Biotech, Inventions (hereinafter defined), and all date collected during the Trial, including without limitation results, reports, technical and economic information, the existence or terms of this or other Trial agreements with Mylin Biotech, commercialization and Trial strategies, trade secrets and know-how disclosed by Mylin Biotech to Principal Investigator and/or the Institution directly or indirectly, whether in writing, electronic, oral or visual transmission, or which is developed under this Agreement.

14.2 **Exclusions.** Confidential Information does not include information that is in the public domain prior to disclosure by Mylin Biotech; becomes part of the public domain during the term of this confidentiality obligation by any means other than breach of this Agreement by Principal Investigator; is already known to Principal Investigator and the Institution at the time of disclosure and is free of any obligations of confidentiality; or is obtained by Principal Investigator and the Institution, free of any obligations of confidentiality from a third party who has a lawful right to disclose it.

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Obligations of Confidentiality. Unless Mylin Biotech provides prior written consent, Principal Investigator may not use Confidential Information for any purpose other than the authorized in this Agreement, not may Principal Investigator and the Institution disclose Confidential Information to any third party except as authorized in this Agreement or as required by law. Required disclosure of Confidential Information to the IEC or to an applicable Authority is specifically authorized.

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14.4 **Disclosure Required by Law.** If disclosure of Confidential Information beyond that expressly authorized in this Agreement is required by Applicable Law, that disclosure does not constitute a breach of this Agreement so long as Principal Investigator and/or the Institution notifies Mylin Biotech or Mylin Biotech in writing as far as possible in advance of the disclosure so as to allow Mylin Biotech to take legal action to protect its Confidential Information, discloses only that Confidential Information required to comply with the legal requirement, and continues to maintain the confidentiality of this Confidential Information with respect to all other third parties.

14.5 **Survival of Obligations.** For Confidential Information other than Trial Data and Biological Sample Analysis Data, these obligations of nonuse and nondisclosure survive termination of this Agreement. Permitted uses and disclosures of Trial Date are described in Sections 18 (Publications) of this Agreement.

14.6 **Return of Confidential Information.** If requested by Mylin Biotech, Principal Investigator will return all Confidential Information, at Mylin's expense, except that required to be retained at the Study Site by Applicable Law. However, Principal Investigator may retain a single archival copy of the Confidential Information for the sole purpose of determining the scope of obligations incurred under this Agreement.

15. **Trial Data, Biological Samples, and Records.**

15.1 **Trial Data.** During the course of the Trial, Principal Investigator will collect and submit data to Mylin Biotech or it agent, as specified in the Protocol. This includes CRFs (or their equivalent) or electronic data records, as well as any other documents or materials created for the Trial and required to be submitted to Mylin Biotech or its agent, such as X-ray, MRI, or other types of medical images, ECG, EEG, or other types of tracings or printouts, or data summaries (collectively, "Trial Data"). Principal Investigator will ensure accurate and timely collection, recording, and submission of Trial Data.

a. **Ownership of the Trial Data** Subject to Principal Investigator's right to publish, with prior written intimation to Mylin Biotech, the results of the Trial and the non-exclusive license that permits certain uses, Mylin Biotech is the exclusive owner of all the Trial Data.

b. **Non-Exclusive License.** Mylin Biotech grants Principal Investigator a royalty free non-exclusive license, with no right to sublicense, to use Trial Data for internal research or educational purposes.

c. **Medical Records.** Medical records relating to Trial Subjects that are not submitted to Mylin Biotech may include some of the same information as is included in Trial Data; however, Mylin Biotech makes no claim of ownership of those documents or the information they contain.

d. **Personal Information Protection.** Each party represents and warrants that procedures compatible with relevant personal information and data protection laws and regulations will be employed so that processing and transfer of such information and data identifiers will not be impeded.

15.2 **Biological Samples.** If so specified in the Protocol, Principal Investigator may collect and provide to Mylin Biotech or its designee biological samples (e.g., blood, urine, tissue, saliva, etc.) obtained from Trial Subjects for testing that is not directly related to patient care or safety monitoring, including pharmacokinetic, pharmacogenomics, or biomarker testing ("Biological Samples").

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a. Use. Principal Investigator will not use Biological Samples collected under the Protocol in any manner or for any purpose other than that described in the Protocol.

b. Sample Date. Mylin Biotech or its designees will test Biological Samples as described in the Protocol. Unless otherwise specified in the Protocol, Mylin Biotech will not provide the results of such tests ('Sample Data") to the Principal Investigator or Trial Subject. Sample Data will be treated as Trial Data; therefore, if Mylin Biotech provides Sample Data to the Principal Investigator, that data will be subject to the permitted use of Trial Data as outlined in this Agreement.

15.3 **Records.** Principal Investigator will ensure that Trial Subject's Trial records, which include that Principal Investigator's copies of all Trial Data as well as relevant source documents (collectively, "Records"), are kept up to date and maintained in accordance with Applicable Law.

a. **Retention.** Principal Investigator will retain all records and documents pertaining to the Trial for a period in accordance with Applicable Law and the Protocol. Principal Investigator will retain Records, under storage conditions conducive to their stability and protection, for a period of fifteen (15) years after termination of the Trial unless Mylin Biotech authorizes, in writing, earlier destruction. At the end of such required retention period, Principal Investigator will not destroy any such records until it has obtained Mylin's prior written permission to do so; provided, however, that if Mylin Biotech does not give written permission to Principal Investigator to destroy such records within thirty (30) days of Principal Investigator's request to Mylin Biotech, then Principal Investigator may forward all such records to Mylin Biotech, at Mylin's expense, or continue to retain such records. Principal Investigator further agrees to permit Mylin Biotech to ensure that the records are retained for a longer period if necessary, at Mylin's expense, under an arrangement that protects the confidentiality of the records (e.g., secure off-site storage).

16. **Inspections and Audits.**

16.1 **Access.** Upon reasonable request by Mylin Biotech, authorized representatives of Mylin Biotech, and/or authorized representatives of the applicable Authority, may during regular business hours examine and copy; all CRFs and other Trial records (including Trial Subject records and medical charts; Trial Subject consent documents; drug receipt and disposition logs); examine and inspect the facilities and other activities relating to the Trial or the IEC; and observe that conduct of the Trial.

16.2 **Notice.** Principal Investigator and/or the Institution will inform Mylin Biotech within twenty-four (24) hours of any effort or request by regulatory authorities or other persons to inspect or contact the Principal Investigator or research staff with regard to the Trial; will provide Mylin Biotech with a copy of any communications sent by such persons; and will provide Mylin Biotech or Mylin Biotech the opportunity to participate in any proposed or actual responses by Principal Investigator to such communications.

16.3 **Cooperation.** Principal Investigator and the Institution will ensure the full cooperation of the researchers and IEC members with any such inspection and will ensure timely access to applicable records and data. Principal Investigator will promptly resolve any discrepancies that are identified between the Trial Data and the Trial Subject's medical records. Principal Investigator will promptly forward to Mylin Biotech copies of any inspection findings that Principal Investigator received from a regulatory agency in relation to the Trial. Whenever feasible, Principal Investigator will also provide Mylin Biotech with an opportunity to

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prospectively review and comment on any responses to regulatory agency inspections in regard to the Trial.

17. **Inventions.** If the conduct of Trial results in any invention or discovery whether patentable or not ("Invention"), Principal Investigator and/or the Institution will promptly inform Mylin Biotech. Principal Investigator will assign all interest in any such Invention to Mylin, free of any obligation or consideration beyond that provided for in this Agreement. Principal Investigator will provide reasonable assistance to Mylin Biotech in filling and prosecuting any patent applications relating to Invention, at Mylin's expense.

18. **Publications.** Principal Investigator acknowledges that Mylin Biotech has the right to use the Study Results in any manner deemed appropriate to Mylin's business interests, both during, and following termination/expiry of , this Agreement. Mylin Biotech shall have to sole right to retain the ownership of any and all data arising out of the conduct of clinical trials in relation to the Study. Upon completion of the Study, Mylin Biotech shall publish the results of the authorized clinical trial, either positive or negative, in scientific journals and with mention of the EC of clinical research that approved the study. Where Principal Investigator requires the use of the Study Results for publication, the Principal Investigator shall seek Mylin's written approval 90 (ninety) days in advance; such consent shall not be unreasonably withheld. If part of a multi-center trial. Principal Investigator agrees that the first publication is to be a joint publication involving all centers. Principal Investigator is free to decline to participate or be listed as an author in the joint publication. If a joint manuscript has not been submitted for publication within twelve (12) months of completion or termination of Trial at all participating sites, Principal Investigator is free to publish separately, subject to the other requirements of this Agreement.

19. **Publicity.** Neither party will use the name of the other party or any of its employees for promotional or advertising purposes without written permission from the other party. However, Mylin Biotech reserves the right to identify the Principal Investigator in association with the listing of the Protocol in the National Institutes of Health (NIH) Clinical Trials Data Bank, other publicly available listings of ongoing clinical trials, or other patient recruitment services or mechanisms.

20. **Indemnification.**

20.1 Mylin Biotech agrees to indemnify and hold harmless ("Indemnify") the Principal Investigator, the Institution, its officers, agents, and employees; and the IEC that approved the Trial (collectively, "Indemnified Parties") against any claim filed by a third party for damages, costs, liabilities, expenses arising out of a Trial Subject injury, the design of the Trial, or the specifications of the Trial protocol. Trial Subject injury means a physical injury or drug-related psychiatric event caused by administration or use of Mylin Biotech required by the Protocol that the Trial Subject would likely not have received if the Trial Subject had not participated in the Trial. Mylin Biotech further agrees to reimburse Principal Investigator for the reasonable cost of diagnostic procedures and medical treatment necessary to treat a Trial Subject injury. Principal Investigator agrees to provide or arrange for prompt diagnosis and medical treatment of any medical injury experienced by a Trial Subject as a result of the Trial Subject's participation in the Trial. Principal Investigator further agrees to promptly notify Mylin in writing of any such medical injury.

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a. **Exclusions.** Excluded from this agreement to Indemnify are any claims for damages resulting from (a) failure by an Indemnified Party to comply with the Protocol or written instructions from Mylin Biotech (b) failure of an Indemnified Party to comply with any Applicable Law

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and governmental regulations, or (c) fraud, negligence or withful misconduct by an Indemnified Party.

b. **Notice and Cooperation.** Principal Investigator agrees to provide Mylin Biotech with prompt notice of, and full cooperation in handling, any claim that is subject to indemnification. If so requested by Mylin Biotech, Principal Investigator agrees to authorize Mylin Biotech to carry out the sole management of defense of an indemnified claim.

c. **Settlement or Compromise.** No settlement or compromise of a claim subject to this indemnification provision will be binding on Mylin Biotech without Mylin's prior written consent. Mylin Biotech will not unreasonably withhold such consent of a settlement or compromise. Neither party will admit fault on behalf of the other party without the written approval of that party.

20.2 Principal Investigator and the Institution shall jointly and severally indemnify and hold harmless Mylin including its directors, employees; representatives, agents etc., and shall be fully liable for all claims, damages, losses, liabilities, costs or expenses (including reasonable legal fees) resulting or arising from:

a. failure by the Principal Investigator and the Study Team (Which shall include his/her employees, agents and representatives) to comply with the Applicable Law, the terms of this Agreement, ICH GCP and/or other nationally established guidelines, the approval of the IEC, Protocol or written instructions from Mylin Biotech;

b. any finding, requirement, determination or observation by any Authority (including but not limited to the FDA) which makes it necessary or desirable for Mylin Biotech to redo the Study;

c. failure by the Principal Investigator, the Study Team and/or the Institution to comply with Applicable Law;

d. any negligent act or omission or wilful misconduct or fraud by Principal Investigator, the Study Team and/or the Institution, fraud or misrepresentation.

20.3 Except in the case of fraud, willful misconduct, gross negligence or breach of any Applicable Law, neither Party shall be entitled to incidental, indirect, consequential nor special damages under any theory of Applicable Law arising in connection with such default or breach of the other Party's obligations under this Agreement, or any documents related thereto.

20.4 In the event of any act of Principal Investigator and/or the Institution, which renders the Study invalid, to the extent Principal Investigator and/or the Institution is liable, Mylin Biotech shall, in addition to any other right that Mylin Biotech may have under law or equity, have the option at its sole discretion to either (a) request Principal Investigator to repeat the Study at Principal Investigator's own cost, or (b) require Principal Investigator and/or the Institution to promptly refund Mylin Biotech the compensation received by Principal Investigator and/or the Institution under this Agreement and bear any additional costs that Mylin Biotech may incur for repeating the Study. Further without prejudice to any other rights that Mylin Biotech may have under law or equity, Mylin Biotech may, at its discretion, forthwith terminate this Agreement.

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21. Termination.

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21.1 **Termination Conditions.** This Agreement terminates upon the earlier of any of the following events:

a. **Disapproval by IEC.** If, through no fault of Principal Investigator, the Trial is never initiated because of IEC disapproval, this Agreement will terminate immediately.

b. **Trail Completion.** For purposes of this Agreement, the Trial is considered complete after conclusion of all Protocol-required activities for all enrolled Trial Subject; receipt by Mylin Biotech of all relevant Protocol-required data, Trial documents and Biological Samples; and receipt of all payments due to either party.

c. **Early Termination of Trial.** If the Trial is terminated early as described below, the Agreement will terminate after receipt by Mylin Biotech of all relevant Protocol-required data, Trial documents and Biological Samples and receipt of all payments due to either party.

(1) **Termination of Trial Upon Notice.** Mylin Biotech reserves the right to terminate the Trial for any reason upon thirty (30) days written notice to Principal Investigator.

(2) **Immediate Termination of Trial by Mylin Biotech.** Mylin Biotech further reserves that right to terminate the Trial immediately upon written notification to Principal Investigator and/or the Institution for causes that include – (i) failure to cure any breach within 15 days of written notice by Mylin Biotech notifying Principal Investigator of such breach; (ii) failure to enrol Trial Subjects at a rate sufficient to achieve Trial performance goals; (iii) material unauthorized deviations from the Protocol or reporting requirements; (iv) circumstances that in Mylin's opinion pose risks to the health or wellbeing of Trial Subjects; or (v) regulatory agency actions relating to the Trial or Mylin Biotech or Comparator Drug.

(3) **Immediate Termination of Trial by Principal Investigator.** Principal Investigator reserves the right to terminate the Trial immediately upon notification to Mylin Biotech or Mylin Biotech if requested to do so by the responsible IEC or if such termination is required to protect the health of Trial Subjects.

21.2 **Payment upon Termination.** If the Trial is terminated early in accordance with this Agreement, Mylin Biotech will provide a termination payment equal to the amount owed for work already performed up to and including the effective date of termination, in accordance with **Attachment-B,** less payments already made. The termination payment will include any non-cancellable expenses, other than future personnel costs, so long as they were properly incurred and prospectively approved by Mylin Biotech, and only to the extent such costs cannot reasonably be mitigated. If the Trial was never initiated because of disapproval by the IEC, Mylin Biotech will reimburse Principal Investigator for any other expenses that were prospectively approved, in writing, by Mylin Biotech.

21.3 **Return of Materials.** Unless Mylin Biotech instructs otherwise in writing, Principal Investigator will promptly return all materials supplied by Mylin Biotech, at Mylin's expense, for Trial conduct, and any Mylin-supplied Equipment. Principal Investigator will return and/or destroy, as required by Mylin Biotech, at Mylin's expense, unless otherwise specified by Mylin Biotech, any unused Mylin Biotech or Comparator Drug.

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22. **Insurance.** The Principal Investigator will secure and maintain in full force and effect throughout the performance of the Trial (and following termination of the Trial to cover any claims arising from the Trial) insurance coverage for medical professional liability with limits in accordance with local standards for all medical professionals conducting the Trial.

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23. **Debarment, Exclusion, Licensure and Response.** Principal Investigator and the Institution jointly and severally certify that they are not debarred or restricted from conducting clinical research and will not use in any capacity the services of any person debarred or restricted from conducting clinical research under Applicable Law with respect to services to be performed under this Agreement. Principal Investigator and the Institution also certifies that they are not excluded from any governmental health care program. Principal Investigator and the Institution further certify that they are not subject to a government mandated corporate integrity agreement and has not violated any applicable anti-kickback or false claims laws or regulations. During the term of this Agreement and for three years after its termination, Principal Investigator and the Institution will notify Mylin Biotech promptly in writing to the extent possible, within two (2) business days if either of these certifications needs to be amended in light of new information or if Principal Investigator becomes aware of any material issues related to the medical licensure of any associated Trial researchers. Principal Investigator and the Institution will cooperate with Mylin Biotech regarding any responsive action necessary.

24. **Assignment and Delegation.** Mylin Biotech may at any time and upon written notice to Principal Investigator and/or the Institution assume the obligations and rights of Mylin Biotech or substitute Mylin Biotech with another independent contractor. None of the rights or obligations under this Agreement will be assigned or subcontracted by Principal Investigator and/or the Institution to another without the prior written consent of Mylin Biotech, and the express agreement of Principal Investigator and/or the Institution, Mylin Biotech, and the requisite new assignee or subcontractor. Principal Investigator and the Institution must notify Mylin Biotech, at least 90 (ninety) days in advance, prior to moving to another location. This Agreement will bind and inure to the benefit of the successors and permitted assigns of Mylin Biotech.

25. **Equipment.** Mylin Biotech may provide, or arrange for a vendor to provide, certain equipment for use by Principal Investigator during the conduct of the Trial ("Equipment"). Equipment use, ownership and disposition terms are further outlined in Attachment C.

26. **Survival of Obligations.** Obligations relating to Research Grant, Confidential Information, Inventions, Records, Publications, Publicity, Debarment and Exclusion, and Indemnification survive termination of this Agreement, as do any other provision in this Agreement or its Attachments that by its nature and intent remains valid after the term of the Agreement.

27. **Entire Agreement.** This Agreement contains the complete understanding of the parties and will, as of the Effective Date, supersede all other agreements between the parties concerning the specific Trial. This Agreement may only be extended, renewed or otherwise amended in writing, by the mutual consent of the parties. No waiver of any term, provision or condition of this Agreement, or breach thereof, whether by conduct or otherwise, in any one or more instances will be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or any prior, contemporaneous or subsequent breach thereof, of any other term, provision or condition of this Agreement whether of a same or different nature.

28. **Conflict with Attachments.** To the extent that terms or provisions of this Agreement conflict with terms and provisions of the Protocol, the terms and provisions of this Agreement will control as to legal and business matters, and the terms and provisions of the Protocol will control as to technical research and scientific matters unless expressly agreed in a writing between the parties.

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29. **Relationship of the Parties.** The relationship of Principal Investigator and/or the Institution to Mylin Biotech is one of independent contractor and not one of partnership, agent and principal, employee and employer, joint venture, or otherwise.

30. **Force Majeure.** Neither party will be liable for delay in performing or failure to perform obligations under this Agreement if such delay or failure results from circumstances outside its reasonable control (including, without limitation, any act of God, governmental action, accident, strike, terrorism, bioterrorism, lock-out or other form of industrial action) promptly notified to the other party ("Force Majeure"). Any incident of Force Majeure will not constitute a breach of this Agreement and the time for performance will be extended accordingly; however, if it persists for more than thirty (30) days, then the parties may enter into discussions with a view to alleviating its effects and, if possible, agreeing on such alternative arrangements as may be reasonable in all of the circumstances.

31. **Governing Law.** Subject to the terms of the Trial Conduct as outlined above, this Agreement shall be governed by and construed in accordance with the laws of India, without giving effect to conflict of law provisions. The Parties agree to submit all their disputes arising out of or in connection with this Agreement to the exclusive jurisdiction of the courts of Lucknow.

32. **Notices.** All notices required under this Agreement will be in writing and be deemed to have been given when hand delivered, sent by overnight courier or certified mail, as follows, provided that all urgent matters, such as safety reports, will be promptly communicated via telephone, and confirmed in writing:

TO MYLIN BIOTECH INDIA PVT LTD:
Attention. To:

TO PRINCIPAL INVESTIGATOR:
Attention. To:

TO INSTITUTION:
Attention. To:

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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 and binding Agreement with the expectation that original documents may later be exchanged in good faith.

[INTENTIONALLY LEFT BLANK; SIGNATURE PAGE FOLLOWS]

ACCEPTED AND AGREED BY:
PRINCIPAL INVESTIGATOR

By:
Signature

Printed Name DR ANTI A SAXENA

Title Professor

19/3/19
Date

ACCEPTED AND AGREED BY:
MYLIN BIOTECH

By: P. PRABHAKARAN
Signature

Printed Name

Title

Date

ACCEPTED AND AGREED BY:
INSTITUTION

By:
Signature

Printed Name

Title

Date 14.05.2019

DIRECTOR
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

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Executive Registrar
SGPGIMS,Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Attachment A

Protocol

The clinical Trial to be performed pursuant to this Agreement shall be that set forth in the Protocol dated 28 August 2018. and incorporated into this Agreement attached hereto by reference in addition to all current and future amendments thereto, which is incorporated into this Agreement by reference and entitled:

Protocol Number: NIZY-BYT-MB-18 A prospective, double blind, multicentric randomized, placebo controlled Interventional study to evaluate the safety and efficacy of Enzobiotics (Synbiotics and Proteolytic Enzymes)in pre dialysis kidney disease patients.

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28

Attachment B

RESEARCH GRANT PAYMENT TERMS

B-1. **General Terms.** Principal Investigator ("Payee") will be paid the per patient grant amount as outlined on **Attachment-D** (Research Grant Worksheet) per Trial Subject properly enrolled in the Trial. This amount constitutes the full compensation for the work to be completed by the Principal Investigator, including all work and care specified in the Protocol for the Trial, along with all overhead and administrative services. No compensation will be available for Trial Subjects enrolled or continuing in the Trial in violation of the Protocol.

B-2. **Payment Terms.** Research grant payments for each Trial Subject will be made in Indian Rupees (INR) quarterly and based on approval of invoices submitted. Invoices will be issued by Payee upon notice delivered by Mylin Biotech. Payments will be made in accordance with eCRFs submitted and monitored, and in accordance with Attachment D "Research Grant Worksheet". Monitoring will occur based on site enrolment and completion of data entry. Payments will be made in quarterly instalments on a pro-rata basis. Undisputed invoices will be paid by Mylin Biotech within 60 (sixty) days of such invoice issue date.

B-3. **Non-Procedural Costs**. Payee will be paid for additional non-procedural costs that are pre-approved by Mylin Biotech, as set forth in Attachment D. To request payment for such costs, Payee will remit an itemized invoice to Mylin Biotech or its designee with documentation and receipts substantiating agreed-upon pass-through expenses. Any non-procedural pass-through expenses will be invoiced only in the amount actually incurred with no mark-up, up to the maximum amounts shown in Attachment D.

B-4. **Final Payment**. At the conclusion of the Trial, all CRFs and Trial-related documents will be promptly made available for Mylin's review. The final payment will be paid once: all CRFs have been completed and received; data queries have been satisfied; all Mylin Biotech is returned; and all close out issues are resolved and procedures completed, including final IEC notification. All queries must be resolved within five (5) days of receipt by Payee any time during the Trial. Mylin Biotech or its designee will perform final reconciliation of all payments made to date against total amount due and will promptly pay Payee amounts remaining unpaid, if any Payee will promptly reimburse Mylin Biotech amounts overpaid within thirty (30) days of notification by Mylin Biotech or designee.

B-5. **Taxes.**

(1) All payments to Payee by Mylin Biotech will be subject to deduction of TDS.

(2) The Payee shall comply with all its obligations under applicable tax laws in force at the time, including all laws, rules and regulations under the Goods and Services Tax ("GST") Regime ("GST"). In particular, the Payee shall pay its taxes and make all filings necessary under GST Law, including the GSTR-1 form, within the prescribed timelines. The Payee shall defend, indemnify and hold Mylin Biotech harmless against all losses, claims and liabilities arising out of any failure by the Payee to meet its obligations under GST Law, including any failure or error that results in denial of any tax credit under GST law to Mylin Biotech, The Payee shall full co-operate with Mylin Biotech to respond to

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the relevant tax authorities' demands, and to resolve any mismatch of Mylin Biotech and the Payee's GST filings within the timelines prescribed under the GST Law.

(3) Payee acknowledges and agrees that it is solely responsible for the payment of any and all contributions and taxes imposed by any applicable Authority with respect to or measured by compensation paid to Payee under this Agreement. Mylin Biotech will not be responsible for the withholding or payment of any such required contributions or taxes. Payee accepts full responsibility for reporting all payments received, under this agreement, to the relevant taxation authorities as required by local regulations.

B-6. **Screen Failures.** A Screen Failure is a consented Trial Subject who fails to meet the screening visit criteria and is thus not eligible for enrolment into the Trial. Screen Failures will be reimbursed, if at all, as outlined in Attachment D, based on work completed pursuant to the Protocol.

B-7. **Patient travel reimbursement.** Mylin Biotech, will reimburse reasonable patient travel related expenses per trial subject visit, up to the maximum amount listed in the Attachment D. Any reimbursement exceeding this limit will require prior written Mylin Biotech approval. Any payment will be based on the invoice together with supporting documentation (i.e. receipts) submitted to Mylin Biotech.

B-8. **Administrative Start-up Fees.** Within sixty (60) days of execution of this Agreement and receipt of a valid invoice, Mylin Biotech, will pay a non-refundable start-up payment in the amount listed in the Attachment D for the work performed to prepare for site activation and enrolment (including but not limited to, feasibility study, initial training of Protocol, briefings, advance talks, provisions of room for the monitoring, initiation of the Study at the Center, training of the future Members of the Study Team, participation in Investigator's meetings, contract review activities, the cost for purchasing small equipment, set-up costs for equipment and all other preparation).

B-9. **Necessary Procedures.** Payee will be reimbursed for valid necessary visits and procedures. Payment for any necessary procedure due to patient safety will be reimbursed at the agreed upon unit cost in the budget, or if there is no such unit cost in the budget, at the appropriate unit cost pre-approved by Mylin Biotech in writing, and will require a separate invoice with documentation for the medical necessity of the procedure. Where practicable, Mylin's prior written consent will be obtained, unless it will compromise the integrity of the Trial or affect Trial Subject safety, in which case Mylin Biotech will be notified as soon as practicable after the fact.

B-10. **Payee.**

The research grant payments will be made to the following payee and address:

Payee Name: Director, SGPGIMS Research Scheme Account, Lucknow
Payee Address: Raebareli Road, Lucknow, Uttar Pradesh 226014
Payee GST Number: 09AAAJS3913N2ZN
Payee PAN No: AAAJS3913N
Payee Bank Account Details: Saving account
Bank Name: State Bank of India
Bank Address: SGPGIMS Branch, Lucknow
Bank Account Number: 10095237491
IFSC Code: SBIN007789
Email address for remittance information: director@sgpgi.ac.in

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In cast of changes in the Payee's bank account details, Payee is obliged to inform Mylin Biotech in writing, but no amendment to this Agreement shall be required.

B-11. **Invoices.** All invoices must be issued and forwarded to the following as instructed:

MYLIN BIOTECH INDIA PVT LTD.
#40/11-1 2nd floor
Govindraj Nagar, Magadi Road
Bangalore - 560040

Each invoice must contain: (1) Mylin Biotech name, (2) Protocol Number, (3) Project Code, (4) a summary of the reimbursement to be made in compliance with the Research Grant Worksheet, and (5) the GST Registration number, (6) if GST reverse charges mechanism applies, the note "GST reverse charges applicable".

Payee will not receive any payments for pass through expenses whereby Payee has failed to produce actual copy invoices or other documentation clearly substantiating that the expenditures were actual, reasonable, and verifiable in the amount submitted for compensation.

Any invoices submitted by the Payee more than 45 (forty five) days after the database lock will not be reimbursed.

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95

CLINICAL TRIAL AGREEMENT

Preamble:

Sanjay Gandhi Post Graduate Institute of Medical Sciences, Rae Bareli Road, Lucknow is a super specialty hospital, established by Government of Uttar Pradesh, as a center of excellence for providing medical care, education and research of high order and is chartered to function as a university under Sanjay Gandhi Post Graduate Institute of Medical Sciences Act, 1983. [Hereinafter referred to as "Act"]

This Clinical Trial Agreement (hereinafter referred to as "Agreement") is entered into on this day 30/10/2018 **AMONG**

MYLIN BIOTECH INDIA PVT. LTD, a company originally incorporated in Bangalore and registered under section 592 of Companies act, 1956 as having place of Business and one of its office is located at #40/11-1 2nd floor, Govindraj Nagar, Magadi Road Bangalore -560040. through it **MYLIN BIOTECH INDIA PVT. LTD** "Sponsor"] of the First part.

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences, an Institute established under Sanjay Gandhi Post Graduate Institute of Medical Sciences Act, at Raebareli Road, Lucknow-226014, Uttar Pradesh, India, through its **"Director/Director's Nominee**..... [herein referred to as "Institute"] of the Second part.

AND

Professor Dr. Anitha Saxena a, Department of Nephrology, Sanjay Gandhi Post Graduate institute of Medical Sciences [hereinafter referred to as **"Principal Investigator"**] of the Third Part.

WHEREAS The Sponsor, Institute and, Principal Investigator are willing to jointly carry out the Study Number:

NIZY-BYT-MB-18 Entitled **A prospective, double blind, multicentric randomized, placebo controlled Interventional study to evaluate the safety and efficacy of Enzobiotics (Synbiotics and Proteolytic Enzymes)in pre dialysis kidney disease patients. [Hereafter referred to as "Study"]** described in Study Protocol;

AND WHEREAS Sponsor is desirous of engaging the said Principal Investigator and Institute for carrying out the Study through **CRO [if needed]**

NOW, THEREFORE, in consideration of the premises and the covenants and Agreements of the parties as hereinafter set forth, the parties have agreed and do hereby agree with each other to the following:

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1.0 Statement of work

1.1 "Study" shall be deemed to be "Clinical Trial" as defined in rule-122 DAA of the Drugs and Cosmetics Rule, 1945.

1.2 Sponsor shall provide Principal Investigator with a sufficient quantity of Study Supplies to conduct the Study at investigational Site in timely manner. Institute and Principal Investigator shall use Study Supplies only to conduct the Study in accordance with the Protocol; All Study Supplies such as Study drug(s) and related devices, equipment, or other trial supplies remain the sole property of Sponsor, unless otherwise designated. The Institute and Principal Investigator will be responsible for the return of excess, unused Study Supplies to the Sponsor.

1.3 Study Timelines: Study Timelines for the purpose of this Agreement will be as per need of Protocol.

2. Obligations and Responsibilities of Principal Investigator

2.1 The Principal Investigator will recruit only qualified participants as per Inclusion and Exclusion criteria.

2.2 The Principal Investigator will conduct the study in accordance with protocol, Schedule Y and ICMR Guidelines along with Helsinki and ICH Guidelines for international studies.

2.3 The Principal Investigator will make necessary arrangement for inspection of documents etc. by sponsor's monitor, official of regulatory agency or IEC nominee.

2.4 The Principal Investigator shall report all serious and unexpected adverse events and/ or death to the Licensing Authority, Sponsor, and IEC as per Appendix XI of Schedule-Y of Rules.

2.5 The Principal Investigator shall forward its report on Serious Adverse Event of Death after due analysis of all factors with his opinion to Chairman of IEC, Chairman of Expert Committee and Head of the Institute and the Licensing authority as per Appendix X of schedule Y.

2.6 The Principal Investigator shall forward its report on Serious Adverse Event other than Death after due analysis of all factors with his opinion to Licensing Authority, Chairman of IEC and Head of the Institute as per Appendix X of schedule Y.

2.7 The Principal Investigator will be responsible for proper and prompt filling of CRF, preservation of investigation reports and recordings.

2.8 During and following a Clinical Trial Subject's participation in Study, the Principal Investigator shall ensure that adequate medical care is provided to the participant (Clinical Trial Subject) for any adverse events.

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2.9 The Principal Investigator will ensure enrolment of trial participants after obtaining informed consent including audiovisual recording and also informing the provisions of adequate treatment and compensation for SAE as per schedule Y.

2.10 Principal Investigator shall complete the Clinical Trial under his supervision as per the agreement and the Statutory provisions, but if for any reason he/she is unable to carry over the study it shall be his/her responsibility to hand over the study to his/her Co-PI or to any of the Faculty members of the Institute, to be decided by the Head of Department of the PI or Director and obtain the approval of the Ethics Committee and the Sponsor.

2.11 The Principal Investigator will be responsible for proper account of receipt, utilization and return of unused sample of trial drug to sponsor and prevent its use for any other study.

2.12 The Principal Investigator will be responsible for providing non-compliance and progress report to Institutional Ethics Committee (IEC) within a week of occurrence or due date.

2.13 The Principal Investigator will be responsible for forwarding to IEC communications from sponsors within a week of receipt with comments for the need of any change in protocol or PIS.

2.14 The Principal Investigator will be responsible for obtaining IEC and sponsors permission for storage of blood or tissue samples for future use.

2.15 The Principal Investigator shall be responsible for obtaining sponsor's permission before publication or conference presentation of any data.

3.0 Obligation and Responsibilities of Institute:

3.1 Study shall be conducted in compliance with the Protocol, Standard Operating Procedure (SOP) and applicable regulatory requirement.

3.2 Ensuring that the rights, safety and well-being of Clinical Trials Subject are protected.

3.3 Fulfillment of necessary obligations by IEC, PI and supporting staff.

3.4 Protection of confidentiality, rights, safety and wellbeing of clinical trial participants.

3.5 Adequate treatment and compensation for SAE to trial participants.

3.6 Necessary infrastructure support to PI.

3.7 Communicating with IEC and obtaining approval for the Clinical Trial Protocol, written informed consent and other trial related Study documents.

3.8 Ensuring accuracy, completeness, legibility and timelines of the Data reported to the Sponsor in the Case Record Forms (CRFs) and in all required reports.

3.9 Study shall be terminated on the recommendation of IEC, when safety and benefit of Clinical Trial Subjects is doubtful.

3.10 Safety reporting as per schedule Y and/or Sponsor policy.

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3.11 Upon request of the monitor, auditor, Institutional Ethics Committee or applicable regulatory authority, Institute should make available for direct access all requested trial related records.

3.12 The confidentiality of record that could identify Clinical Trial subject should be protected and maintained.

3.13 If Sponsor or CRO violates the terms of this Agreement or does not provide the claimed compensation to the subject then the Institute or Principal Investigator may not conduct any other further clinical trials of this sponsor.

3.14 Approval of study within 8 weeks of receipt of Investigator's brochure, protocol including PIS & CRF, regulatory approvals, draft CTA, Insurance policy and IEC fee from sponsor.

3.15 Approval of midterm changes within 8 weeks of receipt of documents.

3.16 Review of progress report DSMB report & SAE from other centers and if necessary to recommend changes in protocol, termination of study or its extension beyond approved period.

3.17 Review of SAE at SGPGI and necessary action within the time frame decided by regulatory agencies.

3.18 Review of final report.

3.19 Approval of storage of blood or tissues for use in future studies.

3.20 Facilitate visit of sponsor's monitor or representative of regulatory agencies.

3.21 Institutional clearance for sample to be sent abroad for non-pharmacogenetic studies.

3.22 Archiving of data for 5 years (or longer if required by sponsor/regulatory agency).

3.23 Safeguarding IPR of sponsor and SGPGI.

3.24 Providing alternate PI if PI unable to continue.

3.25 Audited statement of utilization of Funds.

4.0 Obligation and Responsibilities of Sponsor

4.1 To provide investigator's brochure, Protocol, CRF draft CTA, Insurance policy from an Indian Insurance company and regulatory approvals.

4.2 To provide adequate supplies of trial drug, comparator and /or placebo prepared under proper quality control.

4.3 To provide Insurance cover for treatment and compensation of SAE and undertaking to supplement any amount not covered by the Insurance Company. Sponsor will also provide copy of Policy.

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4.4 Undertaking to provide test drug free of cost to participants after termination of the trial if necessary till it become available in the country.

4.5 Not to send samples for Pharmacogenetic study abroad.

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4.6 To permit the storage of samples for future study if requested by Principle Investigator.

4.7 Provide a copy of final report at termination of the study.

4.8 Appropriate acknowledgement of contribution of SGPGI investigators in any resulting publication.

4.9 To define and follow procedure for premature termination.

4.10 To provide budget which should include cost of treatment, investigations and investigators charges, reimbursement of travel expenses to participants if necessary, Institute's overhead at the rate of 25% of the total budget and INR 25,000/- fee of IEC. Details of release of budget to be mutually settled.

5.0

5.1 Sponsor agrees that any injury or death of the Clinical Trial Subject occurring in Clinical Trial due to following reasons shall be considered as Clinical Trial related injury or death and the subject or his nominee as the case may be, will be entitled for financial compensation for such injury or death as per the notification of the DCGI & Gazette of India issued from time to time.

(a) Adverse effect of Investigational Product(s);

(b) Violation of the approved Protocol;

(c) Scientific misconduct or negligence by the Sponsor or his representative or CRO or Principal Investigator, Co-investigator or any member of his/her team

(d) Failure of Investigational Product to provide intended therapeutic effect;

(e) Use of placebo in a placebo-controlled Clinical Trial;

(f) Adverse effects due to concomitant medication excluding standard care, necessitated as part of approved Protocol;

(g) For injury to a child in utero because of the participation of parent in Clinical Trial;

(h) Any Clinical Trial procedures involved in the Study.

5.2 Sponsor should submit a status report on the Clinical Trial to the Licensing Authority at the prescribed Periodicity;

5.3 In case of studies permanently discontinued for any reason Sponsor shall submit a summary report to the Licensing Authority as per provisions of Schedule-Y of Rules.

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6.0 **Undertaking and Representation of Principal Investigator**

Principal Investigator hereby represents that he/she has furnished an undertaking to Licensing Authority in the format given in Appendix VII of Schedule-Y of Rules.

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(21)

7.0 Undertaking and Representation of Institute

Institute hereby represents that:-

It has constituted the Institutional Ethics Committee as per the guidelines given in the Gazette of India & it has been registered with the DCGI vide letter No:……dated…..

(i) SOP is in compliance with GCP guidelines and applicable regulations;

(ii) It will ensure that IEC will discharge its responsibilities as per provisions of Schedule-Y

8.0 Undertaking and Representation of Sponsor

Sponsor hereby understands and represents that:-

It has furnished an undertaking along with the application for Clinical Trial Permission to the Licensing Authority to provide compensation in the case of clinical trial related injury or death for which subjects will be entitled to compensation; as per provisions of rule 122 DAB (b) of Rules.

9.0 Administration

9.1 Overall responsibilities of the Study will rest with Principal Investigator, Institute and Sponsor to conduct the Study at Institute's premises.

9.2 The following Study plan will apply to the Study:

(a). Subject enrollment up to Institute's Enrollment Maximum (i.e.: Clinical Trial Subjects) shall be completed as stated in protocol. However, if the Institute and Principal Investigator are unable to enroll patients for the Study within 6 months of Investigation Site initiation Sponsor will be having the authority to change the Institute's Enrollment Maximum in a unilateral manner.

(b). Institute or Principal Investigator will not enroll more Study subjects than Institute's Enrollment Maximum Sponsor will not be obligated to make any payment with respect to any subject enrolled in excess of Institute's Enrollment Maximum.

(c). Subject to applicable law: Sponsor and Institute without any further obligation mutually may agree in writing to modify Institute's Enrollment Maximum.

(d). All subject visits will be conducted as proposed in the protocol. The sponsor will be informed is a visit is delayed by more than 2 weeks along with reason of delay.

(e). Case Report Forms ("CRFs") information associated with a subject's visit must be satisfactorily completed within 7 days after the subject's visit or, if applicable, receipt of the subject's test results.

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(f). All Data Queries from Sponsor must be completed and returned to Sponsor within a time frame mutually negotiated.

(g). any intentional changes of inclusion/exclusion criteria by the Principal Investigator or Study team will not be the liability of Sponsor.

10.0 Trial Drug; Materials Transfer; Records Retention; Inspection

10.1 Trial drug:

(i) Institute and Principal Investigator acknowledge that the trial drug/device is owned or controlled by Sponsor and that neither the terms of this Agreement nor the Protocol, nor any activities conducted by Institute or Investigator for the Trial, shall be construed to grant to either Institute or Principal Investigator any rights in or to the Compound.

(ii) Except as otherwise agreed by the Parties, Sponsor will provide the Compound and any control/placebo material to be administered to Trial subjects as part of the Trial (collectively, the **"Trial Drug")** free of charge to Institute for administering or dispensing solely by or under the supervision of Principal Investigator or sub-investigator to Trial subjects at the Trial Site in Strict compliance with the Protocol.

(iii) Institute and Principal Investigator shall use the Trial Drug solely to conduct the Trial in strict compliance with the Protocol and for no other purpose, and shall not transfer the Trial drug to any third parties. Institute and Principal Investigator shall handle, store, ship and dispose of the Trial drug as directed by Sponsor or its designee and in compliance with all applicable laws, rules and regulations.

(iv) Institute and Principal Investigator will ensure that empty and partially used Trial Drug container and any Trial Drug remaining at the Trial close-out visit at the Trial Site or upon early termination of this Agreement are disposed of or returned to Sponsor in accordance with the Protocol.

(v) Neither support of the Trial, nor Institute participation in the Trial, impose any obligation, express or implied, on Institute or Principal Investigator to purchase, prescribe, provide favorable formulary status for or otherwise support Sponsor's products.

(vi) Unless required by the Protocol, Institute will not modify the Trial Drug or its container. If the Institute policy requires any modification to the Trial Drug container, such modification must be approved in advance in writing by Sponsor. Principal Investigator solely for purposes of the Trial and only as specified in the Protocol and this Agreement. They may, however, be retained in the Institute for use in a future study to be approved by IEC.

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19

10.2 Records Maintenance and Retention Investigator and Institute will maintain adequate and accurate records relating to the disposition of the Trial Drug and the performance of all required Protocol procedures on Trial subjects including but not limited to, written and audiovisual documents, medical records, charts pertaining to individual Trial subjects, "Case Report Forms **("CRF")** accounting records, notes, reports, and data. Institution will retain these documents for the longer period of at least 5 yrs. after completion or earlier termination of the Trial.

11.0 Representation and Warranties

11.1 Institute represents and warrants that it has the legal authority to enter into this Agreement and that the terms of this Agreement are not in conflict with any other agreements to which it is legally bound. Institute shall ensure that Investigator will not, enter into any agreement or engage in any activities that would materially impair its or his /her ability to complete the Trial in accordance with this Agreement and the Protocol.

11.2 Institute represents and warrants that the Principal Investigator is qualified as a medical practitioner under applicable laws and regulations.

12.0 Confidentiality

12.1 Institute will (and will cause Principal Investigator and Trial Personnel to) keep strictly confidential and not disclose to third parties all information provided by or on behalf of subject or that is generated, discovered, or obtained by any of the above Party as a result of the Trial (other than patient medical records), including the Trial Results, Trial Inventions and information related thereto **(Confidential Information).** Institute and Investigator will use, and will cause Trial Personnel to use, Confidential Information only for purposes of the Trial. The obligations of this Section will survive expiration or termination of this Agreement. Confidential Information will not include information that:

i. is or becomes publically available through no fault of Investigator or Institution.

ii. was known to Principal Investigator or Institute without obligation of confidentiality prior to receiving it either directly or indirectly from other sources Under this Agreement, as demonstrated by written records predating the date it was learned by Investigator or Institute from other source.

iii. is disclosed to Principal Investigator or Institution by a third party without violation of law or any obligation of confidentiality; or

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(10)

iv. Can be shown by written records of Principal Investigator or Institution to have been independently developed by Principal Investigator or Institution without reference to or reliance upon any Confidential Information.

12.2 Notwithstanding any other provision of this Agreement, Institute and Principal Investigator may disclose Confidential Information to the extent required.

i. to comply with an applicable law, rule regulation or government order, after prompt notice to Sponsor provided that Investigator and Institute cooperate with Sponsor efforts to limit such disclosure by appropriate legal means:

ii. to protect any Trial subject's safety or provide appropriate medical care for any Trial subject, or to prevent a public health emergency with prompt notice to Sponsor

iii. for purposes of insurance or reimbursement by a third party or pay for medical treatment of Trial subject related to the procedures included in the Protocol.

13.0 Return of Confidential Information

Upon either (i) the completion of the Trial or termination of this Agreement; or (ii) Sponsor's Request for any reason, Institute will immediately cease all use of all Confidential Information, and will promptly either return to Sponsor or if instructed by Sponsor destroy all Confidential Information, including any copies, extracts, summaries, or derivative works thereof, and certify in writing to Sponsor the completion of such return and/or destruction, provided, however, that Institute may retain one copy of Confidential Information in its legal archives solely for the purpose of monitoring its surviving obligations under this Agreement.

14.0 Trial Results and Inventions

14.1 Sponsor owns all data, Trial Results, Confidential Information, CRFs and all other information generated as a result of or in connection with the conduct of the Trial, excluding Institution's patient medical records and Principal Investigator's personal notes and hereby grants to the Institute a nonexclusive, non–transferable, non-sub licensable right to use the Trial Results solely for its own internal, non-commercial research, patient care, and educational purposes.

14.2 All inventions, ideas, methods works of authorship, know-how or discoveries that are made, conceived, or reduced to practice by Institute, Principal Investigator or Trial Personnel: (i) as a result of or in connection with the conduct of the Trial (ii) that incorporate or use Confidential Information: or (iii) that are directly related to the Compound and in each case together will all intellectual property rights relating thereto (collectively, **Trial Inventions**"), will be the sole and exclusive property of Sponsor Or its designee. Institute and Principal Investigator will

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promptly disclose all Trial Investigations to sponsor in writing and interest in all Trial Investigations to sponsor or its designee. At sponsor's request and expense, Institute shall take and shall cause Principal Investigator and Trial Personnel to take, all additional actions as it deems necessary to perfect the interest of sponsor or its designee in Trial Investigations or to obtain patents or otherwise protect the interest of sponsor or its designee in Trial Investigations.

15.0 Payment

15.1 In consideration for conducting the Study Sponsor shall pay Institute and Principal Investigator as described in Annexure. All of Sponsor's payment obligations are conditioned upon Institute and Principal Investigator compliance with standards identified in this Agreement. Sponsor will not make payments, or, if payment has been made by Sponsor Institute and Principal Investigator will repay to Sponsor any payments, for Study visits, procedures, or other work associated with a Study subject if Sponsor determines that the Clinical Trial Subject's Data is not evaluable because of a violation of the Protocol by Principal Investigator or Study Staff.

15.2 Sponsor shall pay on a Per Subject Cost for each Satisfactorily Completed Subject (as defined below) in accordance with Annexure as attached to this Agreement. If a subject is discontinued for reason stipulated in the Protocol, the Institute and Principal Investigator shall be paid a prorated rate for work completed.

(a). Per Subject Costs: Payments will be made on a per visit/day basis for visits/days completed, in accordance with Annexure-A. The estimated total amount per Clinical Trial Subject listed in Annexure-A is calculated for a Clinical Trial Subject that completes all the Study visits. Screening Visits are paid for consented Clinical Trial Subjects for whom all screening procedures are performed. All visit costs include Institutional overhead, staff fees and applicable taxes.

(b). the per subject costs is a fixed fee per patient which includes all costs and honoraria, including but not limited to:

-All Study related activities such as conduct of visit assessment and CRF completion -

Time and efforts of Principal Investigator/s and other Institute's Study personnel

-All manpower cost involved in the Study conduct

-All diagnostic test and other investigations

-Hospitalization/ hospital stay for patients including meals

-Patient reimbursement/ Compensation

-All over head costs

-Usage of Instruments/ equipments which during the Study should be having for proper

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-instrument ID, maintenance and calibration certificate/ Annual Maintenance Contract

-Miscellaneous (telephone, fax, courier, storage cupboards and maintenance of

-Institute infrastructure).

(c). A completed and evaluable patient means Patient:

(i). subjected to Study on whom all procedures have been performed and completed according to Protocol;

(ii). who is enrolled for the Study according to inclusion and exclusion criteria;

(iii). for whom all Data documented accurately and completely;

(iv). all Data queries resolved completely in mutually agreed timely manner; and

(v). for whom all source, CRF and other Study related documents completed as per protocol standard requirements as mentioned in Annexure.

15.3 **Screen Failures/ Drop-outs:** For drop-outs payment will be made by Sponsor on a pro rated basis for the number of completed visits and per screen failures (if applicable).

15.4 **Set-Up Fees:** Sponsor will pay the Institute an initial advance amount of **INR 25,000** (twenty five thousand only) within 15 days after obtaining the Ethics Committee and necessary regulatory approval. This up-front advance payment would be exclusive of Institutional overhead and service charges and shall be deducted/ adjusted on pro-rata basis from further subsequent payments.

15.5 **Hospitalization costs:** Apart from Study specific the in-house, treatment of the subject in the event of any SAE shall be paid by Sponsor to the Clinical Trial Subject.

15.6 **Institutional Ethics Committee Fees:** Institutional Ethics Committee review fees will be paid by sponsor as determined.

15.7 **Payments by Sponsor to Institute shall be directed as follows**:

Principal Investigator Fee/ Clinical Trial Subject Reimbursement and Hospitalization:

Payee Name (Account name)	**Director, SGPGIMS, Research a/c**
Account Number	**10095237491**
Bank Name	**State bank of India**
Branch Name	**SGPGI Branch, Lucknow**
Swift/IFSC Code	**SBIN0007789**
PAN Number*	**AAAJS3913N**
Send to	**Dr. ……..**

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<<Cheque Delivery Address>>	**……., Department of ……Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow-226014,U P, India**

15.8 Payments will be made **on monthly** basis according to actual work performed (CRF completion, source Data verification and CRF retrieval for completed visits). Advance payment will be adjusted against the 1st payment. Final payment will be made at the time of Investigation Site close-out visit or immediately after Investigation site close-out visit and payment will not be made until all queries are resolved.

15.9 Subject travel reimbursement is exclusive of Institutional overhead and will be done as mentioned in Annexure-A. However, Sponsor will release the funds to Institute and Principal Investigator for each Clinical Trial Subject, i.e., **Rs. ……**as per the Study schedule. However, it will be the obligation of Principal Investigator to pay the Clinical Trial Subject reimbursement on a pro rata basis (**Rs……..**- per visit). **Sponsor will provide an amount of ……N/A……. only for the future treatment Reimbursement to the Clinical Trial Subject who have completed the study.**

15.10 Payment will be made by Sponsor for Clinical Research coordinator salary per month **Rs. 20,000 (Twenty thousand rupees only)** for his/her efforts contribution to the Study. This payment would be inclusive of Institutional overhead and will be from the Investigation Site initiation visit to Investigation Site close out visit (until all the Data queries are resolved at the Institute's premises).

15.11 In the event there is a refund due to Sponsor at the time of premature termination of this Agreement by any party, the Institute agrees to remit the same to Sponsor within fifteen (15) days of the effective termination date.

15.12 **Tax deduction:** All fees and amounts listed are inclusive of applicable tax (TDS- Tax Deduction at Source). Prevailing TDS rate will be deducted from each payment disbursed to the Institute for the Study as per the applicable existing tax laws in the country. Certificate for the tax deducted at source will be provided at the end of the financial year.

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16.0 **Use of other parties' names**

The Principal Investigator and Institute shall not use Sponsor's name or the name of any party hereto in connection with any advertising or promotion of any product or service without the prior written permission from Sponsor/ CRO/Institute.

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17.0 No joint venture etc.

This Agreement shall not constitute, create, or in any way be interpreted as, a joint venture, partnership, or business organization of any kind.

18.0 Insurance and Indemnification

Insurance:

Institute shall maintain medical professional liability insurance with limits in accordance with local standards for each medical professional involved in the Study, or require that each medical professional maintain such insurance.

Indemnification:

Sponsor shall indemnify the Principal Investigator and Institute for any damages and liabilities including reasonable attorney fees as a result of any claim or lawsuit against Investigator or Institute arising directly out of the performance of the Study pursuant to the Protocol and SOP; provided however

(i) Sponsor will not indemnify any Loss to the extent the Loss arises out of Indemnities' failure to conduct the Study in accordance with: (1) the Protocol except allowing for Protocol deviations which were medically necessary for a Clinical Trial Subject's safety or well-being and which were communicated to and accepted by Sponsor, (2) any other instructions by Sponsor, concerning the Study drug or device or a Study procedure, or (3) applicable local, state and central laws;

(ii) Sponsor will not indemnify any for Loss to the extent the Loss arose out of the negligence or wrongful acts or omissions of an Indemnity or any other person subject to an Indemnities' control;

(iii) The Sponsor will indemnify the subject suffering in any manner as a result of trial for any reason whatsoever including negligence or violation of the protocol by the Principal Investigator or any member of his team as per order of the incensing authority or the Institutional Ethics Committee.

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19.0 MONITORING; AUDIT; REGULATORY INSPECTIONS

19.1 The Principal Investigator and Institute shall, permit authorized personnel of the Sponsor/ Sponsor designate and any Regulatory Authority including IEC to inspect the facilities of the Investigational Site before, during and after the Study.

19.2 The Principal Investigator and Institute shall notify to the Sponsor immediately by telephone

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or facsimile if the Drugs Controller General-India, or any other governmental or regulatory authority requests permission to or does inspect the Principal Investigator and Institute s facilities or research records relating to this Study whenever and will provide in writing to the inspecting authority copies of all materials, correspondence, statements, forms and records which the

Principal Investigator and Institute receives, obtains, or generates pursuant to any such study.

19.3 The Principal Investigator and Institute will permit the Sponsor to

a) Examine, inspect and audit the work performed here under and the facilities, systems and equipment at or with which the work is conducted.

b) Inspect and copy all Data, documents and records related to such work and the Study

19.4 The obligations of this Section shall survive termination of this Agreement.

20.0 Term; Waiver; Severability (The trial on its time extended)

20.1 This Agreement will be in force for a period of the trial or its time extended from the date of its signing. The term of this Agreement may be extended by consent of all parties to this Agreement.

20.2 Unless earlier terminated in accordance with the provisions of this Agreement, the term of this Agreement shall commence on the Effective Date and shall terminate 12 months after the Effective Date. The Date of execution of this Agreement shall be the effective Date.

20.3 This Agreement will become effective after by the last signatory it is fully executed by all the parties hereto and shall continue in effect for the full duration of the Study according to the Protocol unless extended or sooner terminated in accordance with the provisions of this Agreement.

20.4 This Agreement may be terminated by any party upon giving at least a thirty (30) days written notice to that effect to the other parties. The day following the 30th day of such notice shall be "Effective Date of Termination". A reasonable adjustment will be made between the parties to ensure the Principal Investigator and Institute is reimbursed for project costs incurred to the date of termination of this Agreement for completing the study as per protocol or already enrolled subjects.

20.5 Sponsor may terminate this Agreement, in whole or in part, with or without cause, immediately upon written notice to Institute subject to the discharge of their respective obligations under the terms of the agreement.

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21.0 Effect of termination

(i). Upon notice of termination of this Agreement by either Institute or Sponsor or Principal

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Investigator, Institute shall cease enrolling Clinical Trial Subjects into the Study, and shall discontinue conduct of the Study as soon as is medically practicable.

(ii). Upon notice of termination of this Agreement by Institute or Sponsor or Principal Investigator, Institute shall use reasonable efforts to revoke any financial obligations incurred and shall avoid incurring any additional costs in connection with the Study. Institute shall be compensated only for Study-related work actually performed or reimbursed only for expenses actually and reasonably incurred through the effective date of termination which sponsor has agreed to pay as part of the Study under this Agreement. If, upon the Effective Date of Termination, sponsor has advanced funds which remain unutilized or surplus, Institute shall repay such funds within sixty (60) days of the Effective Date of Termination. In the event Institute fails to repay such funds in a timely manner, Sponsor may deduct an equivalent amount from any payment then or later due from Sponsor to Institute under this or any other arrangement between the parties.

(iii). Upon termination of this Agreement, all unused Materials and all Sponsor Confidential Information (except for such records that Institute is required by law or regulation to retain) in Institute's possession shall be promptly delivered to Sponsor at Sponsor's expense, or, at Sponsor's option, destroyed with the destruction certified in writing.

22.0 Recordkeeping

The Institute and Principal Investigator shall prepare and maintain records, reports and Data provided in the Protocol, IEC requirements, and in accordance with all applicable local, state and Central laws and regulations. Institute or Principal Investigator shall cooperate with the Sponsor in making records, reports and Data developed under this Agreement.

Institute or Principal Investigator shall ensure the storage of Data related to Study in accordance with the requirements of current Good Clinical Practices, in suitable and secured storage facilities and under appropriate conditions, for a period of time required under the agreement applicable laws and regulations in INDIA or until 5 years after completion of all regulatory activity, whichever period is longer, unless to the extent that Sponsor requires the return or destruction of this Data, in which case this request shall be complied with to the extent allowed by applicable laws and regulations. Before the destruction or deletion of such Data, Sponsor's written approval shall be obtained.

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23.0 Publication

The parties acknowledge that the Sponsor shall retain ownership of all original Data that result

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from this Study. Data generated during the Clinical Trial Study is the sole property of the Sponsor. Therefore, Principal Investigator agrees not to publish or present the results or any information derived from the study but his name should to be included in any publication either author or as participant in the study.

24.0 Miscellaneous

24.1 Parties to this Agreement shall comply with the current provision of Drugs and Cosmetic Act 1940, Drugs and Cosmetic Rules 1945. For providing insurance to Clinical Trial Subjects in case of injuries or death, The parties to this Agreement have tied up with insurance company (The Oriental Insurance for 25,00000) which cover all patient enrolled in clinical trial. This insurance is valid from the period from 06.02.2019 to 05.09.2019. This insurance shall be extended from time to time till the expiry of Agreement.

24.2 The Study shall be started by Principal Investigator after this Agreement is executed by all the parties and required regulatory approvals/consent is available for the study.

24.3 The parties to this Agreement shall ensure that safety, welfare and right of the research participants (Clinical Trial Subject) are safeguard.

24.4 The Principal Investigator shall forward all Protocol deviation/non-compliance/violation/waiver reports to the IEC.

24.5 The safety completion Report shall be sent to IEC by Principal Investigator.

25.0 Governing Law

The validity, interpretation, and performance of this Agreement shall be governed and construed in accordance with the laws of INDIA as applicable in the State of Uttar Pradesh.

26.0 Jurisdiction

The place of jurisdiction for any dispute or claim before a court or an arbitrator shall be the site of trial, notwithstanding any other provision to the contrary in any law in this regard.

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27.0 Arbitration

All disputes or claims whatsoever arising out of or in respect of the terms and conditions of this agreement or relating to the admissibility or liability or quantity of compensation or damages payable to or by any of the parties to this agreement to the trial subject or his/her legal representative or the nominee shall be referred by the aggrieved party or person to the arbitration of a sole arbitrator to be appointed by the Chairman of the Institutional Ethics Committee of the Institute at the trial site within 30 days of the receipt of a written request by the aggrieved. The

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Indian Arbitration and conciliation Act 1996 as amended from time to time shall be applicable to such arbitration proceedings subject to the exception that the trial subject or his/her legal representative or the nominee shall not be liable to pay the cost of arbitration. The award of the arbitrator shall be final and binding on all the parties thereto.

28.0 Amendment

This Agreement and Protocol may only be amended by the mutual written consent of the parties hereto. The parties agree that this Agreement constitutes the sole, full and complete Agreement by and between the parties and supersedes all other written and oral Agreements and representation between the parties with respect to the Study. No amendments, changes, additions, deletions, or modifications to or of this Agreement shall be valid unless reduced to writing and signed by the parties. All changes and amendments to this Agreement shall be agreed in writing between the parties.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed, in triplicate, by their officers, thereunto duly authorized to sign on behalf of their party.

1. Principal Investigator, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow

Signature and date: _____

Dr. ANITA SAXENA

(Name)

Title/Designation: Professor Department of Nephrology

2. Director/his nominee, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow

Signature and date: _____

Dr. .....

(Name)

Title/Designation: .....

(Director/his nominee)

DIRECTOR
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

12/3/2019

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3. Sponsor

Signature and date: _____

Mr. P.PRABHAKARAN **(Name)**

Title/Designation: G.M – SALES & MARKETING.

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ANNEXURE

It was agreed that the Site will receive INR ...../- (.....) per Satisfactory Completed Subject for the Study according to the schedule indicated below. This Satisfactory Completed Subject amount is intended to cover the following Study- related costs incurred by the Investigation Site which includes (costs related to the Clinical Trial Subject visits, tests etc. Study related Communications, Institute service charges and Overheads).As this Study required inpatient hospitalization, hospitalization fees of INR ..... (..... only) per completed Clinical Trial Subject will be reimbursed by ..... to Institution. Clinical Trial Subject will be paid INR .....(.....rupees only) as a reimbursement for loss of daily wages due to participation in Study. In case of early withdrawal of Clinical Trial Subjects, the reimbursement can be provided on Pro-rata basis.

Apart from the Principal Investigator grant as listed below, on successful completion of all the visits, sponsor will provide the Patient Future treatment Reimbursement of .....- (Rupees ..... only) to the patients (who have completed the Study).

Investigator/ Hospitalization/ Patient reimbursement Grant (Inclusive of Institutional overhead)

Grant Distribution	
Coordinator Payment	INR 20,000 per month (From Investigation Site Initiation to Investigation Site Closeout)
Investigational Cost	Company will pay to SRL
Hospitalization Cost	N/A
Stationary and Miscellaneous	Mylin will provide
Patient Travel convenience	INR 200
Patient Future treatment Reimbursement	N/A Study

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All the above mentioned amount is inclusive of 25% Institutional overhead

Maybe not applicable as Trial is on OPD level

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CLINICAL TRIAL AGREEMENT BETWEEN ACCUTEST, PRINCIPAL INVESTIGATOR & INSTITUTE

(PI Name: Dr Ushakant Misra, Site Name: Sanjay Gandhi Post Graduate Institute of Medical sciences, Protocol Number: E2007-M091-508)

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement is made by and between the following three parties:

1)ACCUTEST: Accutest Research Lab. (I) Pvt. Ltd. A-77, Khairne MIDC, TTC Industrial Area, Khairne, Navi Mumbai, 400 709, Tel.: +91 22- 2778 0718/19 Fax: +91 22- 2778 0720 Email ID: rajendra.talele@accutestgloabal.com **Hereinafter "ACCUTEST"**	**2) PRINCIPAL INVESTIGATOR:** Name: Dr Usha kant Misra Address:. Sanjay Gandhi Post Graduate Institute of Medical sciences Raibareli road, Luknow, Uttar Pradesh, Uttar Pradesh, India. Tel.: +91-8004904627 /+91-9450653685 Fax: +91-05222668811 Email ID: drukmisra@rediffmail.com **Hereinafter "PRINCIPAL INVESTIGATOR"** **CO-INVESTIGATOR** Name: Dr. Jayantee Kalita Address: Sanjay Gandhi Post Graduate Institute of Medical sciences Raibareli road, Luknow, Uttar Pradesh, Uttar Pradesh, India. Tel: +91-9450411673 / +91-8004904630 Email ID: jayanteek@yahoo.com **Hereinafter "CO- INVESTIGATOR"**
3) INSTITUTE: Name of the Authorized Signatory: Dr. Rakesh Kapoor Designation: Director Name of the Institute: Sanjay Gandhi Post Graduate Institute of Medical sciences Address: Sanjay Gandhi Post Graduate Institute of Medical sciences Raibareli road, Luknow, Uttar Pradesh, Uttar Pradesh, India. **Hereinafter "INSTITUTE."**	

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Initial-1 (ACCUTEST): Initial-2 (PI): Initial-3 (INSTITUTE):

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(33)

This Clinical Trial Agreement is effective from the date of last signature("**Effective Date**")

Accutest is engaged in the business of clinical trials management as a contract research organization and intends to carry out a clinical study ("the Study") with "**A prospective, multicenter, post-marketing surveillance to assess safety & efficacy of perampanel in Indian patients as an adjunctive treatment in partial onset seizures with or without secondary generalized seizures in patients with epilepsy aged 12 years or older.**"("the **Protocol E2007-M091-508**") for the purpose of obtaining data for the application of the Study Drug.

The Study Protocol Number: E2007-M091-508

Subject to the condition of obtaining the pertinent ethics committee approval and the regulatory authorities' authorization, the parties intend to participate in the Study by rendering their services and agree to the following:

Section 1: Study Protocol

The nature and scope of the Study are ensured from the Protocol. The Protocol precisely and exhaustively describes the clinical research activities and responsibilities for careful execution by the Principal Investigator. Any changes to the Protocol are subject to Accutest's prior written consent which the Principal Investigator shall obtain, and the approval/notification of the competent ethics committee and the Drug Controller General of India ("**DCGI**"). The Protocol, including any amendments, constitutes an integral part of this Agreement ("The **Agreement**") and shall be valid upon signature of this Agreement. In the case of any inconsistency between this Agreement and the Protocol, this Agreement shall prevail. The Principal Investigator warrant that they have received the Protocol.

Section 2: Rules for the Conduct of the Study

2.1 Legal framework

The parties agree that the duties and obligations of the provisions of the Declaration of the Helsinki World Medical Association Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects including amendments as set out in the Protocol of the "ICH Harmonised Tripartite Guideline, Guideline for Good Clinical Practice", the applicable national legislation on public health and pharmaceuticals including the Central Drugs Standard Control Organization's Good Clinical Practice Guidelines ("**GCP Guidelines**")valid at the time of the performance of this Agreement; and all other pertinent rules and regulations shall be applicable including but not limited to Schedule Y to the Drugs and Cosmetics Rules, 1945 ("**Schedule Y**"), and that the Agreement shall be construed accordingly.

2.2 General Duties and Obligations

The Principal Investigator shall carry out the Study in a professional, competent manner in accordance with the Protocol and the terms of this Agreement.

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The Principal Investigator hereby warrants that they have sufficient resources with regard to time, adequate personnel and facilities for the performance of the Study. Unless expressly agreed otherwise, the responsibility for services of third parties (including, but not limited to sub-investigators and satellite sites) remains with the Principal Investigator. The Principal Investigator shall ensure that all personnel and third parties are bound by and comply with the terms of the Protocol and this Agreement.

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32

The Principal Investigator will inform Accutest, about all changes of personnel, facilities and clinical research methods at the Institute that may affect the Study.

In the event the Principal Investigator becomes either unwilling or unable to perform the duties required by this Agreement, Principal Investigator will inform Accutest within 3 days of the Principal Investigator being unwilling or unable to perform the duties. The Principal Investigator shall continue to be bound by the provisions referred to in Section 5.2.

The Principal Investigator is an employee, of the Institute and Investigator guarantees the proper performance by him following all obligations hereunder.

2.3 Ethics Committee / Review Board / Regulatory Authority Approval / Notifications

Accutest shall undertake the necessary notifications to authorities in accordance with applicable laws. The Study shall not commence until the Principal Investigator is informed by Accutest that the authorities have given authorization.
Accutest will provide the Principal Investigator with all the documentation required for submission to the pertinent ethics committee. Institute/Principal Investigator will obtain the written approval of the appropriate ethics committee prior to the commencement of the Study and will furnish Accutest or its designate with the ethics committee's letter of approval and a list of all ethics committee meeting attendees.

The Study shall not commence until receipt of the ethics committee written approval and shall follow any conditions of approval imposed by the ethics committee, and the time interval has been observed and all regulatory documents that are necessary according to the ICH – GCP,Schedule Y, and other applicable pharmaceutical regulations are available.

Should the ethics committee express objections to the content or the performance of the Study, the parties will collectively develop modifications that accommodate the objections. Should the ethics committee approval be unobtainable nonetheless, the parties shall be entitled to mutually terminate this Agreement. Amendments to the Protocol must be submitted by the Principal Investigator to the pertinent ethics committee.

2.4 Subject Information and Informed Consent

The Principal Investigator shall ensure that during informed consent process, information to the subjects is provided individually and not in a group (in accordance with the provisions specified in Section 2.1 above) in a language that is best understood by the subject about the nature, significance and consequences of the Study, its expected duration, and the potential benefits and risks involved in Study participation.The explanation shall at least include all points listed in the ICH-GCP and Schedule Y.The Principal Investigator should obtain written Informed consent from patient, record necessary source data (like IC-EC, ECG, Physical Examination, Vital,etc.) and submit verify the eligibility criteria prior to enrolling the patient in the study.The Principal Investigator shall conduct complete Informed Consent process as per current regulatory requirement and also document the written consent prior to the Study on a prepared Informed Consent Form (ICF) and shall hand out a copy of the ICF and subject information document to each subject. In accordance with the provisions specified in Section 2.1 above, Principal Investigator shall ensure that consent of the governing local health authorities and/or subject for the submission of ICF mentioned above anonymous data to and/or appropriate regulatory authorities, is obtained.

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SGPGIMS,Lucknow

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All the study related documents should be preserved safely after the completion/termination of the study for at least a period of 5 years if it is not possible to maintain the same permanently, if applicable.

Each subject will be informed accordingly, and his/her consent will be obtained

- that he/she is enrolled in the Study,
- that the subject's insurance has been effected and that each subject has obligations arising from the general insurance conditions; in particular these are:
- during the course of the Study the subject must immediately inform the Principal Investigator about any other medical treatment he/she undergoes;
- any health damage, which may be attributable to participation in the Study, must be immediately reported to the insurance company;
- that the necessary documentation of the subject's health and personal data and its distribution to Accutest, the competent health authorities, and other Institutes, as legally required, may take place.

In the event the patient or his/her legally acceptable representative is unable to read/write, an impartial witness will remain present during the entire informed consent process and who must append his/her signatures to the Study informed consent form. The Principal Investigator will obtain prior approval from the relevant ethics committee in the event of any amendments to the Study informed consent form

2.5 Enrolment Period

The recruitment phase may not commence until the written positive decision of the ethics committee has been obtained.

The Principal Investigator will recruit a maximum of **20 subjects** for the Study, as the enrollment is competitive amongst the investigative sites.

The Principal Investigator is aware that for this multicentre study, a competitive recruitment will apply. Should the total number of subjects enrolled in the study be met prior to the end of the anticipated enrollment period, Accutest shall have the right to end further enrolment of subjects; no payment will be made for any such additional subjects.

2.6 Study Documents and Drug Supplies

Accutest's designee shall ensure appropriate and timely supply of the documents and Study Drugs necessary for the performance of the Study. All supplies shall be returned to Accutest by the Principal Investigator/Institutein a timely manner throughout the performance of this Study, as outlined in the Protocol or when Accutest otherwise requests delivery of data, unused Drug, and clinical specimens.

The Principal Investigator hereby warrants that he/she shall:

a) account for all clinical supplies furnished by Accutest and keep a written inventory of any equipment supplied by Accutest according to guidelines provided by Accutest;

b) use the Study Drug solely for the Study, documenting each usage and to return all used and unused clinical or other supplies provided by Accutest upon conclusion of the Study;

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c) collect data properly and report to Accutest all relevant information and data obtained under the Protocol;

d) submit to Accutest signed CRFs/eCRFs resulting from the Study in a timely manner;

e) retain all necessary records and documents about the Study as required by applicable regulatory requirements, this Agreement, and/or the Protocol;

Moreover, the Principal Investigator shall update/maintain the investigator study file provided at the time of Site Initiation Visit (SIV) andas per ICH-GCP all relevant essential documents which are necessary for the conduct of the Study including but not limited to following:

a) Signed Protocol and amendments;

b) Investigator's Brochure and updates (If applicable);

c) Ethics Committee composition, approval(s)/opinion correspondence/reporting;

d) Notifications/Approval of regulatory authorities;

e) CVs and signature sheet for key study personnel (e.g. investigators);

f) Approved and signed informed consent forms;

g) CRFs/eCRFs (investigator's copy) (If applicable);

h) Serious adverse events documentation and related correspondence/reporting;

i) Instructions for handling of Study Drug;

j) Screening, enrollment, and monitoring logs and subject identification code list;

k) Study related correspondence with Accutest

2.7 Adverse Events

The Principal Investigator is obliged to document and manage all Adverse Events (AEs) in accordance with the Protocol and to notify Accutest of all Serious Adverse Events according to the study instructions ("Serious Adverse Event Reporting") within the timeline specified in the Protocolor as per current regulatory requirement

Section 3: Documentation and Monitoring

3.1 Documentation and CRF/eCRFs handling

The Principal Investigator shall keep all original medical files (paper and print-outs of electronic files) of every subject participating in the Study in addition to the Case Report Forms(CRFs)/electronic Case Report Forms (eCRFs). The medical file is the documentation containing all demographic and medical data of a subject. This medical file will clearly identify each Study subject and where the medical files are termed the source; entries on the CRFs/eCRFs must be traceable to entries in the medical file. In the course of the Study, the Principal Investigator undertakes to express medical data in writing using medical terminology where necessary, the status of the Study for the respective subject and be completed expeditiously following a subject visit. The Principal Investigator must sign all eCRFs/CRFs. The Principal Investigator should inform the general practitioner and, if applicable, any other physicians, treating the subject about his participation in this clinical Study. The Principal

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29

Investigator warrants that all eCRFs/CRFs submitted to Accutest are true, complete and correct and accurately reflect the results of the Study with respect to each person participating as a subject.

The Principal Investigator undertakes to cooperate with Accutest and acknowledges Accutest's right, upon a request, to be granted direct access to all requested trial-related records (including patient medical files).

3.2 Monitoring

The parties agree to frequent monitoring visits to the institute by Accutest. The monitor (CRA) will visit the Institute to discuss study progress with the Principal Investigator who will allow inspection of all study data including medical files requested by the monitor.

The CRAs will check the data entered in the eCRFs/CRFs. CRAs and possibly representatives of Accutest shall perform source data verification, comparing the CRFs/eCRFs with the medical records to validate the data. Despite the CRA's and other representatives' efforts, the Principal Investigator remain primarily responsible for the accurate and complete data entry in the CRFs/ eCRFs. All persons who obtain knowledge of medical records are subject to professional secrecy.

Such monitoring will be carried out during the study, but may also be demanded by the pertinent regulatory authorities after completion of the study. The Principal Investigator are obliged to inform Accutest immediately of any notification of an inspection by the pertinent regulatory authorities.

3.3 Audit and Regulatory Inspection

Audits or inspections may be carried out during the Study, but may also be demanded by the regulatory authorities after completion of the Study. In the event thatAccutest or authorities perform an audit, the Institute,Principal Investigator will allow access to the facilities, make documents available and if necessary provide information. Should a governmental or regulatory authority request or carry out an inspection of the Institute's or Principal Investigator's facilities, Principal Investigator has to immediately notify Accutestby telephone, mail or fax and allow Accutest to be present. The Principal Investigator shall provide to Accutest copies of all materials, correspondence, statements, forms and records that Principal Investigator receives, obtains, or generates pursuant to any such inspection.

Section 4: Confidentiality and Subject Data

4.1 Protection of Subject Data

On the CRFs/eCRFs, which will be used for evaluation of the Study, patient data will be documented in anonymous form only, i.e. without naming the subject, and passed on to Accutest and the DCGIand/or foreign regulatory authorities. The name of the subject, as well as other person-related data, will not be divulged by the Principal Investigator, or by Accutest. Accutest shall ensure that the protection of the data concerning subjects is safeguarded.

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Where, for reasons of the fulfilment of professional obligations or verification purposes, person-related data concerning the Principal Investigator or the subjectare stored or handled, reliable organizational measures must be employed to ensure that these data are not divulged to unauthorized third parties.

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Exception: When IEC or DCGI or any other regulatory authorities require the subject details then Principal investigator shall share photocopy and maintain the record in the file.

4.2 Confidentiality

Principal Investigator shall receive copies of the Study documents and the investigator site file. Principal Investigator/Institute is obliged to retain the documents facilitating identification of the Study patients, and all other Study Documentation disclosed by Accutest, for at least 15 years after the end or the premature termination of the Study or as communicated during site close-outvisit.Institute has no part to play in the closeout of the trial.Accutest is responsible for informing the Principal Investigator when it is no longer necessary to conserve all the Study documentation (ICH 4.9.5).

The Principal Investigator/Institute is obliged to maintain the secrecy of all information related to the Study and the Study Drug ("the **Information**"). The Principal Investigator shall procure that any co-workers assisting the Principal Investigator in the Study shall keep all such Information secure and strictly confidential as well. The Principal Investigator agrees not to use the Information for any purpose other than the performance of the Study.

The information shall not include:

- Information that enters the public domain and only then where this has occurred other than through unauthorized disclosure by the Principal Investigator or his co-workers.
- Information that is properly requested for by the ethics committee responsible for approving the Study may proceed or is requested by the pertinent regulatory authorities in accordance with prevailing legislation, provided that the Principal Investigator shall give prior written notice to Accutest of any such request for disclosure.

The above obligations of confidentiality shall remain in full force and effect.

4.3 Proprietary information

All documents, data, know-how, formulas and unused Study Drug provided to the Principal Investigator for purposes of the Study ("**Data**") are and will remain Accutest's property and will be returned to Accutestor their respective designates upon request. Notwithstanding the preceding, Accutest shall retain full ownership rights in and to all templates, programs and other materials developed or licensed by Accutest prior to or apart from the commencement of this Agreement, regardless of whether such materials are used in connection with this Agreement.The Principal Investigator hereby transfers and assigns to Accutest the Principal Investigator's worldwide right and title to all Data in perpetuity and agrees to undertake such actions reasonably requested by Accutest to give effect to such ownership and agrees to sign, execute, affirm all documents, including, without limitation, all applications, forms, instruments of assignment and supporting documentation and perform all other acts as may be required for this purpose.

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4.4 Rights to results

Accutest shall have the right to use the results of the Study in any manner deemed appropriate to Accutest's business interests. All data attained during the performance of the Study are Accutest's property. The Principal Investigator assign worldwide rights and title to all data obtained in the Study in

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perpetuity to Accutest and agree to undertake such actions reasonably requested by Accutest to give effect to such ownership and agree to sign, execute, affirm all documents, including, without limitation, all applications, forms, instruments of assignment and supporting documentation and perform all other acts as may be required for this purpose. Principal Investigator shall notify Accutest of the results immediately, separately and in writing.

4.5 Intellectual Property

Neither the Principal Investigator nor his employees or agents shall acquire any rights of any kind whatsoever with respect to the Study Drug as a result of their performance under this Agreement. All inventions, discoveries, and technology relating to the Study Drug conceived by the Institute or its Principal Investigator, solely or jointly with others as a result of work done under this Agreement, shall be, and remain, at all times the sole and exclusive property of Accutest (subject to the right expressly reserved under Section 4.3).

The Principal Investigator hereby assign worldwide rights and title to the Intellectual Property in perpetuity to Accutest and agree to undertake such actions reasonably requested by Accutest to give effect to such ownership and agree to sign, execute, affirm all documents, including, without limitation, all applications, forms, instruments of assignment and supporting documentation and perform all other acts as may be required for this purpose.

The Principal Investigator warrant, by the execution of this Agreement, that they have not entered, and will not enter, into any contractual agreement or relationship which would in any way conflict with or compromise Accutest's rights to, any inventions, discoveries, or technology arising out of or related to their performance thereunder.

4.6 Publications

It is the general policy of the ARL & Sponsor to encourage publication of results of Clinical Trial on a case to case basis. However, according to good scientific practice, no interim data should be published by the Principal Investigator/ Institute unless agreed by the Parties in writing. It is further agreed that when the Principal Investigator/ Institute request for publications, the manuscript shall be based on final report of the Study and before any publication it shall be sent to the ARL & Sponsorfor its perusal, comments, and approval. The ARL or Sponsor may at its discretion either refuse the publication or forward it to the Principal Investigator/ Institute/ along with its comments or modifications which shall be final and binding on the Principal Investigator/ Institute.

4.7 Publicity

No party to this Agreement shall use Accutest's name or the name of any party hereto in connection with any advertising or promotion of any product or service without the prior written permission of such party or Accutest, as appropriate.

Section 5: Term and Termination of the Agreement

5.1 This Agreement commences on the Effective Date provided that Accutest has received from the pertinent ethics committees and the DCGI, as required by law, approval to carry out the Study. This Agreement shall remain in force to the full conclusion of the Study according to the Study Protocol unless terminated prematurely. Accutest may terminate this Agreement immediately upon written notice to the Institute/Principal Investigator.

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26

5.2 Termination of this Agreement by any party shall not affect the rights and obligations of the parties accrued prior to the effective date of termination of this Agreement.

Neither termination of this Agreement, however, effectuated, nor the end of the term shall cause the parties hereto to be released from their rights and obligations under Sections 3, 4, 6, 7 and 8, or under any other provisions of this Agreement that by their terms are understood to survive termination.

Upon completion of the Study, the Principal Investigator and the Institute shall return to Accutest, or its designee, all unused Study Drug, compounds, Comparator Drugs (when used), equipment as specified in Section 2.6 that were furnished to the Institute other than the investigator site file documents.

5.3 Should the Principal Investigator recognise within reasonable discretion that continuation of the Study is no longer possible, due to unexpected results medically not justifiable, due to severity of serious adverse events not justifiable or efficacy of the treatment with the Study Drug insufficient, he/she will immediately notify Accutest as well as the ethics committee. Should continuation not be justifiable, the Principal Investigator may arrange for immediate termination of the Study. In the event that the Study is terminated with the consent of Accutest,the Principal Investigator shall receive payment pro rata temporis basis for the efforts of the Study, in accordance with Appendix A.

5.4 Accutest may terminate its cooperation with the Principal Investigator prematurely, provided that:

a) one month after shipment of the Study material, no subjects have been enrolled or the Principal Investigator recruits no subjects or recruits such a low number of subjects that it can be assumed that the agreed number of patients will not be reached during the planned recruitment phase,

b) Accutest terminates the Study for the Study Drug or the indication is discontinued,

c) it is proved that the dosage used for the Study does not seem to be justified any more,

d) regulatory authorities or other pertinent institutions decide to terminate the Study in this center or as a whole,

e) the Principal Investigator fails to sufficiently adhere to the conditions of the Protocol and the need to exact and complete data documentation and the GCP Guidelines and Schedule Y.

5.5 Consequences of Termination: Upon the effective date of termination, the Principal Investigator shall:

a) terminate all services as efficiently and quickly as possible, except to the extent Institute/Principal Investigator is required to continue to follow the procedures and perform such services with respect to the ongoing Study, as may be necessary, until the appointment by Accutest of another Institute/Principal Investigator for the purpose of continuing the Study;

b) within 7 business days, provide copies of all information, data, documents (including but not limited to IPs, ICFs(blank copies), CRFs/eCRFs, Study related material & documents, and any clinical samples obtained with regard to the Study) prepared, conceived, generated or delivered by Principal Investigator as a result of or in connection with the conduct of the Study;

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c) Provide an accounting of all clinical supplies, which is subject to verification by Accutest. If Accutest objects to any charge, the parties shall use reasonable efforts to resolve expeditiously any disagreement.

Section 6: Payment Terms and Conditions

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

Payment of investigator grants on behalf of Accutest will be equatedwith respect to the number of subjects recruited and the services performed as set out in detail in the APPENDIX-I & II entitled "Investigator Grants."

In the case of any inconsistency between this Agreement and the APPENDIX, this Agreement shall prevail. For the avoidance of doubt, if any obligation is specified in one of these documents but not in the other, this shall not constitute an inconsistency.

In the event that Accutest or the Principal Investigator/Institute terminates the Agreement prematurely in accordance with Section 5.4, Accutest shall not pay grants for performance on subjects that do not conclude the Study provided that:

- where a subject has been recruited to the Study in violation of the Protocol, there shall be no obligation of payment;
- where failure by a subject to complete the Study is due to the omission of tests or assessments by the Principal Investigator, there shall be no obligation of payment;
- where failure by a subject to complete the Study is due to adverse effect, lack of effect, concomitant illness, non-compliance or non-attendance, provided that full data is available up to the time of the subject'sdropout and the event is satisfactorily recorded, payment shall be made in accordance with the above-referenced APPENDIX proportionately according to the amount of work carried out by the Principal Investigator pursuant to the Protocol;
- any sums advanced to the Principal Investigator prior to termination of this Agreement will be taken into account in calculating any sum due to the Institute or Principal Investigator and any balance outstanding and due to Accutest shall be paid to by the Principal Investigator;
- "Completed Patients" are subjectswho have completed the Study in accordance with the Protocol, and for whom full case report forms and any ancillary documentation required have been completed by the Principal Investigator to Accutest's satisfaction.

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Section 7: Standard of Care, Insurance, Indemnity

7.1 Subject Insurance

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Thishas been obtained and will be provided to the site personnel before the initiation of the trial.

7.2 Product liability

Study Insurance will be provided to the site personnel before the initial of the trial.

7.3 Standard of care

In no event shall Accutest be held responsible for any controversy, demand or claim for the payment of damages deriving from Principal Investigator for-

(a) injuries or damages incurred if they are the result of or are alleged to be the result of negligence or willful misconduct on the part of the Instituteor agents or the Principal Investigator;

(b) activities contrary to the Protocol;

(c) unauthorized warranties made by the Principal Investigator concerning the product being tested;

(d) in any case, in which written, informed consent was not obtained for the subject involved in accordance with the Protocol.

The Principal Investigator hereby represent and warrant that they have obtained a professional liability insurance policy from a reputed and creditworthy insurance company, covering their liability for any damage, which may be caused as a result of fault or negligence, which they may commit in the performance of this Agreement. The Principal Investigator shall provide evidence of its insurance upon request by Accutest. The Principal Investigator shall be liable under this Agreement for direct damages resulting from negligence or wilful misconduct in the execution of the Study.

The Principal Investigator shall defend and hold harmless, and be responsible for losses suffered by Accutest and any agent and employees of Accutest from any and all liabilities, claims, actions or suits for personal injury or death directly arising out of the improper or negligent administration or use of the Study Drug during the course of the Study.

The Principal Investigator shall also indemnify, defend, and hold Accutest and its affiliates, directors, officers, employees and other representatives ("Accutest Indemnified Parties") harmless from and against any and all loss, costs, claims, actions, liability and/or suits, including without limitation, interest, penalties and reasonable attorneys' fees ("Accutest's Claims"), incurred by Accutest that arose from or was a result of following:

(a) any material breach by Principal Investigator under this Agreement;

(b) the failure, or act, error, deviation, omissions, negligence, gross negligence or intentional misconduct of the Principal Investigator in connection with its performance of the services, obligations, responsibilities and undertakings under this Agreement;

(c) Principal Investigator's violation of any and all applicable laws rules and regulations of India;

(d) Principal Investigator's breach or default in performance of its obligations in connection with the Study;

(e) Principal Investigator's material deviation from the Protocol;

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(f) Principal Investigator's failure to complete the Study and any such delay attributable solely to Principal Investigator's willful misconduct, or failure to comply with its obligations under this Agreement.

Section 8: Parties

8.1 Conflict of Interests

The Principal Investigator warrant that they, as well as all their support personnel, are not presently under any agreement or obligation which conflicts with the duties and obligations owed to Accutest under this Agreement, and further agree not to undertake any such obligations or agreement during the course of the Study.

Where (if applicable) it is intended that the Study Drug will be the subject of a submission to the regulatory authorities for a New Drug Application, the Principal Investigator certifies that he/she shall, in any form or manner reasonably requested by Accutest, disclose, and shall use his/her reasonable best efforts to cause any sub-investigators for the Study to disclose, all of the following that they and their spouses, domestic partners and dependent children own or possess directly, indirectly, or equitably (all collectively "Financial Interests"):

(a) All compensation, payments (including other research grants, consulting or director's fees, honoraria, speaking and meeting travel fees and reimbursement) and items or services of value provided by or on behalf of Accutest (excluding compensation received under this Agreement);

(b) All licenses, assignments, or other conveyances of rights or interests in real, personal or intellectual property ofAccutest or relating to the Study Drug;

(c) All forms of interests in the equity (including stock, options, and warrants) or debt of Accutestor of other entities having a financial interest in the Study Drug; and

(d) All other financial interests, payments, and other compensation.

During the conduct of the Study and for one (1) year after its completion, the Principal Investigator agrees to execute and update such forms, disclosures, and certifications now or subsequently required by Accutest related to the Financial Interests. The Principal Investigator hereby warrants that he/she has implemented a "Conflicts of Interests" disclosure and management policy and program that complies with the requirements and regulations issued or administered by the pertinent regulatory authorities, and the Principal Investigator warrants that he/she has and will continue to comply with such policies and programs.

8.2 Independent Contractor, Employees

The Institute and the Principal Investigator shall perform services under this Agreement only as independent contractors for Accutest, and nothing contained herein shall be construed to be inconsistent with that relationship or status. The Principal Investigator and his respective employees shall not be considered employees or agents of Accutest. This Agreement shall not create a business organization of any kind.

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The parties agree that they shall not directly or indirectly solicit for employment, employ or otherwise retain staff of the other party during the term of this Agreement or within the period of three (3) years following termination of this Agreement.

The Study is performed independently from any business transactions and decision on supply purchases with Accutest. The Instituteandthe Principal Investigator will not receive any benefits from the conduct of the Study beyond the remuneration agreed herein.

8.3 Assignment

Principal Investigator shall not assign his rights or obligations out of this Agreement to any third parties without Accutest's prior written consent. The Institute and the Principal Investigator understand and agree that this Agreement is being entered into to perform services forAccutest and that accordingly, Accutest may freely assign its rights and obligations out of this Agreement.

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

Section 9: Communications

The Parties undertake to notify each other of all cases that influence the performance of this Agreement. Correspondences shall be made to the following addresses:

1)ACCUTEST:	2) PRINCIPAL INVESTIGATOR:
Accutest Research Lab. (I) Pvt. Ltd. A-77, Khairne MIDC, TTC Industrial Area, Khairne, Navi Mumbai, 400 709, Tel.: +91 22- 2778 0718/19 Fax: +91 22- 2778 0720 Email ID: rajendra.talele@accutestgloabal.com	Name: Dr Usha kant Misra Address:. Sanjay Gandhi Post Graduate Institute of Medical sciences Raibareli road, Luknow, Uttar Pradesh, Uttar Pradesh, India. Tel.: +91-8004904627 /+91-9450653685 Fax: +91-05222668811 Email ID: drumisra@rediffmail.com
	CO-INVESTIGATOR Name: Dr. Jayantee Kalita Address: Sanjay Gandhi Post Graduate Institute of Medical sciences Raibareli road, Luknow, Uttar Pradesh, Uttar Pradesh, India. Tel: +91-9450411673 / +91-8004904630 Email ID: jayanteek@yahoo.com

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3) INSTITUTE:

Name: Dr. Rakesh kapoor
Address: Sanjay Gandhi Post Graduate Institute of Medical Sciences,
Raibareli road, Lucknow, Uttar Pradesh, Uttar Pradesh, India.
Tel.: +91-0522-2494001
Email ID: director@sgpgi.ac.in

Section 10: Contractual

10.1 Entire Agreement

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

10.2 Applicable Law, Place of Venue

The parties agree that this Agreement shall be governed by Indian Law, without regard to the conflicts of laws provisions thereof.

The parties will endeavor to settle amicably any dispute having its origin in this Agreement. In case a dispute is brought before a court of law, the courts of Lucknow, india will have sole jurisdiction over the litigation.

10.3 Severability

Should any of the provisions of this Agreement be declared entirely or in part invalid or unenforceable by the pertinent authorities according to the applicable laws, the remaining terms of this Agreement shall not be affected by such declaration. Such invalid provision shall be replaced by a valid provision reflecting - to the extent possible - the intent of the original provision.

10.4 Waiver

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

Section 11: Miscellaneous

Principal Investigator/Institute hereby confirms,

A. that he/she has never been subject to debarment proceedings indicted, convicted, or otherwise engaged in conduct for which a person can be debarred by law,

B. to have received a copy of the Investigator's Brochure and to be informed of its contents.

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The Investigator consents that his/her contact data, as well as information about the conduct of the Study, may be stored and processed for evaluation purposes during and after the completion of the Study by Accutest.

1) ACCUTEST: For Accutest Research Lab. (I) Pvt. Ltd: Signature and Date 20-Apr-2018 **Mr. Rajendra Talele, Head- Clinical Development Services**	**2) PRINCIPAL INVESTIGATOR:** Signature and Date **Dr. Usha kant Misra** **Co- Investigator:** Signature and Date 2/7/18 **Dr. Jayantee Kalita**
3) INSTITUTE: For Signature and Date 23/01/19 DIRECTOR Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226 014, INDIA **Name & Designation: Dr. Rakesh Kapoor-Director**	

APPENDIX I

Financial Support for Investigator:

(a) **Total payment, compliance, completed patients, inclusion Criteria:**

Payment of remuneration will only be made under the condition that the Study is conducted in accordance with the Protocol, the Study documentation is complete and evaluable, can be verified from the subject medical files, and is submitted to Accutest at the stipulated points in time. Should these prerequisites not be fulfilled, the remunerations are forfeited, particularly for patients who are included in the Study despite non-compliance with the inclusion or exclusion criteria.

Unless expressly agreed otherwise in writing, total payment will not exceed the amount set out below.

For each evaluable patient who completes the study visits in accordance with the Protocol, GCP, and applicable regulatory requirement, Accutest will compensate the Investigator remuneration as specified in Appendix II.

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19

Payments for any costs not expressly specified herein, including but not limited to hospital overhead fees, staff costs, pharmacy fees, other tests,(if applicable) and travel costs, must come from the per patient enrolment fee.

(b) Payments will be made based upon the completed CRF/eCRFs collected by Accutest

(Please refer Appendix II for payment detail).

(c) Pro rata temporis payment

Should the Study be prematurely discontinued, the remuneration will be calculated on a pro rata temporis basis. For patients who do not complete the Study, remuneration may be paid on pro rata temporis basis. Payment will include only those patients participating in the Study whose date of joining the Study is not later than the date of the premature termination of the Study.

(d) Protocol violators, exclusion

For Protocol violators due to missed or delayed visits or in the event of a violation on the part of a patient of a Protocol resolution or the Regulations for Good Clinical Practice, no compensation will be paid for that patient /payment may be made at Accutest's sole discretion.

(e) Income tax

All the payments made to the payee are subject to Tax Deducted at Source (TDS) as per the applicable existing tax laws in the country. Accutest will deduct the tax at the time of making payments unless a valid certificate (Form 15 AA – for no TDS) from tax authority is made available in advance.

(f) Payment details

Accutest, on behalf of the Sponsor, shall pay the relevant cost and fee as set out in this Payment Agreement to following payees through A/C Payee Cheque as agreed by all signatories. Full of the grant shall be paid to the PI/ institute according to the payment milestones provided in APPENDIX II.

PI/ Institute payment
Payee Name: Director Research Account, SGPGIMS, Lucknow
PAN number: AAAJS3913N
GST Number: NA

Note:

1. Provide legible scan/photocopy of the PAN cards at the time of the signing of this agreement.
2. All local investigations (local lab tests, CT scans,any diagnostic assessments etc.) would be done to the payee mentioned for "PI/ institute payment" without deducting TDS. (A separate bill for patient payment should submitted).

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PI Name: Dr. Usha Kant Misra Site Name: Sanjay Gandhi Post Graduate Institute of Medical Sciences

Protocol Number: E2007-M091-508

1) ACCUTEST: For Accutest Research Laboratories (I) Pvt. Ltd: Signature and Date Rajendra Talele 20-Apr-2018 **Mr. Rajendra Talele, Head- Clinical Development Services**	2) PRINCIPAL INVESTIGATOR: Signature and Date 27/4/18 **Dr. Usha kant Misra** **Co- Investigator:** Signature and Date 27/4/18 **Dr. Jayantee Kalita**

3) INSTITUTE:
For
Signature and Date

23/01/19

DIRECTOR
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Name & Designation: Dr. Rakesh Kapoor- Director

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Executive Registrar
SGPGIMS,Lucknow

Initial (ACCUTEST): Initial (PI): Initial (INSTITUTE):

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APPENDIX II

Visit	Amount(INR)
Screening	8000
Visit 1 (Enrollment)	3800
Visit 2 (Month 1)	3500
Visit 3 (Month 2)	3500
Visit 4 (Month 3)	3500
Visit 5 (Month 4)	3500
Visit 6 (Month 5)	3500
Visit 7 (Month 6)	3500
Total PI Grant (a)	32800
Institutional overhead (25%) (b)	8200
TOTAL (a+b)	41000
TDS 10% (c)	4100
Grand Total (a+b+c)	45100
TOTAL PI GRANT	45100

Payment Details & Milestone:

1. Principal Investigator Fees will be **INR 32800 /-** per completed patient (Including Clinical Research Coordinator payment and excluding institutional overhead and goods and service tax and/or other taxes if applicable). The taxes may be revised and shall be applicable as per the Government norms from time to time.

   All local investigations (local lab tests, CT scans,any diagnostic assessments etc.) will be paid to the payee mentioned for "PI/ institute payment"on Actuals on Production of the Bills/Invoice/Proof.

   CRC payment of INR 16000/- per month will be adjusted by the PI from the PI grant. The PI grant of INR 45100/- per patient is inclusive of CRC payment.

The above payment also includes following charges:

a) Investigator(s) and other team members fees
b) Stationary, cupboard, courier, telephone, fax, internet and electricity bills, etc.
c) Patient recruitment
d) Electronic Case Report Form/Case Report Forms (CRF/ eCRFs) completion and correction
e) Data Clarification Form (DCF) resolution
f) Consultation charges
g) Document archival

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2. Ethics Committee fee will be paid on actual on the production of Bill/proof/invoice.
3. Institutional Overhead will be paidon production of Bill/proof/invoice
4. Per patient cost will be paid as mentioned above upon confirmation by site monitor of receipt of legible and accurately completed CRF/eCRF for a properly qualified subject.
5. INR 2000/- for screen failure patient.
6. Expense towards the medical management of serious adverse events will be made as per actual.
7. INR 1000/- for unscheduled patient visit.

The following are the milestone for the payments:

1. Every month from SIV, site personnel is supposed to raise invoice.
2. Invoice should be 90% of the SDV completed at the site by the ARL monitor.
3. Rest 10% of study payment will be made after study close out visit once all documents and activities (related to site) are completed.

NOTE: *If above milestones are not achieved than proportionate amount will be paid based on patient randomized and visit completed by the patient.*

Principal Investigator agrees that before incurring any of the aforesaid expenses it shall obtain prior written approval from the Sponsor. Sponsor will generally provide procedural material required by the protocol for the study. However, in the event Sponsor requires Principal Investigator to procure aforesaid items, it shall reimburse the actual cost incurred by Principal Investigator in connection in addition to that.

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

a) Accutest will pay a sum for every complete and evaluable patient.

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

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

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

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

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f) Patient conveyance/ compensation will be paid by Accutest on behalf of the Sponsor and is included in the budget as mentioned. The TDS will not be deductedon payment released for patient compensation.

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

h) If the trial terminates prematurely, any payments made by Accutest exceeding the amount earned will be promptly refunded to Accutest (minus Ethics Committee fees, and patient conveyance/compensation).

i) Payment would be done on the basis of invoices generated by the site in consultation with site CRA on every monitoring after checking the CRF/eCRF completion.

NOTE: Site should generate a monthly invoice and should consider completed milestone from above at the time of invoicing.

1) ACCUTEST: For Accutest Research Lab. (I) Pvt. Ltd: Signature and Date Rajendra Talele 20-Apr-2018 **Mr. Rajendra Talele, Head- Clinical Development Services**	**2) PRINCIPAL INVESTIGATOR:** Signature and Date 17/10 **Dr. Usha kant Misra** **Co- Investigator:** Signature and Date 27/7/18 **Dr. Jayantee Kalita**

3) INSTITUTE:

Signature and Date

DIRECTOR
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

23/10/2018

Name & Designation: Dr. Rakesh Kapoor-Director

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महाराष्ट्र MAHARASHTRA

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13 FEB 2014
अधिकारी

क्रमांक 2325 दिनांक
M/s /Mrs /Mr Amgen Technology Pvt. Ltd.
Dynasty Business Park
A Wing
Andheri - Kurla Road
Andheri (East)
Mumbai - 400059

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement ("**Agreement**") is made and entered into by and among Amgen Technology Pvt. Ltd., Dynasty Business Park, A Wing, Level 4, Andheri-Kurla Road, Andheri (East), Mumbai, 400059 India, and its parent or wholly owned subsidiaries of the parent ("**Company**") and Sanjay Gandhi Post Graduate Institute, Rae Bareli Road, Lucknow, Uttar Pradesh-226014, India ("**Site**"). This Agreement shall be considered fully executed on the latest date that a party executes the same.

1. SCOPE OF SERVICES

1.1 Engagement. The execution of this Agreement alone, in the absence of any duly executed Order, as defined below, shall neither create any obligation of Site to perform hereunder nor create any obligation of Company to give Site any compensation. An "**Order**" is a document executed, at a minimum, by Company and Site, and issued pursuant to, and to be governed by, the terms of this Agreement. Unless otherwise specified, references to Agreement herein include all applicable Order(s).

1.2 Scope of Services. Company may engage Site through one or more Orders. An Order will be in a format similar to the document attached hereto and, among other things, shall set forth the particulars of the services to be performed ("**Study**"), including the clinical research and definition of the applicable Study drug ("**Study Drug**"). If engaged, Site agrees to and shall cause its employees, contractors, agents, representatives, including the principal investigator and sub-investigators (collectively, "**Site Representatives**") to perform the Study in accordance with this Agreement and Study protocol (as defined, including subsequent amendments) ("**Protocol**"). Site represents and warrants that it has the authority to require that Site Representatives comply with the applicable terms of this Agreement. Site shall notify Company of any material changes to Site Representatives, but in no event may Site change the principal investigator or any sub-investigator for a Study without Company's prior written consent. This Agreement,

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together with a duly executed Order, will be used by the parties for one Study only. Should the parties agree to use the Agreement for additional Study(ies), such agreement will be evidenced by an Order duly executed by all parties.

1.3 Biological Materials. All samples derived from Subjects enrolled in the Study, including blood, bone marrow, sera, platelets and other biological materials (the "**Biological Materials**") shall only be used in accordance with the Protocol and the EC approved informed consent.

1.4 Changes. In the event of a change to a Study that results in an increased cost, or if any increase in the compensation due for the conduct of a Study is necessary or appropriate, Company shall provide written notice in the form of a budget increase letter ("**Change**") to the Site to memorialize such increase in compensation. Unless the Site objects to such Change within ten (10) calendar days of the Change's date, said Change shall constitute an amendment to the applicable Order.

1.5 Protocol Deviations. If principles outlined in the ICH Harmonized Tripartite Guidelines for Good Clinical Practice ("**ICH GCP**") relating to the safety of Subjects (as defined herein) require a deviation from the Protocol, ICH GCP should be followed and the deviation shall immediately be reported to the other parties of this Agreement. Site shall also, within twenty-four (24) hours, notify Company of any Serious Breach of which Site becomes aware. For the purposes of this provision, a "**Serious Breach**" shall mean a breach of ICH GCP or Study Protocol, which is likely to affect (i) the safety of physical or mental integrity of the Subjects of any Study; or (ii) the scientific value of any Study. In addition, Site shall promptly inform the Institution Review Board or Independent Ethics Committee ("**IRB/IEC**") and any governmental authority as may be required by Applicable Law (as defined herein) of such deviation or breach.

2. PERFORMANCE PERIOD AND ENROLLMENT OF SUBJECTS

2.1 Site shall use its best efforts to enroll evaluable subjects who meet all of the Protocol eligibility requirements ("**Subject(s)**").

3. COMPENSATION

3.1 Compensation. Compensation and payment terms for the applicable services shall be as set forth in the applicable Order. Site represents and warrants that the compensation provided under the terms of this Agreement as may be amended by subsequent Changes, represents fair market value and complies with Applicable Laws (as defined herein) and is consistent with fees charged for similar activities in Site's geographical area, has been negotiated at arms-length, and is unrelated to any procurement decision or promotion of Company's (or its affiliates') products, the volume or value of any referrals or other business otherwise generated between Company and Site.

3.2 Subject Withdrawal. Company shall have no obligation to compensate Site for a Subject who is determined to be ineligible for a Study, except for screen fails if provided for in the Schedule A, or for additional individuals who are enrolled in a Study without Company's prior written approval. In the event that a Subject (i) withdraws voluntarily; or (ii) is withdrawn from a Study for any reason other than the Subject failing to meet eligibility requirements, then Company shall compensate Site pursuant to the terms of the Schedule A for the procedures completed through the date of such withdrawal.

3.3 Payment Reconciliation. If, at the completion of a Study, Company has paid sums under the terms of this Agreement that exceed the total Study cost as provided in the Schedule A, Site shall, within 30 calendar days reimburse to Company any amount paid by Company that exceeds the adjusted Study cost. Site agrees to provide Company or its representative with all requests for payment under the terms set forth in the Schedule A within 30 calendar days after receipt of the adjusted Study/final payment. Where this is not possible, Site shall make all payment requests at the latest within 12 calendar months thereafter. Company shall not be obligated to make any payments after this period has expired.

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3.4 Taxes, Customs, Fees, and Import/Export Duties. The pricing, fees, and compensation stated herein are inclusive of all applicable employment-related, consumer, use and other similar taxes (except Value Added Tax ("**VAT**")/sales tax), levies, duties, fees, and assessments which are legally enacted on or before the Effective Date (as defined herein), whether or not then in effect. VAT/sales tax, if applicable, will be paid by Company at the applicable rate and upon receipt of a valid VAT/sales tax invoice. Site, not Company, shall be responsible for any and all taxes on any and all income Site receives from Company under this Agreement.

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4. CONFIDENTIAL INFORMATION

4.1 Confidential Information. In view of Company's proprietary rights and interests, Site agrees to maintain as confidential all information received from or on behalf of Company or obtained as a result of the performance of this Agreement or developed under a Study ("**Confidential Information**"), and further agrees to limit access to any Confidential Information to only those persons who, under Site's direct control, will be engaged in employing such information for the purposes of fulfilling the obligations under this Agreement. At no time shall such information be employed for any purpose other than as described herein or disclosed to any third party without the prior written consent of Company.

4.2 Exclusions. The obligations set forth in this Article shall not apply to any portion of Confidential Information which (i) is or later becomes generally available to the public by use, publication or the like, through no act or omission of Site; (ii) Site possessed prior to the latest execution date of this Agreement without being subject to an obligation to keep such Confidential Information confidential; (iii) is lawfully obtained without restriction from a third party who had the legal right to disclose the same to Site; or (iv) is independently developed by the Site without the use or benefit of Confidential Information as evidenced by the Site's written records. In the event Site becomes legally compelled to disclose any Confidential Information, it shall immediately provide Company with notice thereof prior to any disclosure, shall use its best efforts to minimize the disclosure of any Confidential Information, and shall cooperate with Company should Company seek to obtain a protective order or other appropriate remedy.

4.3 Return of Company's Confidential Information. Site must return to Company all of Company's Confidential Information in tangible form, including without limitation all copies, translations, interpretations, derivative works and adaptations thereof, immediately upon request by Company. Notwithstanding the foregoing, if and to the extent required by Applicable Law (as defined herein), Site may retain 1 copy of applicable Confidential Information for record keeping purposes only.

5. PROPRIETARY RIGHTS

5.1 Ownership. Site agrees that all information, inventions, discoveries, know-how and improvements resulting from a Study conducted under this Agreement, including but not limited to material that may be subject to patent, trademark, or copyright protection ("**Intellectual Property**") shall promptly be made known to Company and shall be the sole property of Amgen Inc. Site represents and warrants that it has secured from principal investigator and Site Representatives any and all transferable rights to Intellectual Property. Site hereby transfers and assigns to Amgen Inc. Site's full right and title to all Intellectual Property and agrees to undertake such actions reasonably requested by Company to give effect to such ownership. Amgen Inc. and its subsidiaries or affiliates including the Company shall be free to use the Intellectual Property. For each Study, Site shall furnish to Company all Study data, results, case report forms and an acceptable investigator's report. Any copyright in any such data, results, case report forms and investigator's report shall be the sole property of Company. Neither Company nor Site transfers to the other by operation of this Agreement any patent right, copyright right, or other proprietary right of any party, except as described in this Agreement.

5.2 Use of Study Drug. Site agrees that use of a Study Drug provided under this Agreement for any purpose outside of a Study is prohibited. If Site uses a Study Drug provided under this Agreement for any purpose outside of a Study, all data, results, conclusions, observations, discoveries, inventions, ideas, know-how, procedures, advancements and the like, whether patentable or not, shall be treated in all respects as Intellectual Property in accordance with this Agreement and shall be the sole property of Company.

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6. PUBLICATIONS

6.1 Publication Rights. Site shall have the right to publish or present the results of a Study, and shall exercise all reasonable efforts to do so in a timely manner provided such publication or presentation is consistent with the terms set forth in this Agreement and, unless otherwise agreed in writing, is consistent with Company's publication polices (see high level description at www.amgen.com/about/how-we-operate/policies-practices-and-disclosures/ethical-research/amgen-guidelines-for-publications/). In addition, prior to submission for publication of any manuscript, poster, presentation, abstract, or other written or oral material describing the results of a Study, Site shall provide Company 45 calendar days to review a manuscript and 15 calendar days to review any poster, presentation, abstract, or other written or

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oral material derived from a Study. In addition, if Company requests in writing, Site shall withhold any publication or presentation an additional 60 calendar days. Company reserves the right to remove, or require Site to remove, all Confidential Information from any publications or presentations; however, Company will not otherwise exercise editorial control over the proposed publication. Authorship will be based on scientific contribution. Notwithstanding the Confidential Information Section in this Agreement, Study data for purposes of publication and any resulting publications pursuant to this Section shall not be considered Confidential Information under this Agreement. Site hereby grants Company a non-exclusive, irrevocable, fully paid-up, royalty-free, worldwide license (i) to distribute copies of any publication regarding the Study within the Company and to its licensees, licensors, affiliates, and authorized representatives and (ii) to prepare derivative works of any such publication.

6.2 Multi-Center Study. Site agrees that if a Study is part of a multi-center study, any publication by Site of the results of a Study shall not be made before the first multi-center publication. For the purposes of this Article, "multi-center publication" means a publication of the manuscript in a peer-reviewed scientific journal that reports on the results of the primary outcome measure(s) of a multi-center Study. Authorship of any multi-center publication will be determined by Company based upon substantial contribution to the design, acquisition, analysis, interpretation of data, drafting, and/or critical revisions to any manuscript(s), derived from a Study. In the event that, as verified with Company, there is no multi-center publication within 18 months after a Study has been completed or terminated at all centers, data has been received and analyzed by Company, and all queries have been resolved, Site shall have the right to publish its results from a Study subject to the requirements described above. Subject to the requirements described above, Site may publish the results of a Study earlier to the extent reasonably necessary in the event of any perceived public health risk related to a Study Drug and provided that Site reasonably considers any Company comments regarding such publication.

7. COMPANY-PROVIDED MATERIALS

7.1 Access. Company agrees to provide or, as appropriate, reimburse Site for materials that Company is required to provide per the Protocol including Study Drug, devices, reagents and supplements as further detailed in the applicable Order ("**Materials**"). Only those persons who are under the principal investigator's direct control and who will be using the Materials for the Study shall have access to the Materials. Upon termination or completion of the Study, Site shall destroy all unused Materials or, at Company's sole option, return to Company, in accordance with Company's instruction and Applicable Laws.

8. REQUIRED EQUIPMENT AND SYSTEMS

8.1 Required Equipment. The parties acknowledge that certain equipment may be needed to properly conduct a Study. If Company and Site agree that Site does not have sufficient access to some or all of that certain equipment, then such equipment shall be identified in the Agreement and referred to as "Required Equipment." Unless otherwise specified, Company or its representative shall lend to Site for the duration of the Study such Required Equipment. As applicable, Company or its representative shall arrange for the delivery of such Required Equipment. At the completion or earlier termination of the Study, Company or its representative may retrieve any or all of the Required Equipment, title to which remains with Company or its representative.

8.2 Site's obligations. While the Required Equipment is on Site's premises, Required Equipment shall remain Company's or its representative's property at all times and shall be identified as such and can only be used to perform Studies. The Site shall ensure that the Required Equipment is stored, maintained and used properly. At all times after its delivery to Site and except for normal wear and tear, Required Equipment shall be at the sole risk of the Site as regards damage, loss, or destruction. While in Site's possession or control, Site shall be liable for the repair or replacement of any such Required Equipment that is damaged, destroyed, or lost.

8.3 Customized Required Equipment. If Company or its representative provides Site with Required Equipment that is specifically customized for use in a particular Study, then Site shall ensure that this Required Equipment is not used in any manner or for any purpose other than as set forth in the applicable Protocol. Additionally, at or before the conclusion of a Study, Company or its representative will provide instructions to Site regarding the destruction of or, at Company's expense, return to Company of such

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customized Required Equipment. Site agrees to destroy or return such Required Equipment pursuant to Company's or its representative's direction.

8.4 Required Systems. Site agrees to use any electronic system that Company may specify for use in the reporting and monitoring of clinical data and Study findings.

9. COMPLIANCE WITH APPLICABLE LAWS AND ACCEPTED PRACTICE

9.1 Accepted Practice. Site shall perform and shall cause Site Representatives to perform a Study in a professional and competent manner, using the degree of skill, diligence, prudence and foresight which would reasonably and ordinarily be expected from skilled and experienced professionals engaged in the provision of, and activities comprising, a Study.

9.2 Informed Consent. Site agrees and warrants that it will obtain a valid informed consent form from each Subject in the Study or its legal representative in accordance with Applicable Laws and this Agreement before the Subject is allowed to participate in the Study. Site shall ensure that such consent permits Company's use of Study data for at a minimum the purposes of monitoring the accuracy and completeness of the research data, performing clinical and scientific research, and medical product development.

9.3 Compliance with Applicable Laws. Site agrees to ensure that the Study is conducted in compliance with generally accepted standards of Good Clinical Practice, all laws, regulations, and guidance applicable to its performance hereunder, including the ICH GCP, Company's Protocol, written instructions and policies provided or referenced by Company and, applicable export control and economic sanctions regulations which prohibit the shipment of certain products and technology to certain restricted countries, entities and individuals, as well as applicable anti-bribery laws pertaining to interactions with government agents, officials and representatives ("**Applicable Law(s)**").

9.4 Data Protection. Site shall comply with the data protection provisions set forth by Applicable Law.

9.5 Records. Site shall maintain all records required under Applicable Law and the Protocol for 10 years following completion of a Study or longer if required by Applicable Law. Site shall take reasonable and customary precautions to prevent the loss or alteration of any such records.

9.6 Company Inspections/Monitoring/Audit. Company and its representatives shall have the right during reasonable business hours and after reasonable advanced notice to monitor and audit the activities of Site related to a Study. At no additional cost to Company, Site shall cooperate with any monitoring and audit conducted hereunder and make available to Company or its representatives for examination and duplication all documentation, data, and information relating to any Study. Site shall permit Company and its authorized representatives to inspect (i) the facilities where a Study is or will be performed; (ii) any equipment used or involved in the conduct of a Study; (iii) any records and source documents, including but not limited to medical records (whether in electronic or paper format); (iv) any related authorizations or patient informed consent forms; and (v) other relevant information necessary to determine whether a Study is being conducted in conformance with this Agreement and Applicable Laws. Further, direct access to electronic medical records for the purpose of monitoring/auditing source data is preferred, where possible, and in all cases, Site will provide the same level of access to source records to the monitor/auditor as provided to inspectors.

9.7 Governmental Contact by Site. Site shall not initiate any communications involving or relating to any Study with any governmental or regulatory authority (such as the United States Food and Drug Administration or the Drug Controller General of India) unless required by Applicable Law or requested to do so by Company and, then, only upon prior consultation with Company. However, if any governmental or regulatory authority initiates communications with, or gives notice to Site of its desire to meet with Site, conduct an inspection, or take any regulatory action regarding any subject matter relating to a Study, Site will promptly:

(i) Notify Company thereof;

(ii) Notify Company of any warning, violation or deficiency, including without limitation those noted by any governmental authority, with respect to a Study including without limitation facilities, equipment, or personnel supporting a Study;

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(iii) Provide Company with a copy of any correspondence or inspection reports issued with respect to a Study;

(iv) Provide Company with copies of and opportunities to comment on drafts of documents Site is required to submit to governmental authorities pursuant to its obligations hereunder; and

(v) Take action to correct any such violations or deficiencies or heed any such warnings.

Company acknowledges that it may not direct the manner in which Site fulfills its obligations to permit inspection by governmental authorities. Company representatives shall have the right to be on site during any such inspection by a governmental or regulatory authority, unless prohibited by Applicable Law.

9.8 For the purposes of this Agreement, Site shall ensure that the principal investigator for a Study and other Site Representative with applicable experience and knowledge are present during any inspections.

9.9 Debarment. Site represents and warrants that neither Site nor Site Representatives have been the subject of a debarment, disqualification or exclusion under any rules, in any jurisdiction where they have practiced, in particular in Europe or in the United States (where the main applicable texts are: Generic Drug Enforcement Act of 1992, Title 21 Code of Federal Regulations ("**C.F.R.**") Section 312.70 and 42 C.F.R. Part 1001 et seq.). Site shall notify Company immediately upon any inquiry concerning debarment, disqualification, or exclusion of Site or Site Representatives, or the commencement of any proceeding concerning the same. Notice of or failure to provide any such notice under this Section shall constitute a breach hereunder for which Company may terminate this Agreement immediately for default notwithstanding any right of Site to cure.

10. ANTI-CORRUPTION REPRESENTATION AND WARRANTY

10.1 Anti-Corruption. Site represents, warrants and covenants, as of the Effective Date to and through the expiration or termination of each Order or this Agreement, (i) that Site, and, to the best of its knowledge, Site Representatives, shall not, directly or indirectly, offer, pay, promise to pay, or authorize such offer, promise or payment, of anything of value, to any individual or entity for the purposes of obtaining or retaining business or any improper advantage in connection with this Agreement, or that would otherwise violate any Applicable Laws, rules and regulations concerning or relating to public or commercial bribery or corruption ("Anti-Corruption Laws"); (ii) that the books, accounts, records and invoices of Site related to this Agreement or related to any work conducted for or on behalf of Company are and will be complete and accurate; and (iii) that Company may terminate this Agreement (a) if Site or Site Representatives fails to comply with the Anti-Corruption Laws or with this provision, or (b) if Company has a good faith belief that Site or Site Representatives has violated, intends to violate, or has caused a violation of the Anti-Corruption Laws. If Company requires that Site complete a compliance certification, Company may also terminate this Agreement if Site (1) fails to complete a compliance certification, (2) fails to complete it truthfully and accurately, or (3) fails to comply with the terms of that certification. For the purposes of this Section, Site Representatives shall be deemed to further include owners, directors, officers, or other third party acting for or on behalf of Site.

11. INDEMNIFICATION

11.1 Company's Indemnity. Company shall defend, indemnify, and hold harmless Site and Site Representatives (collectively, "**Site Indemnitees**") from any and all third party liabilities, claims, damages, losses, actions and suits ("**Claims**") for Personal injury or death arising out of, or in connection with the applicable Study. This includes medical management and financial compensation as may be required by Applicable Law.

11.2 Notwithstanding its obligations to the Subjects as defined per Applicable Law, Company's indemnification obligations towards the Indemnitees are contingent upon the following conditions:

(i) Site conducted the Study in accordance with, and otherwise complied with, this Agreement and Applicable Laws and such Claims do not arise out of or in connection with any of Site Indemnitees' failure to comply with the same;

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(ii) Such Claims do not arise out of the negligence or willful misconduct of any of the Site Indemnitees, or any other person on the Site Indemnitees' property who is not a Company employee;

(iii) Site timely provides written notice to Company of Claims such that Company is in no way prejudiced;

(iv) Site Indemnitees fully cooperate with Company and its legal representatives in the investigation and defense of Claims; and

(v) Company has sole control over the defense and settlement of Claims and Site Indemnitees do not settle or compromise Claims without Company's prior written consent (which consent shall not be unreasonably withheld).

11.3 Company's Indemnification Obligations. If Company is obligated pursuant to the terms of this Agreement to provide indemnity, Company shall do so diligently. Company shall not admit fault on behalf of any one or more of the Site Indemnitees without the relevant Site Indemnitees' written permission, such permission shall not be unreasonably withheld, conditioned, or delayed. Without limiting the Company's right to have sole control over the defense and settlement of Claims, Site Indemnitees shall have the right to retain separate legal counsel and representation at Site Indemnitees' sole cost.

11.4 Site's Insurance. Site shall maintain a policy or program of insurance at levels sufficient to support its obligations assumed under this Agreement and as required by Applicable Law, evidence of which shall be provided to Company upon written request, and Site shall provide prompt notice to Company of any cancellation in its coverage.

12. WAIVER OF CONSEQUENTIAL DAMAGES

12.1 IN NO CIRCUMSTANCES SHALL ANY PARTY BE LIABLE TO ANY OTHER PARTY IN CONTRACT, TORT (INCLUDING NEGLIGENCE OR BREACH OF STATUTORY DUTY) OR OTHERWISE HOWSOEVER ARISING OR WHATEVER THE CAUSE THEREOF, FOR ANY LOSS OF PROFIT, BUSINESS, REPUTATION, CONTRACTS, REVENUES OR ANTICIPATED SAVINGS, OR FOR ANY OTHER SPECIAL, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGE OF ANY NATURE, WHICH ARISES DIRECTLY OR INDIRECTLY FROM ANY BREACH OF THIS AGREEMENT ON THE PART OF ANY OTHER PARTY. NOTHING IN THIS SECTION SHALL OPERATE SO AS TO RESTRICT OR EXCLUDE THE LIABILITY OF ANY PARTY IN RELATION TO DEATH OR PERSONAL INJURY CAUSED BY THE NEGLIGENCE OR INTENTIONAL MISCONDUCT OF SAID PARTY OR TO RESTRICT OR EXCLUDE ANY OTHER LIABILITY OF ANY PARTY THAT CANNOT BE SO RESTRICTED OR EXCLUDED BY APPLICABLE LAW.

13. SUBJECT INJURY

13.1 Subject Injury. In the event that a Subject suffers personal injury or death as a consequence of participation in the Study, Company shall bear such responsibilities as may apply to Company under Applicable Law. This does not prevent Company from filing an action against the Site or Site Representatives in case the adverse reactions described above are the result of the negligence or misconduct of the Investigator or any of the Site Representatives. Company does not authorize Site to offer compensation on behalf of Company, or to bind Company to any indemnity obligations in favor of any Subjects.

14. TERM AND TERMINATION

14.1 Effective Date. "**Effective Date**" shall be defined in each Order and such definition shall apply only to that Order.

14.2 Company's Right to Terminate. Company shall have the right, at any time, to suspend or terminate an Order, with or without cause and in whole or in part, by issuing a thirty (30) calendar day written notice to Site specifying the date and extent of termination. In the event of such termination, Site shall be entitled to compensation in accordance with the terms of the applicable Order up to the date of termination.

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Company shall also have the right to terminate immediately if it is reasonably of the opinion that a Study should cease in the interests of the Subjects.

14.3 Site's Right to Terminate. Site shall have the right to terminate any Order (i) if a principal investigator is identified in an Order and such principal investigator is unable to perform its obligations thereunder and a successor acceptable to Company is not available; (ii) if Company is in breach of any of its obligations hereunder and has failed to remedy such breach where it is capable of remedy within thirty (30) calendar days of a written notice from Site specifying the breach and requiring its remedy; or (iii) if Site is reasonably of the opinion that a Study should cease in the interests of the Subjects.

14.4 Obligations Upon Termination. Immediately upon receipt of notice of termination, Site shall stop enrolling Subjects into the relevant Study(ies) and shall cease conducting procedures on Subjects already enrolled in such Study(ies) as directed by Company, to the extent medically permissible and appropriate. Site shall return to Company within 30 calendar days of the effective date of termination any funds not expended or irrevocably obligated by Site prior to the effective date of the termination. Additionally, within 30 calendar days of the effective date of the termination, Site shall submit to Company a final invoice identifying any amounts Company may owe relative to the terminated Study(ies) and pursuant to the terms of this Agreement. Upon termination, Site shall, in accordance with Company's instructions, (i) preserve any data relating to the Study; (ii) turn over such data; and (iii) furnish Company an acceptable investigator's report for the Study.

15. MISCELLANEOUS

15.1 Amendments. Except as otherwise expressly provided herein, the terms of this Agreement may be amended only by the mutual written consent of the parties.

15.2 Use of Names. Company and Site shall not use each other's names (including the names of the other party's subsidiaries or parent, (if any)), symbols or marks, or any derivatives thereof in any form of publicity without the prior written consent of the owning party or parties, except that, without prior written consent of Site, Company may disclose on publicly-accessible clinical trial registries or through a Company-operated call center the general geographic location of Site (e.g., city, state, and/or country) and contact information of any party to this Agreement. In addition, and without prior written consent of Site, Company may identify the existence of this Agreement and/or, the name, and/or contact information of any party to this Agreement as required by applicable law. In addition, and without prior written consent of either party, Company and Site may disclose the other party's name in connection with publications hereunder.

15.3 Entire Agreement. This Agreement, any Order, and any amendments or Changes thereto, shall constitute the entire agreement between the parties hereto regarding the subject matter hereof and sets forth the entire terms and conditions under which this Agreement will be performed. There are no other agreements, oral or written, between the parties with respect to the subject matter of this Agreement, and all oral and written correspondence regarding the subject matter hereof is superseded by this Agreement. In the event of any inconsistency between this Agreement and any Order and the Protocol, if applicable, the terms of this Agreement shall govern, except as otherwise expressly agreed upon by the parties in a specific Order.

15.4 Counterparts. This Agreement and any Order, and any amendments or Changes may be executed in any number of counterparts, each of which shall be an original and all of which together shall constitute one and the same document, binding on all parties notwithstanding that each of the parties may have signed different counterparts. Facsimiles or scanned copies of signatures or electronic images of signatures shall be considered original signatures unless prohibited by Applicable Law.

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15.5 Severability. In the event any provision of this Agreement conflicts with the law under which this Agreement is to be construed or if any such provision is held illegal, invalid, or unenforceable, in whole or in part by a competent authority, such provision shall be deemed to be restated to reflect as nearly as possible the original intentions of the parties in accordance with Applicable Laws. The legality, validity, and enforceability of the remaining provisions shall not be affected thereby, and shall remain in full force and effect.

15.6 Assignment and Sub-contracting. Neither the rights nor the obligations of Site under this Agreement may be assigned, transferred or otherwise disposed of, in whole or in part without the prior

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written consent of Company. In the event Company consents in writing to Site's use of a subcontractor or affiliate in the performance of Site's obligations hereunder, Site shall remain responsible for the proper performance of such Study, in accordance with this Agreement.

15.7 Waiver. No action or inaction by either party shall be construed as a waiver of such party's rights under this Agreement or as provided by Applicable Law. Except as expressly provided for in the Change Section, no other term of this Agreement may be waived except by an express notice in writing signed by the waiving party. The failure or delay of a party in enforcing any of its rights under this Agreement shall not be deemed a continuing waiver of such right. The waiver of one breach hereunder shall not constitute the waiver of any other or subsequent breach.

15.8 Equitable Relief. Each party understands and agrees that money damages may not be a sufficient remedy for any breach of this Agreement and that the non-breaching party shall be entitled to seek specific performance, injunctive, and other equitable relief as a remedy for any such breach. Such remedy shall not be deemed to be the exclusive remedy for breach of this Agreement but shall be in addition to any and all other remedies available at law or in equity.

15.9 Contractual Relationship. Site is engaged in an independent activity and not as an agent, employee, partner, or joint employer of Company. If applicable, Site represents and warrants that it is an employer subject to, and shall comply with, all Applicable Laws. Site shall be responsible for Site Representatives' and subcontractors' acts, errors, omissions, and conduct. Site acknowledges and agrees that Company shall have no responsibility or liability for treating Site Representatives as employees of Company for any purpose. Neither Site nor any Site Representative shall be eligible for coverage or to receive any benefit under any Company provided workers' compensation, employee plans or programs or employee compensation, bonus, incentives, retirement or other arrangements.

15.10 Governing Law. This Agreement shall be governed by the laws of the country where the services are performed, excluding conflict of law rules.

15.11 Survival. The parties' rights and obligations under any provisions set forth in this Agreement related to ownership of Intellectual Property, confidentiality, publications, use of names, Applicable Laws, governing law, Materials, subject injury, privacy, indemnification, and insurance, or which contemplate performance or observance subsequent to termination or expiration of this Agreement issued hereunder shall survive such expiration or termination.

15.12 Cooperation with Company Representatives. Site has been advised that, under separate agreements, Company may retain others (including without limitation contract research organizations) to perform certain services in connection with a Study. Site shall cooperate with, and to the extent appropriate, coordinate its performance hereunder with the services of such others so as to ensure successful completion of the Study.

15.13 Language. The official language of this Agreement is the English language. Should a party translate this Agreement into another language and a conflict in interpretation occur between versions, the original official language version shall prevail.

15.14 Notice. Any notice required or permitted hereunder shall be in writing and shall be deemed given as of the date it is: (i) delivered by hand; (ii) received by registered or certified mail, postage prepaid, return receipt requested; (iii) confirmed as received if by facsimile; or (iv) received by nationally recognized, overnight courier, and addressed to the party to receive such notice at the address set forth below, or such other address as is subsequently specified in writing:

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SGPGIMS,Lucknow

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Executive Registrar
SGPGIMS,Lucknow

If to Company:

Amgen Technology Private Limited
Dynasty Business Park, 'A' Wing Level 4
Andheri-Kurla Road, Andheri (East)
Mumbai, India 400059

If to Site:

Sanjay Gandhi Post Graduate Institute
Rae Bareli Road
Lucknow, Uttar Pradesh-226014
India

With a Copy to:

International Legal Group
Amgen (Europe) GmbH
Dammstrasse 23
6301 Zug
Switzerland
Fax Number: +41 41 369 0411

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Agreement.

AMGEN TECHNOLOGY PVT. LTD.

By: Mansi Malkan

Title: Senior Country Manager

Date: 26th Feb '19

SANJAY GANDHI POST GRADUATE INSTITUTE

(signature)

By: Rakesh Kahsor
(print or type name)

DIRECTOR
Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226 014, INDIA

Title: _____

Date: 14.02.2019

05/03/2019
Dr. Amit Gupta
Professor & Head
Department of Nephrology
S.G.P.G.I.M.S., Lucknow

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Executive Registrar
SGPGIMS,Lucknow

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Executive Registrar
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CLINICAL TRIAL AGREEMENT ORDER

This Order ("**Order**"), effective as of the Effective Date (defined below), is entered into by and among Amgen Technology Pvt. Ltd., Dynasty Business Park, A Wing, Level 4, Andheri-Kurla Road, Andheri (East), Mumbai, 400059 India ("**Company**"); Sanjay Gandhi Post Graduate Institute, Rae Bareli Road, Lucknow, Uttar Pradesh-226014, India ("**Institution**"); and Dr. Amit Gupta, Sanjay Gandhi Post Graduate Institute, Rae Bareli Road, Lucknow, Uttar Pradesh-226014, India ("**Principal Investigator**"), in accordance with, and shall be governed by, the terms of that certain Clinical Trial Agreement (contract number 285105) ("**Agreement**").

1. GOVERNING TERMS AND EFFECTIVE DATE

1.1 Governing Terms. By executing this Order, the parties agree that this Order and the parties' performance hereunder shall be governed by the terms and conditions of the Agreement, which are incorporated by this reference as if fully set forth herein. The parties hereto agree that for purposes of this Order, the term "**Site**" as used herein and in the Agreement shall be defined to include each and every non-Company party identified above, and their respective representatives. Terms used but not otherwise defined herein shall have the meanings ascribed to such terms under the Agreement.

1.2 Effective Date. For purposes of this Order, "**Effective Date**" shall mean the last date on which a party executes this Order. This Agreement shall remain in full force and effect until the completion by the Site of the Study or earlier termination pursuant hereto.

1.3 Records. The parties agree that for this Order the provision regarding Records in the Agreement shall be amended to state: "Site shall maintain all records required under Applicable Law and the Protocol for ten (10) years following completion of a Study or longer if required by Applicable Law. Site shall take reasonable and customary precautions to prevent the loss or alteration of any such records."

1.4 Indian Law. Without limiting the generality of Site's obligations, the Site shall carry out the Study with due observance of safety of Subjects, confidentiality and protection of Subjects' rights. The Study will be conducted by the Site in accordance with the Ethical Guidelines for Biomedical research on Human Subjects issued by the Indian Council of Medical Research Guidelines, 2000, Schedule Y of the Drug and Cosmetics Act of 1945, the Central Drugs Standard Control Organization's Good Clinical Practices Guidelines in India, and all applicable Indian regulatory requirements, whichever affords the greater protection to the Subject.

2. STUDY CONDUCT

2.1 Protocol. The Protocol for the Study is Company Protocol No. 20150238 entitled "A Multicenter, Multiple-dose, Active-controlled, Double-blind, Double-dummy Study to Compare the Therapeutic Efficacy and Safety of Oral Doses of Cinacalcet Hydrochloride With Intravenous Doses of Etelcalcetide (AMG 416) in Asian Hemodialysis Subjects With Secondary Hyperparathyroidism", as may be amended.

Site Representatives and/or Principal Investigator shall attend any meetings regarding the Study as reasonably requested by Company ("**Investigator Meetings**"). Such meetings may be conducted by Company to convey or exchange information with principal investigators, sub-investigators, or other research site staff to support the effective conduct or close-out of a Study. Site and Principal Investigator each agree that Company and its authorized representatives may (i) record any Investigator Meetings through audio and visual recording technology (whether existing or future technology), which may include attendees' (including Site Representatives) names, words, images, and likeness ("**Recordings**"); and (ii) use, edit, and reproduce Recordings worldwide for education and training purposes related to Company's clinical trials. Company will comply with all privacy laws applicable to Company's use of such Recordings. Site and Principal Investigator may contact the Amgen Privacy Office at privacyoffice@amgen.com for further information about any rights to access and remedy information held by Company. Site and Principal Investigator each agree that no additional compensation shall be due hereunder for Site Representatives or Principal Investigators respective participation in Investigator Meetings. Company may reimburse or pay Site for reasonable pre-approved expenses incurred by Site Representatives or Principal Investigator for

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participating in Investigator Meetings upon receipt of documentation in form and detail sufficient for Company to recognize such expenses for Company's tax reporting purposes, provided that Site complies with Company instructions and Company's applicable standards and policies related to travel and hospitality and other policies governing interactions with healthcare professionals.

The Principal Investigator will direct and supervise the Study.

2.2 Data Protection. Subject to applicable law, Company may collect and process information regarding investigators or other personnel involved in Studies. Company will notify such personnel as required by applicable law.

2.3 Use of Electronic Data Capture. Company utilizes Electronic Data Capture ("**EDC**") to collect from Site and deliver to Company Study data, specifically as the electronic case report form ("**eCRF**"). Site agrees that it will (i) enter such Study data into EDC within 5 business days of the Subject visit, and (ii) resolve all queries issued in the EDC system within 5 business days of the query being issued. In the event of delay(s) by Site in complying with these timelines Company, at its option, may delay payment, lock of IVRS, suspend enrollment, conduct quality audit or pursue any other remedy. Principal Investigator is responsible for and warrants quality data entry. Data entry shall be conducted under the supervision of the Principal Investigator.

2.4 Supervision. The Principal Investigator shall supervise and be responsible for all activities performed by members of the Study team or other external personnel to whom the investigator delegates some of his/her responsibilities under the Protocol. The Principal Investigator shall ensure compliance with the Protocol at all times.

2.5 Informed Consent. Site agrees and warrants that it will obtain a valid informed consent form from each Subject in the Study or its legal representative in accordance with Applicable Laws and this Agreement. Site shall ensure that such consent permits Company's use of the Biological Materials and Study data for at a minimum the purposes of monitoring the accuracy and completeness of the research data, performing clinical and scientific research, and medical product development.

3. REAGENTS AND STUDY DRUG

3.1 Company shall provide or reimburse the following Study Drug(s) to Site as required by Protocol: AMG 416 ("**Study Drug(s)**"). If Site is responsible for obtaining Study Drug for use in the Study, Company will reimburse Site for purchase costs of Study Drug as detailed in a proper invoice. Such purchase or reimbursement cost shall not exceed the amount set forth in Schedule A. The Site agrees and warrants that it will not seek payment or reimbursement from any Subject or third party for the cost of the Study Drug(s) or the Study Drug that is provided without charge or reimbursed by Company.

3.2 The cost of non-Company drug(s) and/or materials and/or reagents is not paid or reimbursed by a third party; however it is required by the Protocol for Subjects participating in the Study ("**Required Material(s)**"). Company will supply the Site with the Required Material(s). The Site agrees and warrants that it will not seek payment or reimbursement from any Subject or third party for the cost of any Required Material(s) that is provided without charge or reimbursed by Company. Site also warrants that it shall not seek or accept reimbursement from any Subject or third party payor for procedures, tests, treatments, items or services that are funded or provided by Company pursuant to the Agreement.

3.3 The parties agree that for this Order the section(s) in the Agreement restated below shall be amended and restated in its entirety as follows:

(i) Access. Company agrees to provide or, as appropriate, reimburse Site for materials that Company is required to provide per the Protocol including Study Drug, devices, reagents and supplements as further detailed in the applicable Order ("**Materials**"). Only those persons who are under the principal investigator's direct control and who will be using the Materials for the Study shall have access to the Materials. Upon termination or completion of the Study, Site shall destroy all unused Materials or, at Company's sole option, return to Company, in accordance with Company's instruction and Applicable Laws.

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Executive Registrar
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4. PERFORMANCE PERIOD AND ENROLLMENT OF SUBJECTS

4.1 The Study will commence upon execution of this Order, approval of the IRB/IEC, and any required approvals of applicable governmental authorities, including the Drug Controller General of India (DCGI), and will continue until completion of the Study as required by the Protocol (including any amendments thereto) unless this Order is terminated earlier pursuant to the Agreement.

5. REQUIRED EQUIPMENT

5.1 The parties acknowledge that Site will require the following equipment for the performance of the Study ("**Required Equipment**"): Laptop, AV Camera. Such Required Equipment will be lent by Company or its representative to Site for use in the Study.

5.2 Delivery. As necessary, Company or its representative shall arrange for the delivery of the Required Equipment, which such equipment shall be delivered to the Site at the following address: Sanjay Gandhi Post Graduate Institute, Rae Bareli Road, Lucknow, Uttar Pradesh-226014, India.

5.3 Installation of Required Equipment. Company or its representative shall provide for installation of the following equipment: Laptop, AV Camera.

5.4 Technical Support of Required Equipment. Company or its representative shall provide for technical support and maintenance of the following equipment: Laptop, AV Camera.

6. COMPENSATION

6.1 Compensation and payment terms are as set forth in Schedule A, attached hereto and incorporated herein.

6.2 Unless otherwise specified in Schedule A, in consideration for performance under the terms of this Order, Company will make payment within a reasonable time after receipt of (i) a proper invoice and (ii) the Case Report Forms or any similar document detailing the procedures performed and/or visits completed as set forth in Schedule A, as monitored by Company or its representative. It is expected that the Case Report Forms will be completed between monitoring visits.

6.3 Payments from Company to Site due hereunder shall be made payable and sent to the following:

Payments payable to:	Director, SGPGIMS Research Scheme Account Lucknow **"Payee"**
Tax ID	AAAJS3913N

From time to time, the Site may request in writing a change in Payee information. If Company agrees to the requested change, no additional amendment of the Order will be necessary.

7. MISCELLANEOUS

7.1 Principal Investigator understands and agrees that his/her personal information including name, contact details, financial information relating to, among other matters, compensation and reimbursement payments for study conduct, and other personal data in connection with Principal Investigator's conduct of the Study will be processed both by computer and manually, by Company and its affiliates and contractual partners in order to comply with Company's and its affiliates' obligations imposed by law, guidance or regulatory authorities and for other purposes including considering from time to time potential investigators for future studies or organizing safety reporting. Principal Investigator further understands and agrees that his/her personal data may, if necessary for these purposes, be made available to regulatory authorities and ethics committees. Principal Investigator understands and agrees that the Company's use and disclosure of personal data may involve use and disclosure in countries other than that where the Principal Investigator is located. Such countries may include but not be limited to: the United States, Japan, Canada, Australia, New Zealand, Switzerland, or countries in Latin America or Asia. Principal Investigator further understands that not all countries to which personal information may be transferred offer an equivalent level of protection of privacy of personal information. Principal Investigator is entitled to request access to his/her personal data held by Company or its affiliates and to have such data corrected if necessary.

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7.2 Site acknowledges and agrees that Company shall have the right to disclose publicly the terms and conditions of the Agreement, including, without limitation, Site's name, description of services, and amount of payment.

7.3 The parties agree that for this Order the section(s) in the Agreement restated below shall be amended and restated in its entirety as follows:

(ii) Publication Rights. Site shall have the right to publish or present the results of a Study, and shall exercise all reasonable efforts to do so in a timely manner provided such publication or presentation is consistent with the terms set forth in this Agreement and, unless otherwise agreed in writing, is consistent with Company's publication polices (see high level description at www.amgen.com/about/how-we-operate/policies-practices-and-disclosures/ethical-research/amgen-guidelines-for-publications/). In addition, prior to submission for publication of any manuscript, poster, presentation, abstract, or other written or oral material describing the results of a Study, Site shall provide Company 45 calendar days to review a manuscript and 15 calendar days to review any poster, presentation, abstract, or other written or oral material derived from a Study. In addition, if Company requests in writing, Site shall withhold any publication or presentation an additional 60 calendar days. Company reserves the right to remove, or require Site to remove, all Confidential Information from any publications or presentations; however, Company will not otherwise exercise editorial control over the proposed publication. Authorship will be based on scientific contribution. Notwithstanding the Confidential Information Section in this Agreement, Study data for purposes of publication and any resulting publications pursuant to this Section shall not be considered Confidential Information under this Agreement. Site hereby grants Company a non-exclusive, irrevocable, fully paid-up, royalty-free, worldwide license (i) to distribute copies of any publication regarding the Study within the Company and to its licensees, licensors, affiliates, and authorized representatives and (ii) to prepare derivative works of any such publication.

(iii) Multi-Center Study. Site agrees that if a Study is part of a multi-center study, any publication by Site of the results of a Study shall not be made before the first multi-center publication. For the purposes of this Article, "multi-center publication" means a publication of the manuscript in a peer-reviewed scientific journal that reports on the results of the primary outcome measure(s) of a multi-center Study. Authorship of any multi-center publication will be determined by Company based upon substantial contribution to the design, acquisition, analysis, interpretation of data, drafting, and/or critical revisions to any manuscript(s), derived from a Study. In the event that, as verified with Company, there is no multi-center publication within 18 months after a Study has been completed or terminated at all centers, data has been received and analyzed by Company, and all queries have been resolved, Site shall have the right to publish its results from a Study subject to the requirements described above. Subject to the requirements described above, Site may publish the results of a Study earlier to the extent reasonably necessary in the event of any perceived public health risk related to a Study Drug and provided that Site reasonably considers any Company comments regarding such publication.

7.4 Company Inspections/Monitoring/Audit. The parties agree that for this Order the provision regarding **Company Inspections/Audit** in the Agreement shall be amended and restated as follows: "Company Inspections/Monitoring/Audit. Company and its representatives shall have the right during reasonable business hours and after reasonable advanced notice to monitor and audit the activities of Site related to a Study. At no additional cost to Company, Site shall cooperate with any monitoring and audit conducted hereunder and make available to Company or its representatives for examination and duplication all documentation, data, and information relating to any Study. Site shall permit Company and its authorized representatives to inspect (i) the facilities where a Study is or will be performed; (ii) any equipment used or involved in the conduct of a Study; (iii) any records and source documents, including but not limited to medical records (whether in electronic or paper format); (iv) any related authorizations or patient informed consent forms; and (v) other relevant information necessary to determine whether a Study is being conducted in conformance with this Agreement and Applicable Laws. Further, direct access to electronic medical records for the purpose of monitoring/auditing source data is preferred, where possible, and in all

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cases, Site will provide the same level of access to source records to the monitor/auditor as provided to inspectors."

7.5 The parties agree that for this Order the Agreement shall be amended and supplemented by the following new provision: "Anti-Corruption. Site represents, warrants and covenants, as of the Effective Date to and through the expiration or termination of each Order or this Agreement, (i) that Site, and, to the best of its knowledge, Site Representatives, shall not, directly or indirectly, offer, pay, promise to pay, or authorize such offer, promise or payment, of anything of value, to any individual or entity for the purposes of obtaining or retaining business or any improper advantage in connection with this Agreement, or that would otherwise violate any Applicable Laws, rules and regulations concerning or relating to public or commercial bribery or corruption ("Anti-Corruption Laws"); (ii) that the books, accounts, records and invoices of Site related to this Agreement or related to any work conducted for or on behalf of Company are and will be complete and accurate; and (iii) that Company may terminate this Agreement (a) if Site or Site Representatives fails to comply with the Anti-Corruption Laws or with this provision, or (b) if Company has a good faith belief that Site or Site Representatives has violated, intends to violate, or has caused a violation of the Anti-Corruption Laws. If Company requires that Site complete a compliance certification, Company may also terminate this Agreement if Site (1) fails to complete a compliance certification, (2) fails to complete it truthfully and accurately, or (3) fails to comply with the terms of that certification. For the purposes of this Section, Site Representatives shall be deemed to further include owners, directors, officers, or other third party acting for or on behalf of Site."

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Order.

AMGEN TECHNOLOGY PVT. LTD.

By: Mansi Malkan

Title: Senior Country Manager

Date: 26th Feb' 19

SANJAY GANDHI POST GRADUATE INSTITUTE

(signature)

By: Rakesh Kapoor
(print or type name)

Title:

Date: 14.02.2019

DIRECTOR
Sanjay Gandhi Post Graduate Institute of Medical Sciences
LUCKNOW-226 014, INDIA

DR. AMIT GUPTA

(signature) 05/03/2019

By: AMIT GUPTA
(print or type name)

Title:

Date: 05/03/2019

Dr. Amit Gupta
Professor & Head
Department of Nephrology
S.G.P.G.I.M.S., Lucknow

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Protocol Number	20150238
Site Number	30006
Investigator	Dr. Amit Gupta
Contract Number	
Maximum number of Subjects	10
Number of Sites	1
Currency	INR

CONTRACT SUMMARY	COST	UNIT(S)	TYPE	TOTAL
SUBJECT VISIT TABLE	INR 4,86,390	10	Subject(s)	INR 48,63,900
SCREEN FAILURES	INR 12,005	1	per Subject	INR 1,20,050
ADMINISTRATIVE FEES				INR 50,000
MAXIMUM CONTRACT TOTAL*				**INR 50,33,950**

**Maximum Contract Total is inclusive of Hospital overhead fees, pharmacy costs, laboratory costs. Amgen has provided thermohygrometer for temprature reading.*

SUBJECT FEES (Overheads 25%)

VISIT TABLE: STUDY	Schedule A
Screening	INR 12,005
Day 1	INR 20,690
Week 2	INR 17,160
Week 3	INR 16,700
Week 4	INR 17,620
Week 5	INR 17,300
Week 6	INR 17,160
Week 7	INR 16,700
Week 8	INR 17,160
Week 9	INR 17,300
Week 10	INR 17,160
Week 11	INR 16,700
Week 12	INR 17,550
Week 13	INR 17,300
Week 14	INR 17,160
Week 15	INR 16,700
Week 16	INR 17,160
Week 17	INR 17,300
Week 18	INR 17,160
Week 19	INR 16,700
Week 20	INR 17,160
Week 21	INR 17,300
Week 22	INR 17,160
Week 23	INR 16,700
Week 24	INR 17,160
Week 25	INR 17,300
Week 26	INR 17,160
Week 27	INR 12,915
Follow-Up	INR 12,850
Early Term	INR 13,855
SUBJECT VISIT TABLE SUBTOTAL(S)	Schedule A

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Completers, Screening to Week 27, Safety Follow-Up	INR 4,86,390
Early Termination	INR 13,855
MAXIMUM PER SUBJECT FEE	**INR 4,86,390**

Screening costs are inclusive of costs associated with potential re-screens.
The Maximum Per Subject Fee includes Subject travel reimbursement. Subject travel reimbursement is included at a rate of INR 900.00 per protocol required in-clinic visit

VISIT TABLE: SCREEN FAILURE	Schedule A
Screen Failure	INR 12,005
MAXIMUM SCREEN FAIL	**INR 12,005**

NON-SUBJECT FEES

ADMINISTRATIVE FEES (Schedule A)	UNIT COST	UNIT(S)	TYPE	TOTAL
[1] Document storage/Archiving total 1	INR 0	1	per Site	INR 0
[2] Infrastructure Cost	INR 50,000	1	Total	INR 50,000
SUBTOTAL, ADMINISTRATIVE FEES				**INR 50,000**

1 Site has confirmed that archival fee is not applicable
2 Infrastructure cost will be reimbursed as per actual and upon original invoice. Prior approval of purchase must be obtained by site from study team before placing order for the infrastructure.

PAYMENT TERMS

Initial Payment	**50,000.00** *Amgen will pay Institution this initial payment upon execution of the Agreement. In order to receive further funds towards Subject related costs, the amount earned must exceed this initial payment. In the event that the total amount earned for the Study is less than this initial payment, all unearned funds are fully refundable to Amgen.*
Progress Payment Frequency	Quarterly (based on calendar quarter), in accordance with Budget Schedule - A

The payment of the study will be made in the favor of 'Director, SGPGIMS Research Scheme Account Lucknow' (PAN: AAAJS3913N)

The EC for this study will be 'Bioethics Cee, IEC' and the payment of the EC fees will be made in the favor of 'Director, SGPGIMS Research Scheme Account Lucknow' (PAN: AAAJS3913N)

Site represents and warrants that it shall not seek or accept reimbursement from any Subject or third party payors including any "federal health care program" as defined at 42 U.S.C. section 1320a-7b(f)) for Study Drug(s), procedures, tests, treatments, drugs, reagents, materials, items or services that are funded by Company pursuant to the Agreement or provided without charge by Company for Study purposes.

In the event Site is not reimbursed for routine clinical services contemplated in the Protocol, Site may remit an invoice to Company. If Company is in agreement with the invoice, Company will reimburse Site for the invoiced amount subject to a fair market value assessment by Company.

Company shall pay for or provide those Study Drug(s), procedures, tests, treatments, drugs, reagents, materials, items, or services identified in the Protocol's Schedule of Assessments, except that the following are not paid for or provided without charge by Company:

N/A

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Invoices

1) "Any additional activities/tests/procedures performed for the Study, which are not mentioned in this budget (schedule-A) may be reimbursed on confirmation of approval from the Amgen study team and receipt of an original invoice and rationale provided by the Site."

2) For all items that are payable upon invoice as indicated above, please send invoices to Company as follows:

Amgen Technology Pvt Ltd
Dynasty Business Park,
Level 4, A wing, A.K Road
Andheri (East) Mumbai 400059
Please submit invoices only for items indicated as payable upon invoice.

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CLINICAL TRIAL AGREEMENT – POISE-3

This **CLINICAL TRIAL AGREEMENT** ("**Agreement**"), effective as of the date of last signature ("**Effective Date**") is made between:

Hamilton Health Sciences Corporation ("**HHSC**"), through its **Population Health Research Institute** ("**PHRI**"), at 237 Barton Street East, Hamilton, Ontario, L8L 2X2, Canada, represented by its Director

-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 the "**Society**")

-and-

St. John's Research Institute, ("**SJRI**") a unit of the Society, 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 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, Dr. Denis Xavier, Vice Dean (PG), Professor, Dept. of Pharmacology, St. John's Medical College and Head DCRT (hereafter called "**National Leader**")

-and-

Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow, with its principal place of business at Department of Anaesthesiology, Raebareli Road, Lucknow, Uttar Pradesh, 226014, India (hereinafter the "**Institution**")

-and-

Dr. Sanjay Dhiraaj, as the principal investigator at the institution, with office at Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow, Department of Anaesthesiology, Raebareli Road, Lucknow, Uttar Pradesh, 226014, India (hereinafter the "**Investigator**")

WHEREAS:

A. PHRI is coordinating and is the sponsor of a multi-centre clinical trial entitled **P**eri**O**perative **I**schemic **E**valuation-3 (**POISE-3**) ("**Project**"), the protocol including any amendments from time to time ("**Protocol**") is incorporated hereto by reference;

B. PHRI may also conduct substudies in conjunction with the Project ("**Substudy(ies)**"), and in the event that Site participates in any Substudies, all references to the Project shall include Substudy(ies), and the references to the Protocol shall include any protocols related to such Substudy(ies);

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St. John's Research Institute Bangalore

Surgery

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C. PHRI has an agreement with SJRI to carry out national coordination activities in India for the Project;

D. DCRT, SJRI will be the National Leader Office ("**NLO**") Dr. Denis Xavier, Vice Dean (PG), Professor Dept. of Pharmacology, St. John's Medical College as its Head;

E. 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 site for the Project. The Investigators and Institution are hereinafter referred to jointly and severally as the "**Site**" and the activities carried out by the Site for the Project is referred to as the "**Study**";

F. The Study has been approved by the Institutional Ethics Committee, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Luknow Ethics Committee (wherein such committee would approve the conducting of a clinical trial) at the Institution;

G. NLO obtained regulatory approval from Health Ministry Screen Committee (HMSC), Indian Council of Medical Research (ICMR) for conduct of a clinical trial in human subjects and has been registered on the Clinical Trials Registry of India (CTRI).

Each party is hereinafter referred to individually as a "**Party**" and collectively as the "**Parties**".

NOW THEREFORE, in consideration of the terms and conditions contained herein, the Parties agree as follows:

ARTICLE 1. PERFORMANCE OF THE STUDY

1.1 **Compliance:** The Parties agree to carry out the Study in conformance with the following: (a) all applicable requirements of any governmental, regulatory or other body that has authority with respect to the performance of the Study ("**Regulatory Authority(ies)**"); (b) generally accepted standards of good clinical practice, including but not limited to, to the extent adopted by the relevant Regulatory Authority, the Guidance for Good Clinical Practice of the International Conference on Harmonization, and all applicable laws, regulations and guidelines governing the conduct of human clinical research in the jurisdiction of the Institution (together with (a) as "**Applicable Laws**"); (c) the Protocol; and (d) this Agreement.

1.2 **Investigator:** The Study shall be carried out under the direction and supervision of the Investigator.

1.3 **Study Personnel:** Site represents that, during the course of the Study, all subinvestigators, employees, contractors, affiliates, agents and any other persons performing services for the Study (together as "**Personnel**") shall have the appropriate training, information, licenses, approvals, and certifications necessary to safely, adequately and lawfully perform the Study in accordance with this Agreement. Further, Site shall be responsible to ensure that the Personnel have read and understood the Protocol and shall perform their activities and fulfill their obligations in a timely and competent manner.

1.4 **Informed Consent Form:** PHRI shall provide Site with a template informed consent form ("**ICF**") for the Study. Site shall, prior to initiation of the Study and during the conduct of the Study, obtain and maintain written approval from its/his/her institutional review board or ethics review board ("**IRB**") for the Study. Any changes to the ICF require the prior written approval of both the IRB, NLO and PHRI.

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1.5 **Subjects:** Site shall obtain a completed and signed ICF from each subject participating in the Study ("**Subject**") prior to enrolling the Subject into the Study, and keep the Subjects informed throughout the Study.

1.6 **Recruitment:** Site may commence recruitment of Subjects upon receipt of an authorization to do so from PHRI/NLO. Site will use diligent efforts to recruit Subjects in accordance with the Protocol. The Parties acknowledge that the Project is a multi-centre study and that recruitment is

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on a competitive basis. Once the Project recruitment goal has been reached, PHRI reserves the right to notify Site to limit or cease further recruitment, and Site shall immediately comply upon receipt of any such notice.

1.7 **Conflict:** Site represents and warrants that it/he/she is not presently, and shall not be at any time during the performance of the Study under any obligation to a third party or subject to any impediments which would: (a) prevent, inhibit or negatively affect their performance of the Study, (b) create a conflict of interest or (c) otherwise impair the acceptance by a Regulatory Authority of the data or results collected by Site.

1.8 **Debarment:** Site represents that neither it/he/she nor any of the Personnel has been or is under investigation by a Regulatory Authority for debarment, disqualification, or any similar regulatory action, and that it/he/she has no notice or knowledge of debarment, disqualification, or any similar regulatory action by any Regulatory Authority in another jurisdiction. Furthermore, Site shall, during the term of this Agreement and for three (3) years following its expiration or early termination, promptly notify PHRI in the event of such debarment or threat of debarment, conviction, disqualification, or indictment of Site or Personnel.

1.9 **Subject Safety:** PHRI/NLO agrees to notify Site promptly upon receipt of Study information that would directly affect the health or safety of Subjects. Site shall without delay inform all Subjects and the IRB, as applicable. PHRI shall not be liable for the failure of Site to immediately inform Subjects or IRB of such new information. Site shall promptly report all safety data and information, including but not limited to any failure to comply with or deviations from the Protocols, to PHRI/NLO in accordance with the requirements of the Protocol.

1.10 **Records:** Site shall prepare, maintain and store accurate and complete written records and supporting documentation for each Subject ("**Source Documents**") in accordance with the instructions provided by PHRI/NLO and Applicable Laws. Site shall prepare and submit accurate and complete case report forms and all additional documentation ("**CRFs**") for each Subject to PHRI as required by the Protocol. Site shall reasonably cooperate with PHRI/NLO to promptly resolve all data queries from PHRI/NLO and provide such Source Documents as may be required. In accordance with the obligations in **ARTICLE 5 (Privacy)**, Site and the Personnel shall ensure that any data or Source Documents disclosed to PHRI/NLO does not include any information that would personally identify a subject and/or any personal health information ("**PHI**") unless permitted by signed ICFs and/or other authorizations.

1.11 **Audit and Monitoring:** Site shall cooperate with and permit Regulatory Authorities or PHRI/NLO to examine and inspect the facilities and equipment required for performance of the Study and to inspect and copy all data, reports, work products and results relating to the Study. In relation to visits by PHRI/NLO and/or its representative, the Parties will mutually and reasonably agree upon dates and times taking into account the reason for such visit. For clarity, access to records for monitoring or audit does not entitle PHRI/NLO to make or retain a copy of any Subject's personal identification information or PHI, as more particularly specified in **ARTICLE 5 (Privacy)**, unless such copying is permitted in accordance with the ICF or any other authorizations. Site understands that clinical trial monitoring is essential to good clinical practices and agrees to cooperate with PHRI/NLO to enable its monitoring activities without undue restriction. If Site is notified of an inspection by a Regulatory Authority, Site shall forthwith inform PHRI/NLO about the pending inspection and permit PHRI/NLO, or any person designated by PHRI/NLO, to attend the inspection unless prohibited by Applicable Laws or court order. Site shall forthwith communicate the information that arises from such inspections to PHRI/NLO, unless prohibited by Applicable Laws or court order. The Parties agree that any consideration payable for the assistance of Site for any audits and inspections is included in the consideration payable hereunder, whether or not itemized as such.

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1.12 **Change of Investigator:** Should Investigator leave the Institution or otherwise become unavailable during the term of this Agreement, PHRI/NLO shall cooperate with Institution to find a replacement investigator who is acceptable to both Institution and PHRI/NLO. Institution shall require the replacement investigator to agree to comply with and be bound by all the terms and conditions hereof. Notwithstanding this, PHRI/NLO may elect not to approve any person

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proposed as a replacement investigator, in which event PHRI/NLO shall have the right to terminate this Agreement in accordance with **ARTICLE 10 (Termination)**.

1.13 **Study Product:** Site shall obtain the drug product required for use in the Study ("**Product**") from its local pharmacy, the cost of which is included in the Payment Schedule attached herein as **Exhibit 1**. Investigator shall: (a) use the Product solely for the purposes of conducting the Study, and (b) ensure the Product is stored in accordance with all instructions provided by the local pharmacy and the Product labels. Site shall control and/or limit access to the Product to the Personnel, and provide up-to-date records showing receipt and dispensing of the Product in accordance the Protocol and Applicable Laws.

ARTICLE 2. TERM

2.1 This Agreement shall commence on the Effective Date specified above, and continue until 31st December 2022, unless otherwise terminated earlier in accordance with **ARTICLE 10 (Termination)** ("**Term**").

ARTICLE 3. COMPENSATION AND PAYMENT

3.1 In consideration for the work performed pursuant to this Agreement, PHRI agrees to pay Site in accordance with the Payment Schedule attached herein as **Exhibit 1** and Payment Rule Form attached as **Exhibit 2**.

3.2 Site shall review the details accompanying each payment and inform PHRI in writing of any discrepancies between the payment received and the payment expected. Site shall inform PHRI of any final discrepancies no later than four (4) months after the Project database is locked. Should PHRI not receive written notice of any final discrepancies within such four (4) month period, all payments required to be made hereunder shall be deemed to have been made in full.

3.3 Site represents and warrants that it/he/she is not a resident or citizen of Canada for tax purposes.

ARTICLE 4. CONFIDENTIAL INFORMATION

4.1 Site agrees to maintain or cause to be maintained in confidence all information received, resulting from and related to the Project, including but not limited to, the Protocol and CRFs ("**Confidential Information**"). This obligation shall be binding for a period of ten (10) years from the termination or completion of the Project. Site will not disclose the Confidential Information without the prior written approval of PHRI/NLO. Site may disclose Confidential Information to Personnel and the IRB to the extent required for the proper conduct of the Study, provided that each person to whom disclosure is made is fully informed of the confidential nature of the information and agrees to keep it confidential in accordance with this Agreement.

4.2 The obligations in **Section 4.1** will not apply to Confidential Information if and to the extent only that it: (a) is or later becomes known to the public or is in the public domain, other than by an act or omission of Site; (b) is previously known to Site, before the Effective Date or prior to Site having signed a confidentiality agreement with PHRI in connection with the Project, as evidenced by written records; (c) is lawfully obtained from a third party and such third party has a legal right to disclose the information; or (d) is independently developed by Site without the use of the Confidential Information, as evidenced by written records.

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ARTICLE 5. PRIVACY

5.1 All Parties shall comply with Applicable Laws regarding the Confidential Information, including but not limited to protected or personal information, PHI and all data received or obtained in the course of the Project. Access to PHI and/or personal information shall be provided only to the extent permitted by the Subject's ICF or other authorization and Applicable Laws. Site shall de-identify all information, data and documents prior to providing access to PHRI/NLO, however in the event PHRI/NLO receives or otherwise has access to a Subject's PHI and/or personal

Bangalore

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information PHRI/NLO shall hold the PHI and/or personal information in confidence in accordance with all Applicable Laws, the signed ICF or other authorization.

ARTICLE 6. INTELLECTUAL PROPERTY

6.1 PHRI shall own and have all rights, title and interest in: (a) all Project information, documents and data collected; (b) results derived from the performance of the Project in all forms and formats, and (c) any discovery or invention that may arise in the course of the Project by Site or the Personnel. Notwithstanding this, Site may use the data and results of the Study for its/his/her internal non-commercial research and educational purposes provided that until the Project results are public, as provided in **ARTICLE 7 (Publication)**, Site shall not make the results of the Study available to third parties without the prior written consent of PHRI. Subject medical charts shall remain the property of Site.

6.2 Site disclaims all rights, title and interest to the data and results, to any and all intellectual property arising out of or in connection with the Project, and to information and documents received by Site as a result of or in the course of performing the Study, except to the extent that such rights are expressly granted hereunder. Any discovery or invention shall be promptly communicated to PHRI. PHRI shall file and prosecute any patent applications, at its expense and in its sole discretion. Site and the Personnel agree to provide reasonable assistance with any patent applications. Any compensation payable for the assignment of the inventor rights is included in the consideration payable hereunder, whether or not itemized as such. Institution shall be responsible for payments to Investigator or Personnel according to Applicable Law or Institution policies for the assignment of inventor rights to PHRI.

ARTICLE 7. PUBLICATION

7.1 **Multi-Site Publication By Project Lead:** Site acknowledges that consolidated data from all sites will be analyzed collectively by a Project committee ("**Project Results**"). The Project committee will, regardless of the outcome, submit an initial publication to a peer reviewed, biomedical journal or otherwise make the Project Results public no later than twelve (12) months after the completion of the Project.

7.2 **Single Site Study Publication:** After the Project Results are public, or eighteen (18) months after the conclusion of the Project, Site shall have the right to publish the Study results from the data collected at its location in accordance with the terms of this **ARTICLE 7 (Publication)**. At least sixty (60) days prior to the date for submission of a publication, abstract, and/or presentation ("**Publication**"), Site shall provide copies of any proposed Publication to PHRI/NLO for review and comment by the Project committee. Site agrees to consider the comments, if any, of the Project committee.

7.3 If, in the course of review of the proposed Publication, PHRI/NLO and/or the Project committee identifies any Confidential Information that it or they may wish to protect, PHRI shall have the right to request amendments to the proposed Publication on reasonable grounds including without limitation to: (a) ensure that the proprietary information is not inadvertently divulged, (b) enable intellectual property rights to be secured, and/or (c) enable relevant supplementary information to be provided. Site shall comply with any reasonable request to amend or delete information in a proposed Publication, provided such request does not necessitate removal of Study data and/or results. In addition, on written notice, PHRI may require Site to postpone the Publication to enable PHRI to protect its intellectual property rights. Upon receipt of such written notice, Site shall delay the Publication for the period of time specified in the notice, provided that such period shall not exceed sixty (60) days.

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7.4 Other than as agreed herein, no Party shall use the name(s) of another Party or its/his/her Personnel without the prior written consent of such Party. Site may acknowledge in general terms the existence of this Agreement and its receipt of financial support from PHRI in order to comply with Applicable Laws and for Publication of the Study Results, and with the prior written approval of PHRI/NLO in connection with advertising or promotional materials for the Project. PHRI may disclose the name(s) of Site in any Publication of the Project Results, and may use the

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names and the amount of funding provided to Site for registration of the Project on www.clinicaltrials.gov, www.ctri.in and to comply with Applicable Laws and general industry standards.

ARTICLE 8. DISCLAIMER

8.1 PHRI makes no warranties of any kind whatsoever concerning the efficacy or safety of the Project, the procedures, treatments and medical practices described in the Protocol, the Product, or the Protocol itself. Except as expressly provided herein, PHRI hereby specifically disclaims any and all warranties or conditions, which may be implied by law.

8.2 Site makes no warranties of any kind whatsoever concerning the success of the Study.

ARTICLE 9. INDEMNIFICATION AND INSURANCE

9.1 **PHRI:** PHRI/NLO agrees to defend, indemnify and hold harmless Site and its trustees, directors, officers and Personnel from and against any and all costs, losses, liabilities, damages, actions, proceedings, demands, claims and reasonable expenses including legal fees (**"Claims"**) made by a third party to the extent directly resulting from PHRI's/NLO negligence, wrongful acts and omissions in connection with its performance or non-performance of its obligations under this Agreement.

9.2 **Site:** Site agrees to defend, indemnify and hold harmless PHRI/NLO, and its trustees, directors, officers, medical and professional staff, students, appointees, contractors, agents and sponsors (if any) from and against any and all Claims made by a third party to the extent directly resulting from Site's and the Personnel's negligence, wrongful acts and omissions in connection with its performance or non-performance of their obligations under this Agreement.

9.3 **Notification:** In connection with any Claim, each Party shall notify the other Parties promptly of any Claim and cooperate fully in the investigation and defense of any such Claims.

9.4 **Limitation of Liability:** Notwithstanding any other provision of this Agreement, under no circumstances will a Party be liable to another Party for any indirect, consequential or incidental damages that such other Party may have suffered, including without limitation damages for loss of profit or revenue and regardless of whether such other Party has been advised of the possibility of such damages arising, or for non-compensatory damages of any kind, including without limitation aggravated or punitive damages.

9.5 **Insurance:** During the Term and for the duration of their obligations surviving expiration or termination of this Agreement, PHRI and Institution will each obtain and maintain a policy or program of self-insurance at levels sufficient to support their obligations herein and in amounts appropriate to the conduct of their respective businesses, which at minimum, shall include comprehensive general liability coverage with limits of not less than the equivalent of two million dollars Canadian ($2,000,000) aggregate or amounts required by Applicable Laws.

9.6 **Investigator's License:** Investigator agrees to hold membership in the medical professional association in his/her jurisdiction for the duration of the Project and to provide evidence of such membership on PHRI's request.

9.7 NLO shall maintain in force a **clinical trial indemnity insurance** coverage for all Project Subjects recruited in India as required by Applicable Law. A copy of this will be provided to the Institution for reference and production to regulatory / Ethics office. NLO will provide payment to the Institution for reasonable unreimbursed medical expenses, including hospitalization, which the Institution may incur as a direct result of the treatment of a Subject's injuries that directly results from the Product or its administration during the Study, as determined by PHRI and the Investigator.

9.8 **Research Related Injury:** NLO shall be responsible for payment of the reasonable medical expenses incurred in diagnosing and treating any injury, illness, or adverse reaction of a Study

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Subject that results from the administration of the Product in accordance with the Protocol or the proper performance of any Protocol procedure.

9.9 A Party shall upon request provide the requesting Party with a copy of the relevant certificate of insurance coverage. As per Indian regulations, the expenses on medical management in case of any injury and financial compensation in case of clinical trial injury or death of the Project Subject shall be borne through the insurance cover undertaken by the NLO. Institution will consider building a contingency fund within the institution to meet the costs immediately and later get them reimbursed from NLO.

ARTICLE 10. TERMINATION

10.1 **For Default:** In the event either PHRI/NLO, on the one hand, or Site, on the other hand, fails to perform or performs improperly any of its material obligations under this Agreement, the non-defaulting Party shall provide the other Party or Parties with thirty (30) days' notice in writing to cure the default. In the event the default is not cured to the reasonable satisfaction of the non-defaulting Party, such Party may terminate this Agreement on notice to the other Parties. Either parties have equal rights to terminate this Agreement.

10.2 **For Safety or Other Reasons:** PHRI/NLO may terminate this Agreement at any time, on written notice to Site if: (a) the regulatory authorization or approval to perform the Project is withdrawn; (b) a decision is made to terminate the Project early due to safety or other reasons; (c) Site has not recruited a Subject into the Study within three (3) months of receipt of notice from PHRI to commence recruitment; or (d) Site is debarred or disqualified. Upon written notice to PHRI/NLO, Site may jointly terminate this Agreement if, in the reasonable judgement of Site, serious or life-threatening events raise issues of subject safety.

10.3 **For No Cause:** PHRI may also terminate this Agreement on thirty (30) days' prior written notice to Site for any reason.

10.4 **On-going Obligations:** Termination shall be subject to the on-going obligations of each of the Parties pursuant to **Section 10.5**. Immediately upon receipt of a notice of termination, Site shall cease recruitment of Subjects into the Study and cease conducting procedures as directed by PHRI and to the extent medically permissible.

10.5 **Closing Activities:** Regardless of the cause of termination, the Parties shall in all instances cooperate in closing-out of the Study and, if applicable, comply with all recommendations of the Project steering committee.

10.6 **Payment:** In the event of early termination of this Agreement, other than for a material breach by Site, PHRI shall pay all fees actually earned to the effective date of termination notice and for closing-out activities as determined by the Project steering committee. PHRI will consider payment of other reasonable non-cancellable expenses incurred by Site, but shall not be liable for such costs or expenses unless they have been pre-approved or subsequently agreed between the Parties.

10.7 **Survival:** The rights and obligations of Parties that by intent or meaning have validity beyond expiration or termination (including, without limitation, rights with respect to intellectual property, Publication, Confidential Information, privacy, and indemnification) shall survive the termination or expiration of this Agreement.

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ARTICLE 11. NOTICE

11.1 Any notice required by this Agreement shall be in writing and delivered to the addresses or facsimile numbers specified below or to such other address as each party may from time to time designate to the other in writing. Delivery shall be deemed received as follows - if prior to 4:00 pm on a business day in the jurisdiction of the recipient and otherwise on the next business day by: (a) personal delivery, when delivered personally; (b) courier, upon courier's verification of

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delivery; (c) facsimile, successfully received transmission at recipient's location; or (d) electronic mail transmission successfully received by the recipient.

If to PHRI:
Population Health Research Institute
237 Barton Street East
Hamilton, ON L8L 2X2
Canada
Attention: POISE-3 Project Manager
Tel: 905-521-2100 x 40526
Fax: 905-297-3779
Email: shirley.pettit@phri.ca

If to NLO:
The Dean, St. John's Research Institute
a unit of CBCI Society for Medical Education
St. John's National Academy of Health Sciences
Johnnagar, Bangalore
560 034, India
Tel: +91 80 49467001
Fax: +91 80 25501088
Email: deansoffice@sjri.res.in

If to Site (Institution):
Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow
Department of Anaesthesiology
Raebareli Road
Lucknow, Uttar Pradesh, 226014
India
Tel: 91-522-2495048
Fax: 05222668017
Email: sdhiraaj@gmail.com

If to Site (Investigator):
Dr. Sanjay Dhiraaj
Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow
Department of Anaesthesiology
Raebareli Road
Lucknow, Uttar Pradesh, 226014
India
Tel: 91-522-2495048
Fax: 05222668129
Email: sdhiraaj@gmail.com

With copy marked to:
Dr. Denis Xavier
Head - Division of Clinical Research & Training
St. John's Research Institute
St. John's National Academy of Health Sciences
Johnnagar, Bangalore-560 034, India
Tel: +91 80 49466140, +91 80 4946010, +91 80 49467080
Fax: +91 80 49467090
Email: denis@sjri.res.in

11.2 Where any notice is given to PHRI under this Agreement in relation to any alleged breach or default of this Agreement by PHRI or any Claim against PHRI, Site shall also provide the notice to:

Research Counsel
Population Health Research Institute
237 Barton Street East
Hamilton, ON L8L 2X2
Canada
Fax: 905-296-2369
Email: phri.contracts@phri.ca

ARTICLE 12. CONCLUDING PROVISIONS

12.1 **Entire Agreement, Amendment and Assignment:** The Exhibits and the Protocol are incorporated herein by reference and form part of this Agreement. This Agreement sets forth the entire agreement and understanding of the Parties as to the subject matter herein. Any amendments or modifications to this Agreement shall be in writing and signed by authorized representatives of each Party. Institution and/or Investigator may not assign this Agreement or any obligation hereunder without the prior written consent of PHRI/NLO.

12.2 **Recitals:** The Parties acknowledge the foregoing recitals to be true and correct.

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12.3 **Conflict:** In the event of any conflict between this Agreement and the Protocol, this Agreement will govern for any non-clinical matters and the Protocol will govern for any scientific and clinical matters.

12.4 **Independent Contractors:** As between PHRI/NLO on the one hand, and Site and the Personnel on the other hand, the work performed pursuant to this Agreement shall be as independent contractors and not as partners, joint venturers, employees, subcontractors or agents. No Party has the power or authority to bind another Party.

12.5 **Force Majeure:** In the event that performance of a Party's obligations are prevented by events beyond its reasonable control, including but not limited to, acts of God, regulations or acts of any governmental authority, war, civil commotion, strikes, other labor disturbances, epidemics, fire, earthquakes, storms or other catastrophes of a similar nature, the affected Party will notify the other Parties as soon as reasonably possible and the affected Party shall be relieved of its obligations for the duration and to the extent the performance of an obligation is prevented thereby. During the existence of any such condition, the affected Party shall use diligent efforts to remove the cause and resume performance of its obligations.

12.6 **Governing Law & Jurisdiction:** The interpretation and construction of this Agreement shall be governed by the laws of India excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this agreement to the substantive law of another jurisdiction. The Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the courts where the cause of action arises for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement, and agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts.

12.7 **Invalidity:** The invalidity or unenforceability of any provision of this Agreement shall not affect the validity of any other provision hereof. The Parties shall make commercially reasonable efforts to replace any invalid or unenforceable provision with one that is valid and enforceable, and reflects the originally intended commercial objectives of the Parties.

12.8 **Signing:** This Agreement may be signed in any number of counterparts, each of which so executed is deemed to be an original and when joined together constitute one and the same original agreement. The Parties agree that fax or electronic copies have the same effect as original hardcopies.

- signature page to follow -

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IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

Hamilton Health Sciences Corporation

Signature
Name: Tanya Chow
Position: Director of Contracts, Population Health Research Institute

Date: 2019-MAR-01
(YYYY-MMM-DD)

INVESTIGATOR

Signature
Name: Dr. Sanjay Dhiraaj

Date: 2019-01-29
(YYYY-MMM-DD)

INSTITUTION: Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow

Signature
Name: _____
Title: _____

DIRECTOR
Sanjay Gandhi Post Graduate Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Date: _____
(YYYY-MMM-DD)

On Behalf of ~~CBCI~~ St. John's Research Institute

Signature
Name: Dr. TONY D.S. RAJ
Title: DEAN
St. John's Research Institute
St. John's National Academy of Health Sciences
~~Koramangala, Bangalore~~ 560 034, INDIA

Date: 2019 MAR 26
(YYYY-MMM-DD)

On behalf of ~~St. John's Research Institute~~ CBCI

Signature
Name: Rev. Dr. Paul Parathazham
Title: Secretary

SECRETARY
C.B.C.I. SOCIETY FOR MEDICAL EDUCATION
ST. JOHN'S NATIONAL ACADEMY OF HEALTH SCIENCES
SARJAPUR ROAD, BANGALORE - 560 034

Date: 2019 Mar 28
(YYYY-MMM-DD)

On behalf of NLO

Signature
Name: Dr. DENIS XAVIER, MD, M.SC.
Title: Vice Dean (PG)
Professor of Pharmacology
St. John's Medical College
Bengaluru - 560 034, India.

Date: 2019 mar 16
(YYYY-MMM-DD)

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EXHIBIT 1 – PAYMENT SCHEDULE

Payment will be in **CAD and will be converted to rupees using the exchange rate as of the date of processing**. Payments will be processed on a quarterly basis with payment run cut-offs on March 31st, June 30th, September 30th and December 31st of each year. Payments will be issued within 25 days from the processing/run date (i.e., payment for run date March 31st is mailed on or prior to April 25th). Payments will be made for all CRFs received and validated to be clean prior to the run date, according to the payment schedule.

The fee per subject is inclusive of all costs (i.e. staff time, study lab investigations, event reporting costs, archiving costs, institutional overheads, cost to purchase TXA and any dispensation fees, participant expenses such as travel and parking, all applicable taxes including VAT or its equivalent).

Enrolment and Follow-up:

Visit Type	**Amount in CAD per Study Subject, per visit and receipt of all required CRFs for the visit**
Randomization Visit	75
Baseline	40
Hospital Discharge	50
1 Month	25
1 Year	40
Holdback fee *	20
Total Per Patient Fee (CAD) **	**250**

* Holdback fee will be paid after database lock if all required data for the participant has been collected and provided to PHRI prior to database lock.

** The actual fees paid will be based on completion of visits and collection of all required data.

Additional Payments for Product management at site:

Product management support fees will be provided in installments based on successful randomization of the first Study Subject and subsequent recruitment rate at Site towards various Study activities that will be required to be completed by the Site.

Subjects recruited	**Amount in CAD**
1st Subject recruited	200
20th Subject recruited	200
40th Subject recruited	200
50th Subject recruited	200

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EXHIBIT 2 – PAYMENT RULE FORM

COUNTRY:	**INDIA**
CENTRE #:	**464**
INSTITUTION:	**Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow**
INVESTIGATOR:	**Dr. Sanjay Dhiraaj**

Payment will be in **CAD and will be converted to rupees using the exchange rate as of the date of processing**. Payments will be processed on a quarterly basis with the payment run cut-offs on March 31st, June 30th, September 30th and December 31st of each year. Payments will be issued and sent out within 25 days from the processing/run date (i.e., payment for run date March 31st will be sent on or prior to April 25th) provided that a minimum of **500 CAD** has been earned within such payment period. Payments will be made for all CRFs received and validated to be clean prior to this date, according to the attached payment schedule.

Payments will be made to only one party. **(ALL INFORMATION BELOW MUST BE PRINTED)**

The following information is required in order to generate payment by wire transfer. Incomplete information could result in delay in payment.	
Bank Name:	STATE BANK OF INDIA
Bank Address:	STATE BANK OF INDIA, SANJAY GANDHI PGIMS, RAEBARELI ROAD, LUCKNOW, U.P.-226014
Bank SWIFT code:	SBININBB500
Beneficiary Name:	DIRECTOR SGPGIMS, RESEARCH ACCOUNT
Beneficiary Address:	DIRECTOR SGPGIMS, RESEARCH ACCOUNT, SANJAY GANDHI PGIMS, RAEBARELI ROAD, LUCKNOW, U.P.-226014
Beneficiary IBAN or Account number:	10095237491
IFSC Code (if applicable):	SBIN0007789
Reference (if applicable):	
Contact name and email of person generating the invoice (if applicable):	DR SANJAY DHIRAAJ

Institution Signature:	Date:
Name of the signatory:	
Investigator Signature:	Date
Name of the signatory: SANJAY DHIRAAJ	

The information below is required before PHRI can initiate any payment.

Are you an entity that has to submit value added tax? ___Yes ___ No Tax rate: ___%
If payment to the Investigator please provide following:
Social Security (US)/Social Insurance Number (Canada) or other applicable personal income tax identifier #:
Investigator First Name, Middle Initial and Last Name:
If payment to a business entity such as the Investigator's professional corporation or the institution please provide the following:
Tax ID #/GST Registration:
PAN card no: #:
For HHSC use only – Vendor ID #:

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SGPGIMS,Lucknow

[SGPGIMS]
[Dr. U K Misra]
[Protocol EPIDI066]
[25 July 2019]

महाराष्ट्र MAHARASHTRA ◑ 2019 ◑ UW 337558

Treasury Allotment Date and No. 18.04.2019 (UW 337558)	Serial No. **1598**/19 Date 26.04.2019
Nature of Document/Article No.	
Whether it is to be Registered -	If Registrable Name of S.R.O.-
Property Description in brief	As per the Document
Stamp Purchaser's Name	**Abbott India Limited,** 16, Godrej BKC, Bandra (E), Mumbai 51
If through other person then Name & Address	Anil Gonde,
Name of the Other Party	-
Stamp Duty Amount	Rs.100/-
Stamp Purchaser's Signature and Date	Shri **Jay R. Birwadkar,** Stamp Vendor, Ls. No. 1206030 Kumbhar Chawl, Netivali, Kalyan (E) 421 306 (M) 9890732173

ज्या कारणासाठी ज्यांनी मुद्रांक खरेदी केला त्यांनी त्याच कारणासाठी मुद्रांक खरेदी केल्या पासुन सहा महीन्यात वापरणे बंधनकारक आहे. अधिकारी

18 APR 2019

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EPIDEMIOLOGICAL STUDY AGREEMENT

Abbott India Limited ("Abbott") desires to retain , **Sanjay Gandhi Post Graduate Institute of Medical Sciences**, at, **Raebarel Road, Lucknow, Uttar Pradesh-226014**,India ("Institution") to provide services in support of Institution's employee's **Dr. Usha Kant Misra** (the "Investigator") conduct of a non-interventional, epidemiological study (the "Study") in relation to" **A Cross Sectional, Multicenter Study To Determine The Sociodemographic Characteristics, Clinical Profile, And Usage Pattern Of Antiepileptic Drugs In Persons With Epilepsy In India"** effective as of the date this Epidemiological Study Agreement (the "Agreement") is fully executed (the "Effective Date"). In consideration of the mutual promises set forth herein, the parties agree as follows:

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1. Conduct of Study.

(a) Investigator will conduct the Study pursuant to the terms of this Agreement and in strict adherence to EPIDIO66 study entitled "*A Cross-Sectional, Multicenter Study To Determine The Sociodemographic Characteristics, Clinical Profile, And Usage Pattern Of Antiepileptic Drugs In Persons With Epilepsy In India*" (the "Protocol"), as the same may be amended from time to time in writing by Abbott, and with any other written instruction that may be provided by Abbott. The parties further agree that this Study is epidemiological and will not utilize any Abbott product(s) ("Abbott Product(s)"). Subjects may already be prescribed an Abbott Product prior to, during or after the Study however this is incidental to the conduct of the Study and any such decision to prescribe Abbott Product to any subject at any time shall be the sole decision of the relevant subject's doctor and unrelated to the Study.

(b) Investigator hereby represents and warrants that any and all personnel working by or on behalf of the Investigator, with respect to the Study, are employed by Investigator and will work under the supervision of the Investigator. Further, Investigator shall be responsible for making payments, if applicable, to such personnel upon receipt of funds from Abbott. Investigator will ensure that such personnel will comply with the terms and conditions of this Agreement and Investigator shall remain responsible and liable for the acts or omissions of such personnel as if such activities had been performed by Investigator.

(c) Investigator shall use best efforts to complete enrollment of 10 patients (hereinafter referred to as "subjects") within 03 months of Study initiation. The Investigator's site will be discontinued by the sponsor if there is no enrollment of patients within 01 month of site initiation. Abbott may terminate this Agreement immediately if (i) IRB or IEC (defined below) approval or NOC from Institutional Ethics Committee, if required, is not obtained after central Ethics committee approval within 5-8 weeks of receipt of all necessary materials for IRB/IEC submission; or (ii) all essential documents have not been executed and received by Abbott within 4 weeks of Investigator's receipt of IRB or IEC's written approval, if such approval is required.

Contacts. Investigator's contact(s) at Abbott will be **Sneha Nair-Head- Clinical Operations, Abbott India Limited ,16th Floor, Godrej BKC,Plot C – 68, "G" Block, Bandra Kurla Complex, Near MCA Club, Bandra (East),Mumbai 400 051, India, O:+91 22-38160910, M: 9970780488, Fax # 91-22 2871 7499**, or whomever Abbott may designate in writing. Abbott's contact(s) at Investigator will be retain, **Dr. Usha Kant Misra, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow, Uttar Pradesh-226014, Phone: + 91- 8004904627.**

2. Compliance with Law.

(a) Investigator represents warrants and covenants that he/she will conduct the Study and perform his/her obligations under this Agreement in compliance with all applicable laws, regulations and guidelines. In furtherance of the foregoing obligations and as required by law, Investigator will further ensure that an Institutional Review Board ("IRB"), an Independent Ethics Committee ("IEC"), or both, as applicable, approves and oversees the conduct of the Study. Investigator will comply with the directives of the IRB or IEC, or both, as applicable, respecting the conduct of the Study, and will notify Abbott to the extent any such directives vary from the Protocol.

(b) Prior to the initiation of the Study, Investigator will and will ensure that any subinvestigator for the Study provides Abbott with all essential regulatory documents requested by Abbott including but not limited to current Curriculum Vitae and medical license, or equivalent, to ensure compliance with applicable regulations. Investigator will comply with all applicable requirements regarding reporting and management of conflicts of interest.

(c) Investigator agrees that if services are paid for or provided without charge by Abbott, neither Investigator, nor his/her agents shall separately bill or seek reimbursement for such services from any third party including, without limitation, the subject, any private provider of insurance, or any government program or other public provider of insurance.

Safety Reporting. Institution and Investigator shall comply with the safety reporting obligations attached hereto and incorporated herein as Exhibit B ("Safety Reporting Obligations").

Study Supplies. Due to the epidemiological nature of this Study, Abbott will not be providing any Abbott Product(s) or reimbursement for any Abbott Product(s). Abbott will provide to Investigator, at no cost, sufficient quantities of the case report forms or access to an electronic data capture system ("CRFs") as well as any other materials and information specified by the Protocol or that Abbott deems necessary to conduct the Study (together, the "Study Materials"). All Study Materials and other information provided by Abbott in connection with this Agreement will not be used for any purpose other than to conduct the Study pursuant to the Protocol and will remain the sole property of Abbott. Upon termination of the Study or at

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Abbott's request, the Study Materials will be returned or destroyed pursuant to the Protocol, and Institution will document such disposition, pursuant to Abbott's direction.

4. Delivery of Progress and Post-Study Reports. Upon request, Institution will submit oral or written reports on the progress of the Study to Abbott. Within forty-five (45) days following the completion or termination of the Study, Institution will furnish Abbott with the following, unless Abbott directs otherwise in writing:

   (a) the final IRB or IEC report on the Study prepared by the Investigator for the IRB or IEC or both, as applicable;
   (b) all completed, used and unused CRFs not previously delivered to Abbott; and
   (c) all data, reports and other information generated in relation to the Study.

5. Monitoring and Audits; Record Retention.

   (a) Institution will permit Abbott and/or any Abbott designee access to Study sites during normal business hours to monitor the conduct of the Study as well as to audit records, CRFs, source documents, and other data relating to the Study. Institution may redact such records as may be legally required to protect subject confidentiality consistent with **Section 9** (Subject Confidentiality and Data Protection) of this Agreement. If Abbott requests corrective and/or preventive action as a result of its monitoring or audit activities, Institution shall comply with the timely creation and implementation of a corrective action and/or preventive action plan. Abbott's right to audit shall survive the expiration of this Agreement.

   (b) Institution will ensure that subject data, as required in the Protocol, is entered into the CRFs (whether electronic or paper) within five (5) business days of subject visit.

   (c) Unless prohibited by law, Institution will notify Abbott immediately upon receiving any requests by any regulatory authority to inspect or have access to documents related to the Study and will promptly provide Abbott with a copy of any such request, to include copies of any documents received from or provided to regulatory authorities. In the event a regulatory citation or notice is issued which relates to the services under this Agreement, Institution agrees to produce a summary that includes an explanation of the issues identified by the regulatory authority, any response to the significant issues identified by the regulatory authority, and an explanation of the applicability of such regulatory citation or notice to the service(s) provided hereunder. Institution agrees to provide Abbott with such summary within fifteen (15) days of Institution's receipt of any regulatory citation or notice.

   (d) Institution shall retain the Study documents in accordance with applicable laws and regulations or the Protocol, whichever retention period is longer. At Abbott's request and expense, Institution shall retain the Study documents for an even longer period. Institution shall provide Abbott at least sixty (60) days' written notice before deleting any Study documents from its files.

6. Compensation.

   (a) Abbott shall pay Institution in accordance with the Study budget set forth in **Exhibit A** (the "Budget"). In addition, Institution's employees, including Investigator, may be reimbursed for reasonable and necessary expenses related to travel, consistent with Abbott's travel policy (including economy coach air travel, reasonable and customary lodging and meal rates based on the geographic region of travel), and may be provided meals as may be necessary for the publication/ presentation of study results/data or at investigator meetings or other Abbott required meetings. The parties agree that the amounts set forth in the Budget represent the fair market value for the services to be rendered and have not been determined in any manner that takes into account the volume or value of any referrals or business otherwise generated between or among Institution and Abbott.

   (b) The Budget is based on the full performance of services and compliance with the terms of this Agreement (including the Protocol). Abbott will not remit payments for CRFs containing incomplete or inaccurate data or data collected from subjects enrolled in violation of the Protocol ("Non-conforming CRFs"). If Abbott has paid for such Non-conforming CRFs such payment will be deducted from the next payment (or the final payment, as described in **Section 7(d)** below).

   (c) All payments shall be made in accordance with the terms of **Exhibit A** and only after all parties have signed this Agreement. If applicable, reimbursement of IRB/IEC fees is contingent upon completion of the IRB/IEC's review and final decision regarding all submitted Study documents including, but not limited to, the Protocol and/or Protocol revisions. Abbott will not be obligated to reimburse Institution for pass-through expenses invoiced to Abbott more than one hundred eighty (180) days after the termination date of this Agreement.

   (d) The final payment due to Institution under this Agreement shall be payable upon completion of all services contemplated hereunder, delivery to Abbott of all CRFs, and return to Abbott of all items described in **Section 5**

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(17)

(Delivery of Progress and Post-Study Reports) and will be accompanied by a financial reconciliation performed by Abbott. If the total amount Abbott has paid is less than the amount to which Institution is entitled hereunder as revealed by the reconciliation, Abbott shall pay the outstanding amount due. If Abbott is due a refund for any unearned fees or overpayments, Institution shall remit the amount of such refund with supporting documentation to Abbott at: Clinical Operations, Abbott India Ltd,16th Floor, Godrej BKC,Plot C – 68, "G" Block Bandra Kurla Complex,Near MCA Club, Bandra (East),Mumbai 400 051, India. Any payments due from one party to the other under the reconciliation shall be made within forty-five (60) days of the notice and invoice of amount due.

(e) In the event of a payment dispute, Institution and Investigator shall not withhold Study data or information pending resolution of the dispute because such withholding may cause irreparable harm to the Study.

(f) Upon written notice, Abbott may delegate certain of its payment obligations to a contract research organization ("CRO"). In such event, Institution and Investigator agree that as to any payments delegated by Abbott to a CRO, Institution and Investigator shall first seek redress from the CRO for compensation.

(g) Investigator shall be responsible for direct compensation of Investigator, including any subinvestigators, from funds paid by Abbott to Institution under the Study Budget. Neither Investigator nor any subinvestigators shall receive any separate compensation from Abbott.

(h) In this study; Abbott has delegated its Fee payment obligations under this Agreement to **JSS Medical Research India Pvt Ltd.** The Investigator will hence approach Site Management Organization (SMO) for queries or concerns in relation to compensation under this Agreement.

7. Confidentiality.

(a) During the Term of this Agreement, including any extensions thereof, and for a period of ten (10) years after the expiration or termination of this Agreement, Institution, its employees (including Investigator), agents, subcontractors and affiliates (collectively, "Receiving Party") shall not disclose Confidential Information without Abbott's prior written consent. Notwithstanding the foregoing, obligations of confidentiality and non-use with respect to any Confidential Information identified as a trade secret by Abbott shall remain in place for so long as the applicable Confidential Information retains its status as a trade secret under applicable law. "Confidential Information" shall include any information provided to Receiving Party by or on behalf of Abbott, including but not limited to the Protocol, Abbott Product, Study Materials, and all materials and information concerning Abbott or the Study or developed as a result of conducting the Study, except any portion thereof which:

(i) is known to the Receiving Party prior to receipt, as evidenced by its written records;
(ii) is disclosed to the Receiving Party by a third party who has a right to make such disclosure in a non-confidential manner; or
(iii) is or becomes part of the public domain through no fault of the Receiving Party.

(b) The Receiving Party shall not use Confidential Information for any purpose other than as indicated in this Agreement without Abbott's prior written approval.

(c) Nothing in this Agreement will be construed to restrict Receiving Party from disclosing Confidential Information as required by law or court order or other governmental order or request, provided in each case Receiving Party shall give Abbott prompt written notice (and in any case at least five (5) business days notice) to allow Abbott to take action to protect its Confidential Information. In the event that no protective order or other remedy is obtained, or Abbott waives compliance with the terms of this **Section 8**, Receiving Party shall furnish only that portion of the Confidential Information which is legally required based on the written opinion of legal counsel.

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(d) Receiving Party will not disclose to Abbott any information which is confidential or proprietary to a third party unless Institution has first obtained the prior written approval of such third party and Abbott.

8. Subject Confidentiality and Data Protection.

(a) The parties will comply with all applicable laws and regulations regarding Study subject confidentiality and data protection. Investigator will be responsible on behalf of the Institution for obtaining a signed subject authorization document for the use and disclosure of data and an Informed Consent Form, if required (collectively, "ICF") from each Study subject prior to the subject's participation in the Study. The ICF must permit Abbott and its representatives involved with or evaluating the Study to access, process, obtain copies, transfer and retain Study data. Each ICF must conform with the Protocol and be compliant with: International Conference on Harmonisation, Harmonised

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16

Tripartite Guidelines for Good Clinical Practice ("ICH"); all applicable laws and regulatory requirements; and must be approved in writing by Abbott, and if applicable by the IRB/IEC. A Study subject's participation in the Study will be contingent upon the execution of a proper ICF.

(b) Where Institution and/or Investigator collects, retains, processes or discloses information identifying or, in combination with other information, identifiable to a living individual, including Study subjects and others participating in or associated with the Study (the "Personal Data") it shall only do so in accordance with this Agreement, with all applicable laws and with Abbott's written instructions. Institution and Investigator shall maintain appropriate safeguards to ensure the confidentiality and security of the Personal Data. Institution and Investigator shall promptly inform Abbott of any unauthorized access to or disclosure of Personal Data (the "Security Breach"), including the timing and nature of the Security Breach. Institution and Investigator shall take all reasonable measures to remedy the Security Breach. Where applicable data protection laws require that the parties enter into additional agreements or undertakings, including international data transfer agreements, Institution will undertake to ensure that all necessary agreements are implemented and in place.

(c) Investigator acknowledges and consents to, and shall cause all subinvestigators for the Study to acknowledge and consent to, Abbott's collection, use, processing, and disclosure of Investigator's and sub-investigator's Personal Data including details of his/her name, address, qualifications and clinical trial experience. Additional uses or disclosures may include financial information (including compensation and reimbursement payments), public registration of the Study on web sites designed for this purpose such as www.clinicaltrials.gov, assessments by Abbott of Investigator's suitability for future studies, and for purposes of complying with applicable laws. Investigator understands and expressly agrees and shall cause all subinvestigators for the Study to expressly agree that this information may, if necessary for these purposes, be made available to ethics committees, government authorities and other companies within the Abbott group of companies located both in the country in which the Study is carried out and in other countries, including in the United States or elsewhere as required by applicable law or as necessary for the purposes of Good Clinical Practice or data protection audits or inspections.

9. Publicity. Institution shall not and shall ensure Receiving Party shall not disclose the existence or terms of this Agreement or use the name, trademark, servicemark or logo of Abbott in any publicity, advertising or information, which is disseminated to any third person or to the general public without Abbott's prior written approval. Institution understands that the terms and conditions of this Agreement, including the amount of any payment made hereunder, may be disclosed and made public by Abbott as required by law or regulation or where Abbott deems appropriate.

10. Inventions. Any information, invention, data or discovery (whether patentable or copyrightable or not), innovation, communication or report, conceived, reduced to practice, made, generated or developed by the Receiving Party that either results from use of Abbott Product(s) or results from conduct of the Study will be promptly disclosed to Abbott, assigned to Abbott and will be the sole property of Abbott. Institution and Investigator each agree, upon Abbott's request and at Abbott's expense, to execute or cause to have executed such documents and to take such other actions as Abbott deems necessary or appropriate to obtain patent or other proprietary protection in Abbott's name covering any of the foregoing.

11. Publications and Presentations.

(a) Publication Requirements. To foster the highest standards of conduct related to scientific publications, including manuscripts, abstracts, and poster/oral presentations (collectively, "Publication(s)"), Abbott is committed to transparency and ethical publication practices. If Investigator serves as an author on any Publication emanating from the Study, Investigator must comply with the Requirements for Scientific Publications attached hereto as **Exhibit B**.

(b) Procedures. As the Study sponsor, Abbott retains the first right to disclose the results of the Study through a Publication or any other public disclosure (collectively, a "Study Results Disclosure"). Accordingly, following the earliest of: (i) Abbott's Study Results Disclosure; or (ii) twelve (12) months after completion or termination of the Study at all Study sites, Institution and Investigator shall have the right to prepare and submit for Publication a Study Result Disclosure in appropriate scientific journals or other professional publications. If Institution or Investigator prepares a Study Results Disclosure, Institution shall provide or shall require Investigator to provide Abbott, at least sixty (60) days prior to any submission of a work for a Study Results Disclosure, with a draft of the same for Abbott's review and comment to ascertain whether any patentable subject matter or Abbott Confidential Information (other than the results of the Study generated hereunder) are disclosed therein. Abbott shall return comments to Institution or Investigator within sixty (60) days after receipt of the draft Study Results Disclosure (the "Review Period"). In addition, Institution or Investigator shall delay any proposed Study Results Disclosure an additional sixty (60) days in addition to the Review Period in the event Abbott so requests to enable Abbott to secure patent or other proprietary protection (the "Delay Period"). Institution agrees and shall require Investigator to agree to keep the proposed Study Results Disclosure confidential until the Review Period and, if elected by Abbott, the Delay Period has expired. Institution agrees and shall require Investigator to agree that due consideration will be given to Abbott comments; and further, Abbott Confidential Information (other than the results of the Study generated hereunder) shall be deleted from any

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Executive Registrar
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(15)

Study Results Disclosure. In the event that Institution or Investigator and Abbott differ in their opinion or interpretation of data in the Study Results Disclosure, the parties shall resolve such differences in good faith through appropriate scientific debate.

12. Representations and Warranties. Institution represents and warrants that:

(a) the terms of this Agreement are valid and binding obligations of Institution, and are not inconsistent with any other contractual or legal obligation it or Investigator may have or with Institution's policies and procedures or the policies and procedures of any institution or company with which each of Institution or Investigator is associated;

(b) Institution's performance of the services and acceptance of compensation, including the acceptance of any meals and/or reimbursement of reasonable expenses for investigator meetings or other Abbott required meetings, which may be provided to Investigator or Institution (including its employees and agents) hereunder, is in compliance with all policies and procedures of Institution, and that Investigator's performance of such services does not present a conflict of interest with Investigator's official duties;

(c) Investigator has received any required authorization, written or otherwise, from Institution for Investigator's performance of the services and acceptance of any meals and/or reimbursement of reasonable expenses for investigator meetings or other Abbott required meetings, which may be provided to Investigator hereunder;

(d) If Investigator leaves Institution's employment during the Term, then Institution will promptly notify Abbott in writing and will obtain a written acknowledgement by Investigator's new employer that Investigator is participating in the Study under the terms of this Agreement;

(e) Institution and Investigator have the experience, capabilities, adequate subject population, and resources, including but not limited to sufficient personnel and equipment, to efficiently and expeditiously perform the Study in a professional and competent manner;

(f) any subinvestigators used by Institution for the Study will be selected based upon a consideration of the following: (i) training and expertise in relevant fields; (ii) appropriate research facilities; (iii) experience with the relevant subject population so that the subinvestigator has a reasonably high likelihood of recruiting the appropriate research participants and following through to the completion of the Study; (iv) prior scientific research or clinical experience; and (v) ability to conduct the Study in accordance with applicable legal and regulatory requirements;

(g) Investigator is not under investigation or subject to any disciplinary action by any medical board, and Investigator has a medical license, or equivalent, that has not been restricted or suspended by any medical board in any way. In the event that any of foregoing occurs, Investigator shall immediately notify Abbott, and Abbott shall have the right to immediately terminate this Agreement;

(h) Institution shall ensure that Investigator does not alter in any way Investigator's normal practice for prescribing medications to patients or be influenced in any way to prescribe an Abbott product in place of any other therapy due to the conduct of this Study or payment to Institution of any compensation from Abbott for conducting this Study; and

(i) if any significant changes occur during the Term with regard to the circumstances surrounding this Agreement (e.g., there is a change in a policy or procedure that could reasonably be interpreted to affect the propriety of Institution or Investigator's involvement in this Agreement), Institution agrees to immediately notify Abbott in writing of any such changes.

13. Term and Termination.

(a) This Agreement will be effective on the Effective Date and shall expire on the later of: (i) one (1) year from the Effective Date; (ii) the date of Study database lock if there is subject enrollment under this Agreement; or (iii) the date of completion of all the obligations of the parties hereunder (the "Term"), unless terminated earlier as provided below.

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(b) Abbott may terminate this Agreement at any time upon written notice. Either party may terminate this Agreement upon written notice if (i) the other party has breached a material term of the Agreement, or (ii) if the Study is terminated by any governmental or regulatory authority.

(c) Termination or expiration of this Agreement will not affect any rights or obligations which have accrued prior thereto. In the event of termination of this Agreement, Institution will discontinue all then-enrolled subjects from the Study.

14. Insurance. Each party agrees to maintain a policy or policies of insurance or self-insurance sufficient to satisfy its respective duties and obligations under this Agreement to the extent such duties and obligations are commercially

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(14)

insurable. Each party further agrees to provide written evidence of such insurance (including certificates of insurance or other evidence providing reasonable assurances) to the other party within seven (7) business days following receipt of written request by the other party therefore.

15. Debarment and Exclusion. Institution represents and warrants that none of Institution, any Institution employees, including Investigator, agents and subcontractors performing services hereunder, including any subinvestigators, have ever been, are currently, or are the subject of a proceeding that could lead to Institution or such employees, agents or subcontractors becoming, as applicable, a Debarred, Excluded or Convicted Entity or Individual, nor are they listed on the United States Food and Drug Administrations (the "FDA") Disqualified/Restricted List for clinical investigators. Institution further covenants, represents and warrants that if, during the Term, Institution, or any of Institution's employees, including Investigator, agents or subcontractors, including any subinvestigators, performing services hereunder, becomes or is the subject of a proceeding that could lead to that party becoming, as applicable, a Debarred, Excluded or Convicted Entity or Individual or added to FDA's Disqualified/Restricted List for clinical investigators, Institution will immediately notify Abbott, and Abbott will have the right to immediately terminate this Agreement. The provision of this paragraph regarding notice of acts occurring during the Term will survive termination or expiration of this Agreement. For purposes of this provision, the following definitions will apply:

    (a) A "Debarred Individual" is an individual who has been debarred by the FDA pursuant to Title 21 of the United States Code ("USC") Section 335a (a) or (b) by any other competent authority, including, without limitation, any local competent authority from providing services in any capacity to a person that has an approved or pending drug product application.

    (b) A "Debarred Entity" is a corporation, partnership or association that has been debarred by the FDA pursuant to Title 21 of USC Section 335a (a) or (b) by any other competent authority, including, without limitation, any local competent authority from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or affiliate of a Debarred Entity.

    (c) An "Excluded Individual" or "Excluded Entity" is (i) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General of the U.S. Department of Health and Human Services; or (ii) is an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration.

    (d) A "Convicted Individual" or "Convicted Entity" is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of Title 21 of USC Section 335a(a) or Title 42 of USC Section 1320a – 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.

    (e) "FDA's Disqualified/Restricted List" is the list of clinical investigators restricted from receiving investigational drugs, biologics, or devices if FDA has determined that the investigators have repeatedly or deliberately failed to comply with regulatory requirements for studies or have submitted false information to the study sponsor or the FDA.

16. Independent Contractor. Each of Institution and Investigator's relationship to Abbott under this Agreement is that of an independent contractor, and neither Institution nor Investigator has authority to bind or act on behalf of Abbott.

17. Assignment. Institution may not assign this Agreement to any other party, or subcontract any of its services hereunder, without Abbott's prior written consent. Any attempted assignment without Abbott's prior written consent will be null and void and will constitute a material breach of this Agreement. Any permitted assignee shall assume all obligations of Institution under this Agreement. Assignment shall not relieve Institution of responsibility for the performance of any accrued obligation. Further, in the event that Institution is permitted to subcontract any duty hereunder to any third party, such subcontractor shall execute an agreement in a form acceptable to Abbott obligating such subcontractor to comply with the terms and conditions hereof, and Institution shall remain responsible and liable for the acts or omissions of such subcontractor activities as if such activities had been performed by Institution.

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18. Subinvestigators. Institution will not use any subinvestigator for the Study without Abbott's prior written consent, and only upon Institution's agreement to ensure any subinvestigators compliance with the terms and conditions of this Agreement.

19. Notices. Any notice required or otherwise made pursuant to this Agreement shall be in writing, personally delivered or sent by certified mail, return receipt requested, or recognized courier service, properly addressed, or by facsimile with confirmed answer-back, to the other party at the address set forth below. Notices shall be deemed effective (a) on the date received if personally delivered or sent by certified mail or recognized courier, or (b) upon the date of confirmed answer-back if sent by facsimile.

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Executive Registrar
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(13)

If to Institution
Dr. Usha Kant Misra

Address: , Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow, Uttar Pradesh-226014

Phone: +91- 8004904627.

If to Investigator:
Dr. Usha Kant Misra

Address: Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow Uttar Pradesh-226014

Phone: + 91- 8004904627.

If to Abbott:
Sneha Nair,
Head- Clinical Operations,
Abbott India Limited,
Floor 16, Godrej BKC,
Plot No.C- 68, BKC,Near MCA Club,
Bandra (E)
Maharashtra- 400051, India
Direct 91-22 38160910,
Mobile No : +91-9970780488

with a copy to:
Kaiyomarz Marfatia
Director- Legal & Secretarial
Abbott India Limited,
Floor 16, Godrej BKC,
Plot No.C-68, BKC,Near MCA Club,
Bandra (E)
Mumbai-400051,
Maharashtra, India
Phone:91-022-28717488

20. Survival. Notwithstanding termination of this Agreement for any reason, rights and obligations which by the terms of this Agreement survive termination of the Agreement, will remain in full force and effect.

21. Severability. If any provision, right or remedy provided for herein is held to be unenforceable or inoperative by a court of competent jurisdiction, the validity and enforceability of the remaining provisions will not be affected thereby.

22. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same agreement. Each party acknowledges that an original signature or a copy thereof transmitted by facsimile or by PDF shall constitute an original signature for purposes of this Agreement.

23. Applicable Law, Place of Venue-The parties agree that this Agreement shall be governed by Indian Law, without regard to the conflicts of laws provisions thereof. The parties will endeavor to settle amicably any dispute having its origin in this Agreement. In case a dispute is brought before a court of law, the courts of Lucknow, India will have sole jurisdiction over the litigation

24. Arbitration. Any dispute, controversy or claim arising out of or relating to this Agreement which cannot be resolved within thirty (30) days by mutual consent of the Parties, shall be settled by arbitration in accordance with the Indian Arbitration and Conciliation Act, 1996, as amended from time to time, by one arbitrator appointed in accordance with the said Act. The arbitration shall take place in Mumbai and shall be conducted in the English language. The award of the arbitrator shall be final and binding on both parties.
The parties bind themselves to carry out the awards of the arbitrator. This Section shall survive termination or expiration of this Agreement.

25. Entire Agreement. This Agreement, including all exhibits hereto, contains the entire understanding of the parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. This Agreement may be modified only by written agreement signed by the parties. This Agreement is being signed in the English language only. If another language version is created, it shall not affect the interpretation of this Agreement and the English language version shall prevail.

26. Financial disclosure certification: Prior to the initiation of the study, institution will ensure that each investigator and any sub-investigator(s) completes and returns to Abbot the financial disclosure certification. Investigator understands and will be required to certify that investigator and all sub investigator conducting the study, and their immediate families [illegible] a direct ownership interest(e.g., intellectual property rights) in the Abbott Product, nor may they be compensated with

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Executive Registrar
SGPGIMS,Lucknow

(12)

If to Institution
Dr. Usha Kant Misra

Address:, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow, Uttar Pradesh-226014

Phone: + 91- 8004904627.

If to Investigator:
Dr. Usha Kant Misra

Address: Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow Uttar Pradesh-226014

Phone: + 91- 8004904627.

If to Abbott:
Sneha Nair,
Head- Clinical Operations,
Abbott India Limited,
Floor 16, Godrej BKC,
Plot No.C- 68, BKC,Near MCA Club,
Bandra (E)
Maharashtra- 400051, India
Direct 91-22 38160910,
Mobile No : +91-9970780488

with a copy to:
Kaiyomarz Marfatia
Director- Legal & Secretarial
Abbott India Limited,
Floor 16, Godrej BKC,
Plot No.C-68, BKC,Near MCA Club,
Bandra (E)
Mumbai-400051,
Maharashtra, India
Phone:91-022-28717488

20. Survival. Notwithstanding termination of this Agreement for any reason, rights and obligations which by the terms of this Agreement survive termination of the Agreement, will remain in full force and effect.

21. Severability. If any provision, right or remedy provided for herein is held to be unenforceable or inoperative by a court of competent jurisdiction, the validity and enforceability of the remaining provisions will not be affected thereby.

22. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same agreement. Each party acknowledges that an original signature or a copy thereof transmitted by facsimile or by PDF shall constitute an original signature for purposes of this Agreement.

23. Applicable Law, Place of Venue-The parties agree that this Agreement shall be governed by Indian Law, without regard to the conflicts of laws provisions thereof. The parties will endeavor to settle amicably any dispute having its origin in this Agreement. In case a dispute is brought before a court of law, the courts of Lucknow, India will have sole jurisdiction over the litigation

24. Arbitration. Any dispute, controversy or claim arising out of or relating to this Agreement which cannot be resolved within thirty (30) days by mutual consent of the Parties, shall be settled by arbitration in accordance with the Indian Arbitration and Conciliation Act, 1996, as amended from time to time, by one arbitrator appointed in accordance with the said Act. The arbitration shall take place in Lucknow and shall be conducted in the English language. The award of the arbitrator shall be final and binding on both parties. The parties bind themselves to carry out the awards of the arbitrator. This Section shall survive termination or expiration of this Agreement.

25. Entire Agreement. This Agreement, including all exhibits hereto, contains the entire understanding of the parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. This Agreement may be modified only by written agreement signed by the parties. This Agreement is being signed in the English language only. If another language version is created, it shall not affect the interpretation of this Agreement and the English language version shall prevail.

26. Financial disclosure certification: Prior to the initiation of the study, institution will ensure that each investigator and any sub investigator(s) completes and returns to Abbot the financial disclosure certification. Investigator understands and will be required to certify that investigator and all sub investigator conducting the study, and their immediate families may not have a direct ownership interest(e.g., intellectual property rights) in the Abbott Product, nor may they be compensated with

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Abbott securities in exchange for being an Investigator or subinvestigator in the Study. Investigator and any subinve... will promptly notify Abbott of any change in the accuracy of the Financial Disclosure Certification during the Term and for one (1) year following completion of the Study.

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

ABBOTT INDIA LIMITED

By: _____

Name: Sneha Nair

Title: Head-Clinical Operations

Date: 25/07/2019

INVESTIGATOR NAME

By: _____

Name: Dr. Usha Kant Misra

Title _____

Date: _____

SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES

By: _____

Name: Prof. Rakesh Kapoor

Title: Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow

Date: 03.09.2019

Exhibit A - Budget
Attachment 1 to Exhibit A
Exhibit B - Safety Reporting Obligations
Exhibit C- Requirements for Scientific Publications

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(10)

EXHIBIT A
BUDGET

INVESTIGATOR	Dr. Usha Kant Misra
ADDRESS	Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow, Uttar Pradesh-226014
PHONE	+ 91- 8004904627

DISEASE BEING STUDIED: Epilepsy	PROTOCOL: EPIDI066	Visits: Baseline
Number of subjects required per Protocol/Study by Investigator		80
Total per subject cost (see **Attachment 1**, per subject breakdown; payments to be made per the Subject Visit Payments schedule, described below, every 3 months)		INR 1000(Visit) = 1000*
Total cost for all CRFs for all subjects		INR 80,000**
ADDITIONAL STUDY FEES: Payments will be made as follows, in accordance with Compensation Section of the Agreement.		
	TOTAL COMPENSATION)	INR 80000

*** On completion of visit 1(Baseline)**
**** depends on the total no of patients enrolled / CRF completed**

SUBJECT VISIT PAYMENT SCHEDULE: Payments will be made as follows, in accordance with the Compensation Section of the Agreement:

Subject Visit Payments: Payments for subject visits will be made quarterly following enrollment of the first subject. Payments will be made after data is entered by Investigator into the CRFs and reviewed by Abbott, and will correspond to amounts listed in **Attachment 1 to Exhibit A**. Investigator understands that such payments are subject to subsequent verification by Abbott and will be adjusted per Section 7(d) (Compensation) of the Agreement if necessary. Total payment mentioned in the agreement is for a recruitment of 20 patients.
A CRO, JSS Medical Research India Private Limited has been contracted to provide the site with a CRC for subject recruitment, source documentation& data entry purpose. The cost of the CRC will be paid by Abbott India Limited to JSS Medical Research India Private Limited.

A final payment shall be made following termination of the Study, delivery to Abbott of the remaining Completed CRF(s), final reconciliation of any remaining amounts due, and the return to Abbott of all items described in Section 4 (Study Supplies) of the Agreement. Abbott will not be obligated to reimburse Investigator for pass-through expenses invoiced to Abbott more than one hundred eighty (180) days after the termination date of this Agreement.

CHECQUE PAYMENT INFORMATION:

Cheque shall be made payable to:	**DIRECTOR SGPGIMS RESEARCH ACCOUNT**
Individual's name and address	Dr. Usha Kant Misra Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow, Uttar Pradesh-226014
Individual's name and e-mail address at site to receive detailed payment information:	Dr. Usha Kant Misra drukmisra@rediffmail.com
Individual's name and address to receive Invoices at Abbott:	Dr. Prachi Sudhir Bhoyer Site Management, JSS Medical Research India Private Limited
Pan Card Number of Institute:	**AAAJS3913N**
(Information must be accurate for FDA purposes)	

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NEFT payment Information:

Payee Name:	**DIRECTOR SGPGIMS RESEARCH ACCOUNT**
Bank Account No.	**10095237491**
IFSC Code:	**SBIN0007789**
Bank Name, Branch & address:	**STATE BANK OF INDIA** **SGPGIMS, LUCKNOW.**
GSTN, If applicable:	**09AAAJS3913N2ZN**

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ATTACHMENT 1 TO EXHIBIT A

Study Budget Breakdown

- **For participation as Principal investigator**

  1. Scope of work

  Table 1: Subject grant

  Fee Per completed CRF per Subject- 1000

  Other Payment terms:

- **Cost for minimum 80 patients completing the study = 80*1000**
- **Total Investigator Grant = INR 80,000/-**
- **Per patient grant as outlined in table 1, is inclusive of overheads**
- **With reference to clause 8/g towards compensation: Abbott India Limited has delegated its payment obligation towards the investigators to a service provider (i.e. JSS Medical Research India Private Limited). Thus payment shall be made from Abbott to Investigator through (JSS Research).**
- **An invoice addressed to Abbott India Limited will have to be provided by the investigator (on institution letterhead) to the personnel from JSS Research India Private Limited prior to release payment. A template for the same will be shared by JSS Research. Any and all invoices raised by the institution/ site under the agreement shall be paid by the Abbott within 60 days from the date of the receipt of the invoice from the institution/ site to the Abbott.**
- **Travel Expenses: Expenses towards domestic travels, hotel stay, meal and car rental for any of the study related meeting would be done by Abbott with prior written approval from Abbott.**
- **All payments under this agreement are subject to applicable taxes including service tax and the same shall be borne by Abbott. As per the Indian Tax Laws TDS would be applicable. A TDS certificate would be provided to your site before the end of the financial year.**
- **Payment will be released within 60 days of receipt of the invoice.**

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EXHIBIT B

SAFETY REPORTING OBLIGATIONS

(a) Institution and Investigator shall comply with all applicable adverse event reporting and other regulatory obligations applicable for investigators and Abbott shall comply with all applicable adverse event reporting and other regulatory obligations applicable for sponsors. In addition, Institution and Investigator shall report to Abbott the following Pharmacovigilance-relevant information if spontaneously reported to Institution or Investigator and only in case relating to an Abbott product(s):

(i) adverse reactions (a response to a medicinal product which is noxious and unintended. Response in this context means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility);

(ii) product exposure (including maternal, paternal or fetal exposure) associated with a pregnancy;

(iii) trans-mammary exposure of an infant (transmission via breast milk) to a product;

(iv) overdose (i.e. administration of a quantity of a medicinal product given per administration or cumulatively which is above the maximum recommended dose according to the authorized product information (Note: Clinical judgment should always be applied));

(v) abuse (i.e. persistent or sporadic, intentional non-therapeutic excessive use of a product by patient/consumer which is accompanied by harmful physical or psychological effects)

(vi) misuse (i.e. intentional and therapeutic but inappropriate use of a product by patient/consumer not in accordance with the authorized product information);

(vii) off-label use (i.e. intentional prescribed therapeutic use of a product not in accordance with the authorized product information);

(viii) occupational exposure (i.e. exposure to a product as a result of one's professional or non-professional occupation);

(ix) medication errors (i.e. unintended failure by patient/consumer or health care professional in the drug treatment process that leads to, or has the potential to lead to, harm to the patient);

(x) lack of therapeutic efficacy (i.e., "lack of effect" reports), which will be handled as a serious adverse reaction if associated with vaccine or contraceptive product or drugs used for critical conditions or for the treatment of life-threatening diseases;

(xi) suspected transmission of an infectious agent, which will be classified as a serious adverse reaction;

(xii) an unexpected therapeutic or clinical benefit from use of the product.

(b) Such information shall be reported by Institution and/or Investigator to Abbott within 24 hours of becoming aware of such occurrences. Institution and Investigator shall promptly make available to Abbott such records as may be necessary and pertinent to investigate such occurrences.

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Exhibit C

REQUIREMENTS FOR SCIENTIFIC PUBLICATIONS

1. Criteria for Authorship. Based on the October 2007 guidelines of the International Committee of Medical Journal Editors (ICMJE), authorship credit must be based on:

   (a) Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; and
   (b) Drafting or revising the article for important intellectual content; and
   (c) Final approval of the version to be published.

   A person must meet all three of the above criteria to warrant authorship.

2. Acknowledgement of Medical Writers and Other Contributors. Those individuals who have made a significant contribution to the Study or Publication, but do not meet the criteria for authorship noted above, must be listed in an acknowledgments section, including disclosure of the source of any financial support given to such contributors. All persons must give written permission to be acknowledged.

3. Conflict of Interest. In the interest of transparency and maintaining the highest possible standards of conduct, authors will comply with each journal's or congress's requirements for conflict of interest disclosure in the Publication. Such conflict of interest disclosure requirements may include, but are not limited to, disclosure of an author's receipt of research grants, author's receipt of payments for consultant or speaker services, and/or author's ownership of stock.

4. Sponsorship. Authors must acknowledge Abbott as the funding source of a Study, and must also comply with additional sponsorship-related disclosures required by the journal or congress.

5. Access to Data. Abbott will provide all authors with the final Protocol, statistical analysis plan, relevant statistical tables generated from the plan, figures, and reports needed to prepare the planned Publication. Abbott will provide a copy of the Protocol and plan for statistical analysis when requested by a medical journal considering a submitted manuscript for publication, with the understanding that the documents are confidential, the property of Abbott, and should not be disclosed to any third party without Abbott's prior written permission.

6. Redundant Publication. Duplicate or redundant publication of the Study results in peer-reviewed journals is not permitted. Secondary Publications that present significant and scientifically sound additional analyses or groupings of data are permitted. Publication of foreign language translations of the original manuscript, in accordance with the policies of the journals involved is permitted. Encore presentation of data, when permitted by scientific congress policy, is permitted.

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INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA53015018441773R
Certificate Issued Date	:	04-Dec-2019 01:19 PM
Account Reference	:	NONACC (FI)/ kacrsfl08/ K R PURAM/ KA-BN
Unique Doc. Reference	:	SUBIN-KAKACRSFL0822883039667938R
Purchased by	:	NOVO NORDISK INDIA PVT LTD
Description of Document	:	Article 12 Bond
Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	NOVO NORDISK INDIA PVT LTD
Second Party	:	Dr NARAYAN PRASAD SANJAY GANDHI P G I OF M SCIENCE
Stamp Duty Paid By	:	NOVO NORDISK INDIA PVT LTD
Stamp Duty Amount(Rs.)	:	200 (Two Hundred only)

Karnataka SDDM-Co Society Ltd. # 30/10, K.R. Puram, Bangalore
Sign.....

Please write or type below this line

This non-judicial stamp of INR 200 forms an integral part of the **INVESTIGATOR AGREEMENT** (Novo Nordisk Sponsored Clinical Trial) executed between the following three parties, for the trial ID: NN9535-4321.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

05 FEB 2020

1) Novo Nordisk India Private Limited

2) Dr. Narayan Prasad

10.02.20

3) Sanjay Gandhi Post Graduate Institute of Medical Sciences

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Executive Registrar
SGPGIMS,Lucknow

INVESTIGATOR AGREEMENT
NOVO NORDISK SPONSORED CLINICAL TRIAL
Trial ID: NN9535-4321

This Investigator Agreement (hereinafter referred to as the "**Agreement**"), is entered into and executed at Bangalore, India and shall become effective as of on the last date of execution by the Parties to this Agreement (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
CIN: U24111KA1994PTC015194

(hereinafter referred to as "**Sponsor**")

And **Dr. Narayan Prasad**

a healthcare professional, having address at Department of Nephrology, C block Sanjay Gandhi Post Graduate Institute of Medical Sciences Raebarli Road Lucknow

PAN: AAAJS3913N
(hereinafter referred to as the "**Principal Investigator**")

And **Sanjay Gandhi Post Graduate Institute of Medical Sciences**

a healthcare organization, located at Department of Nephrology, C block Sanjay Gandhi Post Graduate Institute of Medical Sciences Raebarli Road Lucknow

PAN: AAAJS3913N
(hereinafter referred to as "**Institution**")

In the following, Sponsor, Principal Investigator and Institution are also referred to individually as "Party" and collectively as "Parties".

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PREAMBLE

WHEREAS Sponsor wishes to conduct the following clinical trial in India: FLOW - Effect of semaglutide versus placebo on the progression of renal impairment in subjects with type 2 diabetes and chronic kidney disease; **Protocol ID:** NN9535-4321 (hereinafter referred to as the '**Trial**'). The nature of the Trial is further elaborated upon in this Agreement;

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WHEREAS Sponsor wishes to conduct the Trial in cooperation with Investigator at the Institution;

WHEREAS The 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 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.

1. DEFINITIONS

1.1 "Adverse Event" shall be defined as in APPENDIX 1.

1.2 "Confidential Information" shall mean all information, whether written, oral, or in any other form, pertaining to either Party's business, whether developed or acquired hereunder and whether kept in its original form.

1.3 "CRF" shall mean Case Report Form.

1.4 "FPFV" shall mean First Patient First Visit.

1.5 "Healthcare Organisation (HCO)" shall mean any legal person (i) that is a healthcare, medical or scientific association or organisation (*irrespective of the legal or organisational form, whether it is a Company, Sole Proprietorship, Partnership, Trust or otherwise*) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organisations within the scope of the EFPIA Patient Organisation Code) or (ii) through which one or more HCPs provide services.

1.6 "Healthcare Professional (HCP)" shall mean any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of their professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product. For the avoidance of doubt, the definition of HCP includes: (i) any official or employee of a government agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply or administer medicinal products and, (ii) any person whose primary occupation is that of a practising HCP irrespectively of any other employment

1.7 "Intellectual Property" shall mean any and all know-how, inventions, improvements and discoveries, whether patentable or not, arising from or related to the clinical trial covered by this Investigator Agreement.

1.8 "LPFV" shall mean Last Patient First Visit.

1.9 "LPLV" shall mean Last Patient Last Visit.

1.10 "Personal Data" shall mean the personal data as stipulated in APPENDIX 3.

1.11 "Protocol" shall mean protocol number [NN9535-4321]: [FLOW - Effect of semaglutide versus placebo on the progression of renal impairment in subjects with type 2 diabetes and chronic kidney disease], attached herein as APPENDIX 1.

1.12 "Serious Adverse Event" shall be defined as in the Protocol.

1.13 "SPC" shall mean Summary of Product Characteristics.

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1.14 "SUSARs" shall mean Suspected Unexpected Serious Adverse Reactions.

1.15 "Termination Date" shall mean [24] weeks after LPLV unless this Agreement is terminated pursuant to Clause 12.4.

1.16 "Trial Materials" shall mean the materials used to conduct the Trial, including but not limited to CRF and auxiliary supplies.

1.17 "Trial Product" shall be defined as in the Protocol.

1.18 "Trial Subject" shall mean any subject participating in the Trial.

2. INTRODUCTION

2.1 The Parties hereby agree that the Principal Investigator shall carry out the Trial in accordance with the Protocol, as amended over time, and this Agreement. All appendices and amendments to the Protocol and the Agreement shall be deemed to be an integral part of this Agreement and may be updated from time to time by mutual agreement.

3. OBLIGATIONS OF THE INSTITUTION AND THE PRINCIPAL INVESTIGATOR

3.1 Prior to the Trial the Principal Investigator must:

a) assist the Sponsor to obtain all necessary approvals from the Institutional Ethics Committee (IEC) and relevant regulatory bodies, from the relevant departmental head of the Institution and from any other authority that is responsible for the administration of the Institution;

b) be fully informed of the Trial Protocol and the Trial Product and attend, or ensure a delegate attends, all Investigator's meetings for the Trial from time to time as required by Sponsor;

c) ensure all the Institution's employees and collaborators who are involved in the Trial fully understand and adhere to the Trial Protocol and the obligations of both the Institution and the Principal Investigator;

d) obtain prior written approval from Sponsor and the Institutional Ethics Committee (IEC) for any proposed recruitment material to be used for the purpose of Subject recruitment in the Trial;

e) resolve any revenue issues in respect of the Trial with the Institution and keep Sponsor informed of such issues and the progress of resolution of such issues;

3.2 During the Trial each of the Institution and Principal Investigator must:

a) conduct the Trial in accordance with the terms of this Agreement and:

i. all applicable laws and regulations in India including any guidelines governing the conduct of clinical studies, including but not limited to the Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research and the Indian GCP Guidelines

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ii. the International Conference on Harmonization Guideline for Good Clinical Practice (ICH-GCP),

iii. the Declaration of Helsinki as referenced in the Protocol,

iv. the Protocol, any amendments, separate manuals and specific procedures provided by Sponsor applicable for conducting the Trial, depending on which of the stated options ensures the greatest protection for the patient;

b) ensure that all Trial Materials are handled correctly and stored securely for the duration of the Trial and any period thereafter as required by law or this Agreement, whichever is later, in accordance with Article 7 Treatment of the Protocol;

c) ensure that Trial Product is used only for the conduct of the Trial in accordance with Article 7 Treatment of the Protocol;

d) do all possible efforts to ensure that the target number of 15 eligible subjects are recruited for the Trial and that data from all eligible subjects are available on or before the Termination Date. Any over-recruitment of Subjects not authorised by Sponsor will not be financially compensated;

e) have all available data entered in the CRF [5] days after each visit. Principal Investigator shall ensure that the patient record is updated with final information and signed as applicable as soon as possible after each visit;

f) maintain accurate data collection and up-to-date records of all Trial Materials and Trial related correspondences by the Principal Investigator, the Institution's employees, Sponsor and any other person involved in the Trial, during the Trial;

g) submit written reports, in accordance with all laws, regulations and guidelines including the Ethics Committee standards, to Sponsor and the Ethics Committee regarding the Trial being conducted at the Institution on request.

h) record and evaluate all Adverse Events experienced by the Trial Subjects in accordance with Article 9.3 Adverse events of the Protocol;

i) retain Trial Records in accordance with the Protocol, Article Appendix 3, point 11, and under storage conditions conducive to their stability and protection. The Principal Investigator and the Institution further agree to permit Sponsor to ensure that the records are retained for a longer period if necessary, at Sponsor's expense, under an arrangement that protects the confidentiality of the records (e.g. secure off-site storage);

j) provide to Sponsor timely updates of their contact data; and

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Principal Investigator shall comply with the requirements of Appendix 3: Data Protection.

3.4 In the cooperation with Sponsor the following shall apply:

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a) The Institution and Principal Investigator must allow any person nominated by the Sponsor during regular business hours and with one Business Day notice in advance access to the following:

i. subject records relating to the Trial;

ii. the Institution and facilities where the Trial is being conducted; and

iii. any Trial Materials.

Regulatory or other authorities shall be allowed direct and immediate access to the same information.

b) Subject to Clause 8 of this Agreement the Institution and the Principal Investigator must not, without the prior written approval of Sponsor, disclose any Confidential Information to any third person other than for the proper conduct of the Trial and in accordance with this Agreement provided that such recipients are bound by obligations of confidentiality and non-use to Sponsor which are equal to the terms of this Agreement. Principal Investigator shall ensure that said recipients be fully aware of the obligations of confidentiality of this Agreement and shall be responsible for any breach of these provisions by such recipient.

c) Institution and Principal Investigator acknowledge and agree that in accordance with Protocol, Article 5, Trial Design,

i. the Trial is being conducted as part of a multi-centre clinical trial,

ii. that the number of clinical trial sites will be decided solely by Sponsor,

iii. that these sites may enroll Trial Subjects in mutual competition, and

iv. that Sponsor reserves the right to end Trial Subject enrolment under this Agreement when the desired number of Trial Subjects for all clinical trial sites has been reached. Institution and Principal Investigator agree that further screening or randomisation of subjects must not take place after Trial Subject enrolment has been sended by Sponsor.

d) If electronic systems are used in the Trial, it may be required to file these site specific data at the Trial site. If the Sponsor provided media is found not readable during the retention period, a new copy can be provided by Sponsor.

4. OBLIGATIONS OF SPONSOR

4.1 Sponsor shall obtain all necessary approvals from the Institutional Ethics Committee (IEC) and relevant regulatory bodies, from the relevant departmental head of the Institution and from any other authority that is responsible for the administration of the Institution;
Sponsor must:

a) conduct the Trial in accordance with the terms of this Agreement and:

i. all applicable laws and regulations in India including any guidelines governing the conduct of clinical studies,

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ii. the International Conference on Harmonization Guideline for Good Clinical Practice (ICH-GCP),

iii. the Declaration of Helsinki as referenced in the Protocol.

iv. the Protocol, any amendments, separate manuals and specific procedures provided by Sponsor applicable for conducting the Trial, depending on which of the stated options ensures the greatest protection for the patient.

4.3 Sponsor agrees to provide:

a) all Trial Materials necessary for the conduct of the Trial;

b) all relevant clinical pharmacology and toxicology information and advice to the Principal Investigator and the Institution which are required for the proper planning and conduct of the Trial throughout the Trial period. Such information will include the Investigator's Brochure and information on SUSARs for unlicensed products or the SPC for licensed products; and

c) reasonable supervision, training and monitoring during the conduct of the Trial.

4.4 The Parties agree to adhere to all applicable laws and regulations pertaining to medical confidentiality of the subjects. The Principal Investigator shall not disclose to Sponsor the identity of the subjects or information from which the identity of the subject can be deduced without prior written consent of the subject.

4.5 Any amendment to the Protocol must be agreed upon by both the Principal Investigator and Sponsor and be documented in writing. Implementation of amendments cannot take place until approval by health authorities, as applicable, and IEC/IRB's has been obtained unless required for the safety of the Trial Subjects or for administrative reasons in accordance with ICH/GCP.

5. DISCLOSURE REQUIREMENTS

5.1 The Principal Investigator shall ensure that he/she provide the appropriate financial disclosures required for compliance with DCGI, and under any other applicable law, rules or codes.

5.2 The Principal Investigator and the Institution represent and warrants that neither he/she nor the Institution involved in conducting the Trial nor any member of the staff of the Institution, has been debarred, excluded, disqualified or restricted in their ability to practice medicine, participate in a clinical trial, or perform services in connection with the evaluation of a pharmaceutical product under any laws, regulations or professional code of conduct. The Investigator shall immediately notify the Sponsor should he/she be so debarred, excluded, disqualified or restricted, or should a procedure or action be initiated against any of them that could result in their being so debarred, excluded, disqualified or restricted, at any time during the term of this Agreement.

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6. PAYMENT

6.1 Each payment under this Agreement shall be made on the basis of an invoice stating all relevant details regarding number of Trial Subjects and number of

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visits. Furthermore, each invoice shall include full details regarding the bank account to which the payment shall take place. Any payment payable by sponsor is due forty-five (45) days after receipt of a correct and proper invoice prepared in accordance with the sponsor invoicing instructions set out in Appendix 2. The parties acknowledge that this payment deadline has been actively negotiated and agreed between the parties as fair and reasonable. For the avoidance of doubt, all bank fees related to receipt of interbank transfers must be borne by the recipient.

7. TRIAL TIME SCHEDULE

7.1 For the whole project the following dates are in force:

FPFV: 23 Sep 2019
LPFV: 01 Feb 2021

LPLV: 19 Aug 2024

The date of the FPFV can be delayed locally; however, in such case date of LPFV shall still be valid.

7.2 If the Principal Investigator has not screened 03 Trial Subjects after 12 weeks from FPFV, it may be decided by Sponsor to re-allocate Trial Subjects to other sites and the site may be closed.

8. CONFIDENTIAL INFORMATION

8.1 The information obtained during the conduct of this trial is considered Confidential Information and will be used by Sponsor for registration purposes and for the general development of the drug.

8.2 All information supplied by Sponsor in connection with this Trial shall at all times during the term of this Agreement and thereafter remain the sole property of Sponsor and is to be considered Confidential Information. The Parties shall take all reasonable steps to ensure that any Confidential Information shall not be disclosed, whether directly or indirectly, to third (3rd) parties without the prior written consent of the other Party, which consent shall not be unreasonably withheld, except:

a) for the purpose contemplated, pursuant to and in accordance with the terms of this Agreement;

b) with the consent of the other Party and then only to the extent specified in such consent; and

c) to the extent as may be required by law or in accordance with the order of a court of competent jurisdiction, regulation, effective government policy or by any regulatory authority arising out of this Agreement or relating to or in connection with the other Party, provided that the Party so required must give the other Party prompt written notice and make a reasonable effort to obtain a protective order.

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8.3 The restrictions on disclosure of Confidential Information described above shall not extend to information which:

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a) is, at the time of the disclosure hereunder in the public domain, or subsequently enters the public domain through no breach of this Agreement,

b) can be shown by the receiving Party to have been in its possession at the time of disclosure hereunder,

c) is lawfully acquired by the receiving Party from a third party under no obligation of confidentiality to the disclosing Party,

d) is independently developed by an employee of the receiving Party or its Subsidiaries without reference to or reliance upon Confidential Information disclosed by the other Party, or

e) is required to be disclosed by law, or by order of a court of competent jurisdiction; provided, however, that the receiving Party shall provide the disclosing Party with notice as soon as possible enabling the disclosing Party to contest such potential use or disclosure.

9. INTELLECTUAL PROPERTY

9.1 All Intellectual Property provided by Sponsor shall remain the sole property of the Sponsor.

9.2 The Principal Investigator shall promptly disclose and assign to Sponsor all inventions and discoveries made by the Principal Investigator related to the Trial.

9.3 The Principal Investigator/ Institute shall have a royalty-free right to use the results for non-commercial research and teaching purposes.

10. REPORTS AND PUBLICATIONS

10.1 Preparation and publication of information obtained during the conduct of the Trial shall be carried out in accordance with Article 12 Appendices – Appendix 3 Trial governance considerations of the Protocol.

11. INSURANCE & INDEMNIFICATION

11.1 Principal Investigator and Institution hereby confirm that they have adequate insurance coverage for employers' liability and professional liability for all its activities under this Agreement. Principal Investigator and Institution shall provide Sponsor with proof of the existence of such insurances. Such proof, to be received by Sponsor before the proposed starting date, shall include the duration and cover of the insured and the insured amounts.

11.2 Sponsor will indemnify and defend the Principal Investigator and personnel working under his/her direct supervision against any claim or suit brought against any of them by or on behalf of Trial Subjects taking part in the Trial and based on a bodily injury directly resulting from the use of any product submitted by Sponsor for clinical investigation or any procedure provided for or required by the Protocol to which the Trial Subjects would not have been exposed but for the participation in the Trial.

11.3 For this indemnification under Clause 11.2 to apply, use of the product and the conduct of the investigation must be in accordance with the relevant laws and regulations and the approved Protocol for clinical investigation and any other

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information, instructions, or warning furnished by Sponsor. Also, Institutional Review Board or other Ethics Committee approval must be obtained and the Subject Informed Consent Form must comply with all relevant regulations and a copy must be received by Sponsor at commencement of the investigation.

11.4 In addition, for this indemnification under Clause 11.2 to apply, Principal Investigator must immediately notify Sponsor, upon receipt of notice of any claim or lawsuit and must permit Sponsor authorised attorneys and personnel (at Sponsor's discretion and cost) to handle and control the defence to such claims or suits. Principal Investigator cannot settle any such claims or suits without the prior written consent of Sponsor. By signing this Agreement, Principal Investigator agrees to fully cooperate and aid in such defence. Principal Investigator understands that the sole liability of Sponsor to the Principal Investigator and those employees engaged in conducting the approved clinical investigation at the request of Sponsor will be the indemnification described above.

11.5 Sponsor does not agree to indemnify, defend or hold harmless any person or Institution against any claim or suit in which it is determined that the individual or Institution was negligent, committed malpractice or breached a representation or warranty given by any of them; such a person or Institution will repay to Sponsor any defence costs incurred by the Sponsor on its behalf.

11.6 The Principal Investigator and Institution will indemnify, defend and hold harmless Sponsor and any Sponsor Affiliate, staff and subcontractors against any claim or suit brought against any of them by or on behalf of Trial Subjects taking part in the Trial and based on an injury caused by the Institution's or Principal's Investigators or staff working under their supervision negligence, wilful misconduct, mal practice, breach of Protocol, Sponsor's instructions, applicable laws and regulations or otherwise breach of this Agreement.

12. TERM AND TERMINATION

12.1 This Agreement shall commence on the date set forth at the beginning of the Agreement and shall terminate without further notice upon completion of the Trial in accordance with the Protocol. Clauses 3.2b), c), h), i), j), 8 and 12 shall survive the termination of this Agreement.

12.2 The anticipated FPFV date for the Trial is 23 Sep 2019, provided applicable approvals have been obtained, and provided that all Trial Materials except Trial Products have been received from Sponsor 5 (five) working days before the FPFV date.

12.3 Sponsor shall be entitled to have FPFV date delayed by up to 3 (three) weeks for ethical reasons. However, in case Sponsor notifies Investigator of the delay later than 1 (one) week before the FPFV date Sponsor may upon negotiation between the Parties compensate Investigator for his/her direct and fully documented costs caused by such delay.

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12.4 Sponsor may terminate this Agreement as follows:

a) if Principal Investigator negligently fails to perform or performs negligently any material work in accordance with this Agreement and such failure continues for thirty (30) days after receipt of written notice of Sponsor;

b) if Investigator for administrative or other reasons becomes unable to recruit Trial Subjects for the Trial;

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c) with immediate effect, if Sponsor and/or regulatory authority recognise that any safety concerns necessitate discontinuation of the Trial;

d) if continuation of the Trial becomes unfeasible for Sponsor for efficacy reasons, by giving Principal Investigator one (1) month's prior written notice;

e) if Sponsor licenses the Trial product to a third party who wishes to conduct the remaining part of the Trial themselves, by giving Investigator one (1) month's prior written notice.

f) forthwith upon written notice in the event of either Principal Investigator's or Institution's voluntary or compulsory liquidation, dissolution, insolvency, suspension of its payments, bankruptcy or any statutory or private composition or agreement with its creditors in order to escape a bankruptcy, or if either of the Principal Investigator or the Institution discontinues substantial parts of its established business or its business is placed in the hands of a receiver, assignee or trustee in bankruptcy, whether voluntarily or otherwise.

In the event of termination of this Investigator Agreement by Sponsor pursuant to Clause 12.4b), c), d), e) or f) above, Sponsor shall pay Principal Investigator for all services properly performed in accordance with this Investigator Agreement until the point in time of the expiry of the notice of termination, if relevant. Upon receipt of a termination notice Investigator shall cease any work not deemed necessary by Sponsor for the orderly close out of Trial or for the fulfilment of regulatory requirements.

12.5 The Principal Investigator may terminate this Agreement as follows:

a) if Sponsor negligently fails to perform or performs negligently any material work in accordance with this Agreement and such failure continues for thirty (30) days after receipt of written notice of the Principal Investigator;

b) if the Principal Investigator becomes incapacitated or terminates his/her relationship with the Institution and a replacement suitable and agreeable to Sponsor cannot, after reasonable efforts by the Institution, be found.

13. GOVERNING LAW AND DISPUTE RESOLUTION

13.1 Both Parties will use commercially reasonable efforts to settle all matters in dispute amicably. All disputes arising out of or in connection with this Agreement must be settled under Rules under the Arbitration and Conciliation Act, 1996, as amended from time to time, by one arbitrator appointed in accordance with the said Rules. The arbitration shall take place in Lucknow, India and shall be conducted in the English language. The award of the Arbitrator shall be final and binding on both Parties. The Parties bind themselves to carry out the awards of the Arbitrator.

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13.2 This contract shall be construed and interpreted pursuant to the Laws of India and shall be subject to the exclusive jurisdiction of the Courts at Lucknow.

14. GENERAL

14.1 Any notice, report, request, approval, consent, invoice, payment or other communication required or permitted to be given under this Agreement shall be in writing and shall for all purposes be deemed to be fully given and received if

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delivered in person or sent by registered mail, or by facsimile transmission (with an appropriate transmission receipt) to the respective Parties at the following addresses:

If to the Sponsor:

Novo Nordisk India Private Limited
Plot No. 32, 47-50
EPIP Area, Whitefield
Bangalore – 560 066

Att: Director - CMRQ

If to the Principal Investigator: Dr. Narayan Prasad
Sanjay Gandhi Postgraduate Institute of Medical Sciences
Raebareli Road, Lucknow- 226014

If to the Institution:

Sanjay Gandhi Postgraduate Institute of Medical Sciences
Raebareli Road, Lucknow- 226014
Att:

15. ASSIGNMENT

15.1 This Agreement shall not be assigned by either Party, in whole or in part, without the prior written consent of the Parties hereto.

15.2 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 Holdings A/S, Novozymes A/S, NNIT A/S, NNE Pharmaplan 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.

16. INDEPENDENT CONTRACTOR

16.1 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 Sponsor.

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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, or principal and agent, or partners in a joint venture, nor any similar relationship whatsoever. Neither Party shall exercise control over the business of the other Party, nor is neither Party granted any right or authority to assume or to create any obligation or responsibility, express

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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.

16.2 IN WITNESS HEREOF, the Parties have executed and delivered this Agreement,

(SIGNATURE PAGE FOLLOWS)

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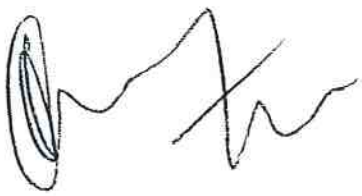
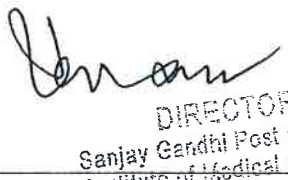
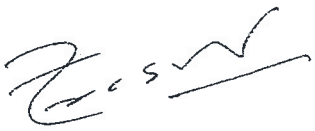
Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Signed and Delivered by the within named **Novo Nordisk India Private Limited**	Signed and Delivered by the within named **Institution**
	 DIRECTOR Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226 014, INDIA
Name: Vikrant Shrotriya Title: Managing Director Date: 05 FEB 2020	Name: Title: Director Date:
	Signed and Delivered by the within named **Principal Investigator** 
Name: Dr. Anil N Shinde Title: Director - Clinical, Medical, Regulatory Affairs & Quality (CMRQ) Date: 05 FEB 2020	Name: Dr. Narayan Prasad Title: Principal Investigator Date: 10.02.20

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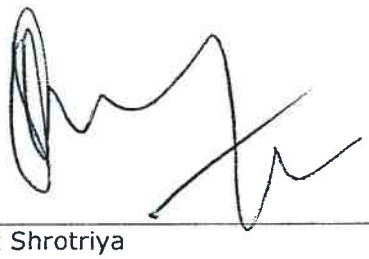
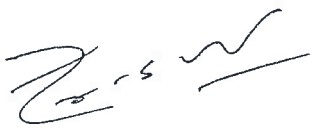
Executive Registrar
SGPGIMS,Lucknow

Signed and Delivered by the within named **Novo Nordisk India Private Limited**	Signed and Delivered by the within named **Institution**
	
Name: Vikrant Shrotriya Title: Managing Director Date: 05 FEB 2020	Name: Title: Director Date:
	Signed and Delivered by the within named **Principal Investigator** 
Name: Dr. Anil N Shinde Title: Director - Clinical, Medical, Regulatory Affairs & Quality (CMRQ) Date: 05 FEB 2020	Name: Dr. Narayan Prasad Title: Principal Investigator Date: 10.02.20

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APPENDIX 1: (THE PROTOCOL)

Attached herewith is a link to the soft copy/electronic copy of the Protocol. The Sponsor, through its Authorized Signatory, and the Principal Investigator have already agreed upon in writing to conduct the trial as outlined in the Protocol. The Parties hereby agree that for the sake of convenience, the hard copies of the Protocol are not annexed to this Agreement. The updated, as amended from time to time, electronic copy of the Protocol shall be made available at all times to the Institution and the Principal Investigator by the Sponsor, upon request, or as a standard procedure, whichever applies. The Protocol shall at all times be considered to be an integral part of this Agreement and reference to this Agreement includes reference thereto to the Protocol.

Link -

4321-protocol-versi
on-2.pdf

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APPENDIX 2: PAYMENT

a) Following the screening phase, payment shall only cover eligible Trial Subjects. Payment for screening and randomization and for each fully performed visit per Trial Subject shall be as follows:

	Amount in INR (Rs.)
Visit 1	17740
Visit 2	17690
Visit 3	4100
Visit 4	4100
Visit 5	14600
Visit 6	13600
Visit 7	15500
Visit 8	14600
Visit 9	4100
Visit 10	17100
Visit 11	4100
Visit 12	14600
Visit 13	4100
Visit 14	17100
Visit 15	4100
Visit 16	14600
Visit 17	4100
Visit 18	17100
Visit 19	4100
Visit 20	14600
Visit 21	4100
Visit 22	17100
Visit 23	4100
Visit 24	14600
Visit 25	4100
Visit 26	17100
Visit 27 (V-EOT)	16250
Visit 28 (V-FU)	15350
Total Cost per Trial Subject: (The payment will be made on pro-rata basis depending upon the Subjects recruitment. The Institution is allowed to recruit additional Subjects for this Trial based on the confirmation from the Sponsor. The Invoice shall be raised on pro-rata basis and accordingly payment will be made)	314330

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The travel allowance for the Subjects is included in the above cost up to INR 600.

In addition, a start-up fee of INR 50000 shall be paid for the time spent for Health Authority documentation, undertaking study specific training, patient identification, Ethics Committee submission and approval activities. The

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payment shall be made on the receipt of Ethics Committee approval unless discontinued due to regulatory obligations.

b) If Trial Subjects drop-out of the Trial, payment will be calculated on the basis of the visits performed.

c) Full fee will only be paid for patients fulfilling all inclusion and exclusion requirements as defined in the Protocol (eligible Trial Subjects). Patients that do not fulfil all inclusion and exclusion requirements will only be reimbursed the screening and randomization fee set above.

d) Patients that do not fulfil all inclusion and exclusion requirements must be withdrawn from the study, unless exception to allow the specific patient continuing in the study is granted by Sponsor and the Ethics Committee/Institutional Review Board according to local regulations;

e) Payment will be made every 06 months. Payment for the last 06 month visits for all subjects will be paid as soon as all queries have been solved and data are clean.

f) The Institution will be paid 25 % overhead to cover administrative costs which is included in the per patient cost mentioned in Appendix-2.

g) All payments shall be made by Sponsor to the Institution in the following bank account:

Bank details of Institution:

Recipient:	Sanjay Gandhi Post Graduate Institute of Medical Sciences
Bank name:	State Bank of India
Bank address:	SANJAY GANDHI PGIMS, LUCKNOW, RAEBARELI ROAD, LUCKNOW- 226014
IFSC Code:	SBIN0007789
Account Holder:	Director SGPGIMS Research A/C
Account Number:	10095237491
Transfer Purpose:	Conduct of Clinical Trial

h) All invoices shall be sent to Sponsor as follows:

Novo Nordisk India Private Limited
Plot No. 32, 47 - 50,
EPIP Area, Whitefield,
Bengaluru - 560 066

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APPENDIX 3: DATA PROTECTION APPENDIX

1. **Scope**. This Data Protection Appendix sets out the requirements and obligations applicable to the Supplier and/or its sub-processors processing of Personal Data on behalf of Novo Nordisk.

2. **Parties**. For the purpose of this Data Protection Appendix:

    a. "Novo Nordisk" means Novo Nordisk India Private Limited and any Novo Nordisk subsidiary or other group company that in accordance with the Data Protection Requirements is data controller in respect of the Personal Data;

    b. "Supplier" means [Dr. Narayan Prasad, Department of Nephrology, C Block, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Raebareli Road, Lucknow- 226014] who will act as a data processor in respect of Personal Data processed under the Agreement.

3. **Precedence**. This Appendix shall govern the processing of Personal Data by the Supplier, notwithstanding any other obligations made by the Parties under the Agreement or otherwise agreed by the Parties.

4. **Terms used in this Appendix**. Capitalised terms used in this Data Protection Appendix, unless defined in this Appendix or in the Agreement, will have the meaning given in the Data Protection Requirements, which include any requirements under the EU Directive 95/46/EC and the General Data Protection Regulation (EU) 2016/679 as well as any applicable laws implementing or amending the same.

5. **Purpose of processing Personal Data**. The Supplier will, during the term of the Agreement, be processing Personal Data on behalf of Novo Nordisk for the purpose of performing its obligations under the Agreement.

6. **Type of Personal Data**. The Supplier will be processing the following types of Personal Data under the Agreement:

    a. ***Categories of (non-sensitive) Personal Data***:

        i. Contact information, including name, address, phone number, email etc.;
        ii. Job related information, including title, position, work tasks, department, performance; and

    b. ***Special (sensitive) categories of Personal Data***:

        i. Genetic data, biometric data for the purpose uniquely identifying a natural person;
        ii. Clinical data originating from clinical trials, studies and other research work;
        iii. Other data concerning health; and
        iv. Data concerning a natural person's sex life or sexual orientation.

7. **Categories of data subjects**. The Personal Data regards the following categories of data subjects: employees, customers, healthcare professionals, patients, trial subjects etc.

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8. **Obligation to comply with Data Protection Requirements**. The Supplier represents and warrants that:

   a. It will comply with and ensure that all sub-processors will comply with all of applicable obligations under the Data Protection Requirements that arise in connection with the Agreement;

   b. It will perform its obligations under the Agreement and ensure that all sub-processors perform their obligations in such a manner that allows Novo Nordisk to comply with the Data Protection Requirements;

   c. Unless otherwise requested by Novo Nordisk, process Personal Data only to the extent necessary for the performance of the Agreement; and

   d. Subject to any other notification requirements set out in this Data Protection Appendix, notify Novo Nordisk of any unauthorised or unlawful processing or any accidental loss, destruction, damage, alteration or disclosure of the Personal Data as soon as it becomes aware and keep Novo Nordisk informed of any related developments.

9. **Reliance on Supplier's skills**. Novo Nordisk is relying upon the Supplier's skill and knowledge to assess what is "appropriate" to protect Personal Data against unauthorised or unlawful processing and against accidental loss, destruction, damage, alteration or disclosure.

10. **Requirements to Supplier personnel**. The Supplier will ensure that all its employees and sub-processor personnel perform their duties strictly in compliance with the confidentially obligations imposed under the Agreement by treating such Personal Data as confidential information and are informed of the security procedures applicable to the processing of or access to the Personal.

11. **Compliance with the processing instruction**. The Supplier will and will procure that it's sub-processors Process the Personal Data only to the extent strictly required in order for the Supplier to perform its obligations in accordance with the Agreement or as instructed by Novo Nordisk, from time to time.

12. **Access to information and assistance**. Upon request by Novo Nordisk and without undue delay, the Supplier will and will cause its sub-processor to:

   a. Make available to Novo Nordisk and/or any Data Protection Authority having jurisdiction over Novo Nordisk, documentation and any and all other information that is reasonably necessary for Novo Nordisk to comply with its obligations under the Data Protection Requirements

   b. Provide Novo Nordisk with full cooperation and assistance in relation to any complaint or request from Data Subjects or a Data Protection Authority;

   c. Permit Novo Nordisk, or any third party appointed by Novo Nordisk (subject to reasonable and appropriate confidentiality undertakings), to inspect and audit the Supplier's data processing activities (and/or those of its group entities, agents, subsidiaries and sub-contractors)

   d. Comply with all reasonable requests or directions by Novo Nordisk to enable Novo Nordisk to verify and/or procure that the Supplier and/or sub-processors are in full compliance with their obligations under the

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Agreement, including by providing an account of the technical and organisational security measures implemented by the Supplier or its sub-processor to comply with applicable security controls; and

e. Provide Novo Nordisk with detailed information on the current location of any Personal Data being Processed or stored by the Supplier and/or any of its sub-processors.

13. Use of sub-processors.

a. The Supplier will be entitled to assign processing of Personal Data under the Agreement to a designated sub-processor subject to the following requirements:

   i. Novo Nordisk pre-approves the sub-processor in writing; or

   ii. The Supplier gives Novo Nordisk at least six (6) months written notice before engaging the sub-processor and Novo Nordisk has the right to object to the engagement such that (i) Supplier refrains from engaging the sub-processor; (ii) Supplier amends the sub-processor engagement so that it becomes acceptable to Novo Nordisk; or (iii) Supplier allows Novo Nordisk to terminate the Agreement without incurring any liability to pay compensation or termination fees.

b. The Supplier's agreement with sub-processor(s) must be in accordance with the Data Protection Requirements and may not contain terms that are less restrictive than those agreed between Novo Nordisk and the Supplier.

c. The Supplier must ensure that its sub-processors do not engage any further sub-processors without prior written approval by Novo Nordisk.

d. Supplier will remain responsible for all acts and omissions of its sub-processors and the acts and omissions of those employed or engaged by the sub-processors as if they were its own.

14. Technical and organisational security measures. The Supplier will implement and maintain throughout the term of the Agreement and will procure that its sub-processors implement and maintain throughout the term, appropriate technical and organisational security measures to protect the Personal Data against unauthorised or unlawful processing and against accidental loss, destruction, damage, alteration or disclosure. These measures will be appropriate to prevent the harm which might result from any unauthorised or unlawful processing, accidental loss, destruction or damage to the Personal Data and having regard to the nature of the Personal Data which is to be protected.

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15. Notification of a Personal Data breach. Supplier will, in writing, notify Novo Nordisk of a Personal Data breach (including any security breach affecting Personal Data or any breach as defined under applicable law) immediately after becoming aware of such breach. Such notice must be provided in accordance with the provisions of the Agreement.

16. Documentation of Personal Data breaches. The Supplier will, upon request, submit to Novo Nordisk documentation on any breaches of Personal Data. The documentation should include information sufficient to enable a Data Protection Authority to verify compliance with the Data Protection Requirements.

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17. **Other notifications**. The Supplier will:

a. Notify Novo Nordisk in writing immediately if it receives (i) a request from a data subject to have access to that person's Personal Data; or (ii) a complaint or request relating to Novo Nordisk's obligations under the Data Protection Requirements; and

b. Notify Novo Nordisk immediately in writing if it receives a request from any Data Protection Authority or other governmental body requiring the Supplier or any of its sub-processors to grant the Data Protection Authority or other governmental body access to inspect or provide information regarding the Supplier's and/or the sub-processor's processing of Personal Data covered by the Agreement.

18. **Liability**. The Supplier shall hold Novo Nordisk, fully and effectively indemnified against any and all claims, expenses, losses and damages or liabilities suffered due to the Supplier or sub-processors not fulfilling the data protection obligations under this Schedule.

19. **Transfer of Personal Data**. The Supplier will process or permit processing of Personal Data outside the European Economic Area (EEA), Switzerland, or any country determined officially by the relevant Data Protection Authority to have adequate data protection measures in place, only pursuant to a signed agreement between on the Supplier and Novo Nordisk using the European Commission's Standard Contract Clauses.

a. With respect to any sub-processors, the Supplier will either (i) enter into the above mentioned agreement on behalf of the sub-processors or (ii) cause the sub-processors to enter into the agreement with Novo Nordisk.

b. The Supplier will provide Novo Nordisk with a copy of all such signed agreements in advance of permitting the transfer or processing.

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APPENDIX 4: NOTICE OF PERSONAL DATA PROCESSING

NOTICE OF PERSONAL DATA PROCESSING

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Novo Nordisk India Private Limited is required by law to protect your Personal Data. This Notice explains how we process (e.g. collect, use, store, and share) your Personal Data. We will process any Personal Data about you in accordance with this Notice and with applicable law.

1. WHO ARE WE?

The company responsible for processing your Personal Data is:

Novo Nordisk India Private Limited
CIN: U24111KA1994PTC015194
Plot No.32, 47-50,
EPIP Area, Whitefield,
Bangalore - 560 066

Toll-free number: 18001039527
Switchboard: +91 80 4030 3200
Fax No.: +91 80 4112 3518
prindia@novonordisk.com

You can always contact Novo Nordisk India Private Limited or the Novo Nordisk Data Privacy Officer at privacy@novonordisk.com with questions or concerns about how we process your Personal Data.

2. HOW DO WE COLLECT PERSONAL DATA ABOUT YOU?

We get your Personal Data from the following sources:

- From you directly
- From publicly available publications, websites, or social media
- From a previous employer
- From other Novo Nordisk entities
- From vendors or consultants

3. WHY DO WE PROCESS YOUR PERSONAL DATA?

We process Personal Data about you for the following purposes:

- To analyse data for compliance
- To meet transparency obligations
- To investigate compliance/fraud
- To coordinate a conference or event
- To reimburse you
- To conduct interviews as part of a research project
- To respond to your questions or request for information

You are not required to provide us with your Personal Data. If you do not want Novo Nordisk to use your Personal Data, we will not be able to enforce this Agreement.

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4. WHAT PERSONAL DATA DO WE PROCESS ABOUT YOU?

For the purposes described above in Section 2, we may process the following types of Personal Data:

- Contact information (name, address, telephone number, email address)

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- Financial information (bank account number, amounts paid to you for services rendered)
- Emergency contact (e.g., name and telephone of family members)
- Data concerning health;
- Data on trade union membership;
- Genetic data, biometric data for the purpose uniquely identifying a natural person;
- Data concerning sex life or sexual orientation.
- Data relating to criminal convictions and offences

5. WHY ARE WE ALLOWED BY LAW TO PROCESS YOUR PERSONAL DATA?

Our processing of your Personal Data requires a legal basis. By law, we are allowed to process your Personal Data described above in Section 1 based on the following legal bases:

- You gave consent for us to process your Personal Data;
- The processing is necessary to fulfil a contract with you;
- The processing is necessary for our compliance with a legal obligation;
- The processing is necessary to protect your vital interests or the interests of another person;
- The processing is necessary for our legitimate interests.

6. HOW DO WE SHARE YOUR PERSONAL DATA?

We may share your Personal Data with:

- Suppliers or vendors that assist our company (e.g., consultants, IT service providers, financial institutions, law firms)
- Other Novo Nordisk entities (e.g., Novo Nordisk affiliates in other countries)
- Public authorities

7. WHEN DO WE TRANSFER YOUR PERSONAL DATA OUTSIDE INDIA?

For the purposes described above in Section 2, we transfer your Personal Data to countries outside India. We therefore use the following safeguards, as required by law, to protect your Personal Data in case of such transfers:

- The transfer is to a Novo Nordisk entity covered by Novo Nordisk's Binding Corporate Rules, available at https://www.novonordisk.com/about-novo-nordisk/corporate-governance/personal-data-protection.html.

8. HOW LONG WILL WE KEEP YOUR PERSONAL DATA?

We will keep your Personal Data for the following period of time:

- For as long as needed to provide you with the services requested by you
- For as long as required by applicable law.

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9. WHAT ARE YOUR RIGHTS?

In general, you have the following rights:

- You can get an overview of what Personal Data we have about you
- You can get a copy of your Personal Data in a structured, commonly used and machine-readable format

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- You can get an update or correction to your Personal Data
- You can have your Personal Data deleted or destroyed
- You can have us stop or limit processing of your Personal Data
- If you have given consent for us to process your Personal Data (see Section 5), you can withdraw your consent at any time. Your withdrawal will not affect the lawfulness of the processing carried out before you withdrew your consent
- You can submit a complaint about how we process your Personal Data to a Data Protection Authority.

Under applicable law, there may be limits on these rights depending on the specific circumstances of the processing activity. Contact us as described in Section 1 with questions or requests relating to these rights.

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SGPGIMS,Lucknow

ગુજરાત गुजरात GUJARAT

BE 84835

અનુ.નં. ૮૪૩૨૮ તા. ૧૧/૦૧/૨૦૧૮ રૂા. ૧૦૦/-
અંકે રૂપિયા એકસો પુરાનો સ્ટેમ્પ જે સાંધણ સાથે
રૂા. --- તે આજરોજ
શ્રી મેરીલ લાઈફ સાયન્સ પ્રા. લી.
રે. ચલા તા. વાપી ને વેચાણ આપ્યો

લેનારની સહી

સ્ટેમ્પ વેન્ડરનું નામ અને સહી લા.નં. ૧/૨૦૦૨
હીરેન જે. પટેલ, રતનવાડી, પારડી.

CLINICAL TRIAL AGREEMENT

This Agreement (Hereinafter **"Agreement"**) is made and entered into on this 23rd day of Mar 2018 by and among:

Meril Life Sciences Pvt. Ltd.,with its principal office located at **Bilakhia House, Survey No.135/139, Muktanand Marg, Chala, Vapi-396191, Gujarat, India**represented by **Dr.Ashok Thakkar, Head-Clinical Research.** [hereinafter "the **SPONSOR" or "Meril**" (which expression shall unless it be repugnant to the context or meaning thereof be deemed to mean and include its successors and permitted assigns)] of the First Part.

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Executive Registrar
SGPGIMS,Lucknow

And

Sanjay Gandhi Postgraduate Institute of Medical Sciences with his principal office located at **Rae Bareli Road, Lucknow-226014, Uttar Pradesh, India** (Hereinafter "**Institution** or **Centre** or **Study Site**") represented by **Prof. Rakesh Kapoor** having registered office at **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow - 226014, Uttar Pradesh, India** [Hereinafter referred to as the "**Institution**" (which expression shall unless it be repugnant to the context or meaning thereof be deemed to mean and include its successors and permitted assigns) of the Second Part.

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ગુજરાત गुजरात GUJARAT BE 848358

અનુ.નં. 28330 તા. 22/06/2018 રૂા. 100/-
અંકે રૂપિયા એકસો પુરાનો સ્ટેમ્પ જે સાંધણ સાથે
રૂા. --- તે આજરોજ
શ્રી મેરીલ લાઈફ સાયન્સ પ્રા. લી.
રે. ચલા તા. વાપી ને વેચાણ આપ્યો

લેનારની સહી

સ્ટેમ્પ વેન્ડરનું નામ અને સહી લા.નં. ૧/૨૦૦૨
હીરેન જે. પટેલ, રતનવાડી, પારડી.

And

Dr. Nirmal Gupta with his principal office located at **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow - 226014, Uttar Pradesh, India** (hereinafter "**Investigator**") of the Third Part.

(Hereinafter individually "**Party**" or collectively "**Parties**")

WHEREAS the Sponsor is a Medical Devices company involved in research, development, manufacture and sale of medical devices for use in humans;

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WHEREAS the Institute is recognized for its expertise and interest in multispecialty and have the facilities, infrastructure and expertise to conduct the clinical study entitled:

Dafodil™ 1 - A prospective, multi-center, single-arm clinical study to evaluate safety and performance of the Dafodil Pericardial Bioprosthesis in patients who require replacement of their natural or prosthetic aortic or mitral valve.

(Hereinafter referred to as the "**Clinical Trial**" or "**Study**")

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WHEREAS the Sponsor is desirous of conducting the Clinical Trial; and

NOW, THEREFORE, the Parties mutually agree as follows:

1 Definitions

1.1 "**Affiliate**" means a business entity which controls, is controlled by, or is under the common control with the Sponsor or the Institute. For the purpose of this definition, a business entity shall be deemed to control another business entity if it owns, directly or indirectly, in excess of 50% of the voting interest in such business entity or the power to direct the management of such business entity.

1.2 **"Agent(s)"** shall include, but shall not be limited to, any person (including the Investigator, any nurse or other health professional), any such person's principal employer in the event it is not the Centre and where such person is providing services to the Centre under a contract for services or otherwise, and/or any contracted third party providing services to the Centre under a contract for services or otherwise for the Study.

1.3 "**Agreement**" means this agreement, any signed amendment to it, as well as any documents which are signed consequently in relation to the study including Protocol, exhibits, schedules, or other addendums attached and/or referred to in this Agreement. In case of discrepancy between the numbered Clauses of this Agreement and any addition to this Agreement such as exhibit, Protocol, etc., the numbered Clausesof this Agreement shall prevail.

1.4 **"Confidential Information"** includes, but is not limited to,any knowledge and information pertaining to a Party's products and processes, ingredients, recipes, know-how, product plans , business plans, management reports, financial statements, internal memorandum, reports, patient information, inventions, designs, drawings, methods, processes, systems, technology, technical information relating to the disclosing Party's research, improvements, materials, data, trade secrets, marketing and regulatory strategy, customer lists, supplier lists, database and any other information pertaining to the business of a Party, which is not readily available to the public and does not constitute Results.

1.5 **"Effective Date"** means the date of the latest to occur of the following two conditions:

(i) Signature of this Agreement by the last Party to sign and

(ii) Approval of the Study by the competent ethics committee, institutional review board or equivalent body.

1.6 **"Fee"** shall mean the fee payable by the Sponsor for performing the Study.

1.7 **"ICH GCP"** shall meanE6(R1) guideline for Good Clinical Practise (GCP) issued by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use(ICH) in 1996 with applicable updates and amendments thereof.

1.8 **"Intellectual Property"** means any registered and unregistered intellectual property rights, such as, but not limited to, patents, designs, trademarks, trade names as well as copyrights, know-how, trade secrets and Confidential Information.

1.9 **"Lead Investigator"** means a physician chosen by Meril to provide scientific and medical supervision of the entire multi-centre Study.

1.10 **"Investigator"** means the person designated by the Centre and agreed upon by Meril who will take primary responsibility for the conduct of the Clinical Trial at the Centre, or any other person as may be agreed from time to time among the Parties as a replacement.

1.11 "**Protocol**" means the Study protocol no.MLS/MYV-1and all its amendments duly signed by the Investigator and the Sponsor.

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1.12 **"Research Subject"** means any person recruited to participate in the Study as a patient.

1.13 **"Results"** means the contents and results of all work and activities realized by the Centre including the Agents pursuant to this Agreement, limited to results, clinical data and medical conclusions related to the treatment of the Research Subjects with the Study Device in accordance with the Protocol.

1.14 **"Study Device"** means **Dafodil Pericardial Bioprosthesis** as defined in the Protocol.

1.15 **"Study"** means the **Dafodil™ 1 - A prospective, multi-center, single-armclinical study to evaluate safety and performance of the Dafodil Pericardial Bioprosthesis in patients who require replacement of their natural or prosthetic aortic or mitral valve.**

1.16 **"Study Deliverables"** shall mean the completed case report forms, any electronic databases required to be created under the Protocol, and any Study reports prepared by the Institute for the Sponsor (including, with respect to the data contained in such case report forms, electronic databases, and reports, only the compilation of data or any substantially similar compilation).

1.17 **"Trial Monitor"** mean one or more persons appointed by the Sponsor to monitor compliance of the Clinical Trial with ICH GCP and to conduct source data verification.

2 Scope of the Agreement

2.1 Meril is sponsoring the Study entitled: **Dafodil™ 1 - A prospective, multi-center, single-arm clinical study to evaluate safety and performance of the Dafodil Pericardial Bioprosthesis in patients who require replacement of their natural or prosthetic aortic or mitral valve.**

2.2 Name of the study: **Dafodil™ – 1**

2.3 Meril shall act as the Sponsor of the Study, and the Centre shall act as one of the clinical sites at which the Study will be conducted. The Investigator has agreed to serve at the Centre as Principal Investigator in connection with the conduct of the Study. The Institute shall notify the Sponsor in advance if the Investigator is unable or unwilling to continue the Study or if the Investigator's affiliation with the Institute ceases, whereupon the Centre shall identify a successor whose appointment shall be subject to Meril's written approval.

2.4 The Investigator shall perform the Study in conformance with; (i) ICH-GCP guidelines, (ii) ISO 14155,(iii) Medical Device Directives of Global Harmonization Task Force and European Union,(iv) the Protocol, (v) all reasonable written instructions of the Sponsor and (v) all applicable laws, rules and regulations (including, but not limited to the Indian Drug and Cosmetic Act 1940, the Indian Drug and Cosmetic Rules, 1945, any other guidance and notification issued by Central Drug Standard Control Organization (as may be amended from time to time).

2.5 The Institute/the Investigator shall seek approvals which may be required to carry out the Study, including approval from Ethics Committee (EC) or Institutional Review Board (IRB) or equivalent body as required by the applicable laws and applicable standards before commencing the Study.

2.6 The Institute shall comply with applicable laws in the collection, storage, and transfer of any clinical samples or other human materials taken from Study Subjects, and shall obtain any consents required from Study Subjects for the use of such materials in accordance with the Protocol. The Institute shall ensure that any use of such materials, whether in the Study or otherwise, shall be consistent with such consents and applicable laws.

2.7 The Institute shall ensure that the clinical samples or other human materials taken from Study Subjects are tested in accordance with the Protocol and at a laboratory designated by the Sponsor.

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2.8 The Sponsor shall comply with applicable laws in the performance of its activities relating to the Study, and shall obtain all approvals and consents required in connection with such activities. The Sponsor shall conduct such Study-related activities in a manner consistent with the Informed Consents and all other applicable consents.

2.9 The Investigator shall ensure the study participation is voluntary and the participants have the right to withdraw at any time during the conduct of the study.

2.10 The Sponsor may amend the Protocol at any time. Any such amendment shall be in writing and sent to the Institute, and will not take effect until approved by the appropriate approving bodies such approval shall not be unreasonably withheld, conditioned or delayed.

2.11 The Centre shall enrol approximately 10-15 eligible Research Subjects for participation in the Study.

2.12 The Centre shall collect Research Subject specific data as per the prescribed study schedule in the Protocol on Case Report Form (paper or electronic) (hereinafter CRF) for the entire duration of the study. The Centre shall provide appropriate resources and facilities to enable the Investigator to conduct the Study in a timely and professional manner and according to the terms of this Agreement. The Centre shall ensure that only individuals who are appropriately trained and qualified will assist the conduct of the Study. The Centre is responsible for ensuring that all personnel of the Centre and Agents participating in the Study comply with the terms and conditions of this Agreement.

2.13 The Centre and the Investigator shall use their best endeavours to ensure that the recruitment of the Research Subjects is achieved in accordance with the timelines as specified. The Study being a multi-centre clinical trial, the Sponsor may amend the number of Research Subjects to be recruited at the Centre. If in the reasonable opinion of the Sponsor, recruitment at the Centre is proceeding at a rate below that required meeting the timeline, the Sponsor may, by a notice to the Centre, cease further recruitment. On the other hand, if the recruitment at the Centre is proceeding at a rate above that required meeting the timeline, the Sponsor may, with agreement of the Centre increase the number of the Research Subjects to be recruited.

2.14 Subject to the Centre's and the Investigator's overriding obligations in relation to the Research Subjects and individual patient care, neither the Centre nor the Investigator shall, during the term of this Agreement, conduct any other trial which might hinder the Centre's or Investigator's ability to recruit and study the required cohort of the Research Subjects.

2.15 Meril shall provide training to the personnel designated by the Centre for conducting the Study related activities. In addition, Meril shall conduct follow-up monitoring as it deems appropriate.

2.16 The details of activities of the Study (notably detailing scientific goals, methodology, and time schedule) are provided in the Protocol. The Centre and the Investigator shall not deviate from the Protocol except to the extent necessary for safety of the Research Subject/s and shall promptly notify the Sponsor and the EC/IRB in writing of any deviation from the Protocol with reasons.

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2.17 The Institute shall refrain from, and shall cause the Investigator and the Agents to refrain from using the Study Device in any manner that is contrary to the provisions of, or outside the scope of, the Protocol or that is contrary to the written instructions of the Sponsor.

2.18 The decision to include any Research Subject in the Study shall occur only after the decision to use the Study Device on said Research Subject has been made exclusively on medical grounds by the Investigator. On enrolling the subjects in the study, the Centre shall complete the Electronic Case Report Forms (hereinafter "**eCRF**") for the Research Subject specific data as per the prescribed study schedule in the Protocol for the entire length of the Study. The Centre shall provide all necessary and sufficient facilities, equipment, resources and personnel to perform the services required hereunder.

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2.19 The Institute and the Investigator shall supervise Agents employed by the Institute for conduct of the Study (the Study Staff), and shall ensure (directly in the case of employees, and by contract in the case of contractors) that all Study Staff are appropriately trained, qualified, and certified, and are informed of and abide by the applicable terms of this Agreement.

2.20 The Institute shall keep and maintain, diligently and in sufficient detail to satisfy all applicable legal requirements, such Study data and records as are required by the Protocol and applicable laws, including any source data, clinical data of Research Subjects and Study Deliverables (the "Study Documents").At the Sponsor's request, the Institute shall retain the Study Documents beyond the period required by the applicable laws Study Documents in accordance with applicable laws. After the required retention period (including any additional period requested by the Sponsor) has expired, the Institute shall provide the Sponsor sixty (60) days' written notice before destroying any Study Documents.

2.21 In order for Meril to monitor the progress of the Study, a regular exchange of letters, emails and phone calls between Meril and the Investigator shall occur during the performance of the Study. Face-to-face meetings may also be held between Meril and the Investigator as often as reasonably necessary. The Institute and the Investigator will allow, with reasonable prior notice, Meril and /or the regulatory authorities to perform facility and site audit.

2.22 The Institute shall permit the Trial Monitor to access the Study Documents during regular business hours, upon reasonable advance notice to the Institute by the Sponsor. The Sponsor shall comply with applicable laws regarding the confidentiality of Study Subjects' medical records and other health information, shall hold the Study Subjects' personal identifying information in confidence, and shall act in accordance with the Informed Consents and the HIPAA Authorizations. Subject to the foregoing, the Trial Monitor may copy Institute records containing such information. The Institute may redact personal identifying information of Study Subjects before giving them to the Study Monitor for copying these records. The Sponsor shall not attempt to contact any Study Subject except to the extent expressly permitted by the IRB or as required to comply with applicable laws.

2.23 During monitoring as per Clause 2.19, the Trial Monitor has the right to inspect any facility being used for the Study and to examine any procedures or records relating to the Study. The Trial Monitor/Sponsor will alert the Centre and the Investigator to significant issues (in the opinion of the Trial Monitor/Sponsor) relating to the conduct of the Study.

2.24 The sponsor's monitor to send the post-monitoring visit report promptly to the site.

2.25 In the event that the Sponsor reasonably believes there has been any research misconduct in relation to the Clinical Trial, the Centre and the Investigator shall provide all reasonable assistance to any investigation into any alleged research misconduct undertaken by or on behalf of the Sponsor. The Sponsor shall, subject to any obligations of confidentiality, communicate the results of such investigation to the Centre. In the event that the Centre reasonably believes there has been any research misconduct in relation to the Clinical Trial, the Sponsor shall provide all reasonable assistance to any investigation into any alleged research misconduct undertaken by or on behalf of the Centre, the results of which shall, subject to any obligations of confidentiality, be communicated to the Sponsor.

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2.26 The Institute shall make available to the Sponsor or its designated agent the Study site, the Study Staff, and, subject to applicable laws relating to patient confidentiality, all Study Documents for purposes of review and audit upon reasonable advance notice during regular business hours. If the Investigator fails to correct any violations of the Protocol, this Agreement, or applicable laws found in such audit after receiving written notice thereof, the Sponsor may provide notice to the Institute of such violations, whereupon the Institute shall promptly take action to correct them.

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2.27 The Institute shall provide the Sponsor prompt, advance notification of any audit by a regulatory authority, which audit is directly related to the Study (or, when advance notification is impracticable, prompt notification of any completed audit). To the extent possible, the Institute shall permit the Sponsor to review and comment in advance on any written communication from the Institute to the regulatory authority in connection with such an audit; provided, however, that such review does not adversely impact the timeliness of the Institute's response to the regulatory authority. The Institute shall promptly provide the Sponsor with copies of all communications between the Institute and the regulatory authority related to such audit unless prohibited from so doing by the regulatory authority, and shall promptly take action to correct any deficiencies found by the regulatory authority during the audit. With respect to a pending audit directly related to the Study by any regulatory authority, the Institute shall permit the Sponsor's representatives to be present at such audit unless prohibited from so doing by regulatory authority. With respect to any audit by any regulatory authority, which audit is not directly related to the Study, the Institute shall promptly notify the Sponsor of any findings of such an audit that would be likely to have an adverse effect on the Institute's ability to conduct the Study.

2.28 The sponsor to send the DSMB report if applicable and its timely submission to Ethics Committee.

2.29 The Sponsor shall reimburse actual and reasonable medical expenses incurred in treating any injury or illness to a Study Subject that is directly related to the conduct of the Study in accordance with the Protocol and the Sponsor's written instructions to the Institute (or to the extent that the Sponsor's written instructions conflict with the Protocol, the Sponsor's written instructions to the Institute only). The Sponsor is not required under this Section 2.26 to provide compensation for (a) other injury- or illness-related costs (such as lost wages), (b) medical expenses that are paid for by a third party (provided that neither the Institute nor the Study Subject shall be obligated to seek reimbursement from a third party insurer), (c) medical expenses that are incurred as the result of a violation of the Protocol or other misconduct or negligence, in each case by any Agent of the Institute (including the Study Staff and the Investigator), or (d) medical expenses for injury or illness unrelated to the Study Device and unrelated to the proper performance of any other procedure required by the Protocol or Sponsor's written instructions to the Institute. The Sponsor confirms that it has taken appropriate insurance policy for the conduct of the Study as per the applicable laws.

3 Confidentiality

3.1 The Centre and the Investigator agree that any Confidential Information (or any evaluation thereof including but not limited to analysis, deconstruction, disassembling or reverse engineering) received from Meril shall be held in strict confidence and centre shall not disclose or use (other than in connection with or expressly permitted by this Agreement). All Confidential Information shall remain the property of Meril. Such information shall be used by the Centre and its Agents including the Investigator only in the performance of their duties hereunder, and shall not be used or disclosed, directly or indirectly to any third party, except as necessary to accomplish the purposes of this Agreement and then only if such Agents, and third party/parties are bound by an obligation of confidentiality consistent with the terms of this Agreement or as required by the law. The Centre hereby assures that their Agents including, but not limited to, the Investigator shall comply the provisions of this Clause. Upon the request of Meril, the Centre shall promptly return to Meril all Confidential Information of Meril in the possession of the Centre, the Investigator or other personnel and Agents, together with any documents or notes containing such Confidential Information, except for one archival copy which may be retained by the Centre if required in order to monitor compliance with the terms of this Agreement and the applicable laws.

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3.2 The Centre, the Investigator, or any other personnel of the Centre, or Agents shall not publicly or privately disclose or divulge any term or provision of this Agreement or the transactions contemplated hereby without the prior written consent of Meril, except as may be required by applicable law, rule, regulation or order and the internal reporting requirements of the Centre, and

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except for communications to employees or Agents in order to perform the work required under this Agreement.

3.3 In the event the Centre, the Investigator or any of their personnel including Agents are required to disclose Confidential Information of Meril under any applicable law, regulation, legal process, judicial order or by any applicable order or requirement of any governmental or regulatory authority, it may do so only to the extent required; provided, however, that the Centre and the Investigator shall:

(a) give prompt notice to Meril of the required disclosure of Confidential Information sufficiently in advance of making the required disclosure to allow Meril a reasonable opportunity to take steps to object to, prevent, and/or limit its disclosure or obtain a protective or other similar order with respect to the required disclosure; and

(b) Restrict the disclosure to only that portion of the Confidential Information which is required to be disclosed.

3.4 Subject to Clause 6 below, the Centre and the Investigator undertake to keep the Results confidential and not to disclose to any third party.

3.5 Meril agrees to keep confidential, the Confidential Information received from the Institute or Investigator related to the Study. Meril agrees that all such information will not be disclosed to any of its agents or affiliates, including the Contract Research Organization, which will be involved in execution of one or more processes of the Study, for any purpose other than execution and conduct of the Study.

4 Privacy and Data Protection:

The Parties agree that each will comply with their respective obligations as required under applicable privacy and data protection laws. The Institute and the Investigator will obtain the consent of each Research Subject for the use, processing, holding and transfer of their data to other countries that may not have same level of data protection as in India.

5 Publication of Results

5.1 Meril reserves all the rights of publication and presentations of all the aspects of the Study including the outcomes of the study; interim and final.

5.2 Meril shall follow publication guidelines related to such publications and presentations.

5.3 The Chief Investigator shall be first author of the main scientific publication (multi-Centre Results), while other investigators shall appear in accordance with generally accepted standards for authorship, followed by Sponsor's Study Head – Clinical Research, the Medical Writer and the statistician, and the relevant persons from the CRO. Study publication will be registered in a manner that meets the criteria of the International Committee of Medical Journal Editors. The publication of the Results from the Centre shall not be allowed until principal scientific publication of the main Study is published. The Centre shall be allowed to publish sub-studies of the whole Study only after written approval by the Sponsor. All publications will follow the uniform requirements for manuscripts submitted to biomedical journals by the International Committee of Medical Journal Editors.

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5.4 Subject to and without prejudice to above, the Centre may publish or present the Results collected or produced as a result of its participation in the Study in appropriate scientific journals, meetings or other professional publications, only under the following conditions:

(a) The proposed publication or presentation is consistent with the rules and conventions governing similar studies in all relevant jurisdictions.

(b) A draft of the proposed publication or presentation has been provided to Meril at least thirty (30) working days prior to the first intended submission for publication or presentation. Meril

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will review and respond with its comments, if any, within (30) working days of receipt of such copy. If Meril believes that any proposed publication or presentation contains any Confidential Information of Meril, then Meril shall so notify the Centre and the Centre and Investigator shall delete such Confidential Information of Meril from the proposed publication or presentation. If Meril believes that any proposed publication or presentation contains any patentable Results, the disclosure of such proposed publication or presentation to any third party shall be delayed for an additional ninety (90) working days to permit the filing of a patent application by Meril. Should Meril request such a delay, Meril shall use its best efforts consistent with reasonable business and scientific practice to do all things which it believes would expedite the filing of such patent application.

(c) Meril retains the right of final review prior to publication.

(d) The Centre shall give credit to Sponsor for its sponsorship of the Study in all publications or presentations related to the Study.

6 Results and Intellectual Property

6.1 The Centre and its Agents (including employees, the Investigator, contractors, consultants and other personnel) shall promptly disclose in writing to Meril, all the Results and Intellectual Property pertaining to the Results. Meril shall own and retain all right, title and interest in and to any Results and Intellectual Property resulting from all work performed in connection with the Study. To the extent that such Intellectual Property pertaining to Results does not vest automatically in Meril, the Centre hereby irrevocably agrees to assign and does hereby assign to Meril all rights, title and interest in and to any Intellectual Property that may inure to its benefit in connection with work performed pursuant to this Agreement and will execute and will cause its Agents including the Investigator to execute all documents which may be necessary to give effect to the provision contained herein. The Centre shall not assign, transfer or waive any rights it may have as an employer to any Results or any Intellectual Property pertaining to Results that is conceived or developed by personnel at the Centre (including the Investigator) in the performance of this Agreement to any entity other than the Sponsor.

6.2 Meril shall own complete data sets and Results produced under this Agreement and shall own all right, title and interest in and to any and all copyrights or copyrightable material, including software programs, produced, composed, or fixed in any tangible medium of expression in the performance of work under this Agreement. Meril shall have sole right to determine the disposition of all or any part thereof.

6.3 Neither the Centre nor the Investigator shall use any name, trademark, logo, symbol, or other image of Sponsor in advertising, publicity or otherwise, without the prior written consent of Meril. Neither the Centre nor the Agents including the Investigator, and representatives, shall issue or disseminate any press release or statement, or initiate any communication of information regarding the Study, written or oral, to the communications media or to any third party without the prior written approval of Meril.

6.4 The Parties acknowledge and agree that certain pre-existing Intellectual Property owned by Meril, Institute and Investigator shall not be affected by this Agreement. Except as otherwise expressly provided herein, no right or interest in or to any patents, trade secrets or other Intellectual Property owned or otherwise held by Meril or the Institute or the Investigator is granted or implied hereunder.

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7 Financial terms and conditions – Fee and taxation

7.1 Meril shall pay Fee as per the attached Exhibit-A.

7.2 In case of death of the Research Subject, all the balance remuneration till the last completed follow-up will be paid after submission of death form duly monitored for completeness, and report of the Ethics Committee to the Sponsor. In case of Research Subject lost to follow-up,

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terminated by the Investigator or Research Subject withdrawing consent, payment up to the last completed visit will be made.

7.3 If as a part of the Study and as directed by Meril, the Clinical examinations/investigations are conducted as per the Protocol; the payment for such Clinical examinations/investigations will be made as per Exhibit-A. Meril shall not be liable to pay any such charges if the Clinical examinations/investigations are not conducted in compliance with the Protocol.

7.4 The Fee will be paid by Meril every three months during the study duration. The final payment will be settled at the time of site close-out visit.

7.5 The payee will generate an invoice addressed to the Study Director/Head – Clinical Research of Meril. The invoice should include all details relevant to the milestone payment (as in Exhibit-A) during the period of the invoice with clear statement of amount of the Fee to be paid. The payment will be released by Meril within 30 working days of receipt of such invoice.

7.6 Meril will deduct tax on all payments as per the applicable law for which tax deduction certificates will be provided.

7.7 Invoicing address: Dr Ashok Thakkar, Head-Clinical Research,Meril Life Sciences Pvt. LtdBilakhia House, Muktanand Marg, Chala, Vapi 396191 Gujarat, India
Email: ashok.thakkar@merillife.com

Shipping address:

Dr. Ashok Thakkar
Head-Clinical Research
Meril Life Sciences Pvt. Ltd.
Survey No.135/139, Bilakhia House,
Muktanand Marg,
Chala, Vapi – 396 191
Gujarat, India.

The Invoices shall include details of enrolled, followed up and completed subjects during the period of the invoice with clear statement of amount of Fee to be paid. The due date of the invoices shall be 60 days from the date of receipt of invoices by Meril.

Bank details for payment:

Payee Name (Account Name): Director, SGPGIMS, Research a/c.

Account Number: 10095237491

Bank Name: State Bank of India

Branch Name: SGPGI Bank, Lucknow

Swift/IFSC Code: SBIN0007789

PAN Number: AAAJS3913N

Send to: Dr. Nirmal Gupta
Prof. & Head of Department of Cardiovascular and Thoracic Surgeon,
Sanjay Gandhi Postgraduate Institute of Medical Sciences,
Rae Bareli Road, Lucknow - 226014, Uttar Pradesh, India

All bank charges in India shall be borne by Meril. All bank charges outside India shall be borne by payee.

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8 Ownership:

All documents, protocols, data, know-how, methods, operations, formulas, Confidential Information and materials provided to the Centreby the Sponsor pursuant to this Agreement are and shall remain Sponsor's Property. The completed CRFs, the final reports and other Results of the study shall also be owned by the Sponsor. Sponsor shall not own patients' medical records.

9 Quality of performance - representation and warranties

9.1 The Centre and Investigator shall perform their obligations with care, skill and diligence, in accordance with the highest applicable professional standards recognized in the profession, and shall be responsible for the quality, accuracy and completeness of all medical treatments and procedures, and shall ensure the accuracy of the data obtained from the research and procedures conducted at the Centre. The Centre shall comply with all applicable legal and regulatory requirements. The Centre shall comply with Good Clinical Practice (GCP) guidelines during the course of the Study. The Centre and the Investigator shall comply with all provisions of this Agreement and the Centre shall be liable for any breach of the same by the Investigator.

9.2 The Centre and the Investigator hereby undertake:

(i) To comply with the Protocol and with the recommendations, suggestions and relevant literature provided by Meril;

(ii) To maintain proper written records concerning all matters in connection with the Study;

(iii) To submit to Meril any written report(s) as provided in the Protocol;

(iv) To report adverse and serious adverse events to Meril in writing within 24 hours after the occurrence thereof; and

(v) To obtain informed consent from the Research Subjects in the format and manner provided in the Protocol.

9.3 The Centre shall, in all respects and at all times, protect the personal rights of the Research Subjects, in particular regarding informed consent procedures and personal data. All information and data relating to the Research Subjects collected during the course of the procedures and research performed in connection with the Study by the Centre and its Agents including the Investigator will be treated as confidential and maintained in a safe and secured manner consistent with the Protocol. The Centre shall take all actions necessary to ensure compliance with this section by its Agents including, without limitation, the Investigator, the treating physicians, other participating investigators and all hospital personnel. All information and data delivered to Meril shall be stripped of all information that identifies the Research Subject as required by the applicable laws and regulations. For this reason, a Research Subject identification code shall be used for the transmission of data and other information of the Study.

9.4 Unless otherwise instructed by Meril, the Centre shall be permitted to distribute the data and other information to any data management company/CRO designated in writing by Meril.

9.5 The Centre and the Agents including the Investigator shall not make any representations, warranties or guarantees with respect to the specifications, features or capabilities of the Study Device that are not consistent with Meril's documentation accompanying the Study Device or Meril's literature describing the Study Device, including the limited warranty and disclaimers. Neither the Centre, nor the Agents including the Investigator shall change, extend, or alter any warranty, representation or obligation which is binding upon Meril or its Affiliates.

9.6 The Centre and the Investigator shall cooperate with Meril's designated representatives and regulatory authorities regarding all matters related to the Study, including, but not limited to, auditing, monitoring and enabling full access to all documents, records, reports or other information related to the Study. Meril shall notify the Investigator in advance if and on what dates it intends to visit the Centre to inspect, monitor and/or audit the conduct of the activities related to the Study. The Centre and the Investigator will render whatever assistance is reasonably requested by Meril to enable it to conduct such activities, including, without

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limitation, providing access to requested information and documentation and correcting any matters that have been identified as items requiring attention or correction. All monitoring by Meril shall be conducted in accordance with applicable GCP Guidelines.

9.7 The Centre hereby represents and warrants that it has the physical facilities, equipment and personnel adequate to perform the Study in a proper manner in accordance with its obligations.

9.8 The Centre and the Investigator represent and warrant that the execution, delivery and performance of this Agreement will not, directly or indirectly, result in any violation or breach of any material contract, license, or permit to which they are a party or by which they are bound, or result in a violation of any law, rule, regulation, order, judgment or decree (including any rule or regulation of a medical professional society or similar group) to which the Centre or its personnel including the Investigator are subject. The Centre and the Investigator further represent and warrant that the execution, delivery and performance of this Agreement does not and shall not require any consent, approval, authorization or permit of, or filing or notification to, any governmental or professional entity which the Centre or the Investigator has not timely obtained.

10 Liability

10.1 Meril undertakes to indemnify, defend or cover costs for defence and release from liability ("Indemnify") the Investigator associated with the Study, Institute, their management staff, representatives (collectively referred to as the "Indemnified Parties") in relation to any claim of a third party regarding compensation for damages, costs, liabilities, expenses, including costs for legal representation of the Indemnified Parties, incurred as a result of a damage to the health of Research Subjects due to the failure of the Study Device provided, however, that to the extent that the claim is a direct result of (a) the failure of the Institute or one of its Agents (including the Investigator) to follow the Protocol or the Sponsor's written instructions (each when applicable), accepted medical practice, or applicable laws, or (b) any other negligence or wilful misconduct of the Institute or one of its Agents (including the Investigator), the Sponsor shall have no such obligation, and the Institute shall indemnify, defend, and hold harmless the Sponsor (and its officers, directors, employees, and agents, as applicable) from any loss, liability, damage or expense, but only to the extent arising from any such claim.

10.2 **Indemnification Procedure.** The Party seeking indemnification (the "Indemnitee") shall promptly notify the other Party (the "Indemnitor") of any claim, loss, or expense likely to lead to a claim for indemnification, along with all material related information. If such notice is not prompt, the Indemnitor's obligation under this Clause11 will be reduced to the extent that such delay prejudices the Indemnitor's defense of the claim. The Indemnitor shall have the right to manage the defense and settlement of any claim, except that the Indemnitor may not enter into any settlement admitting fault on behalf of the Indemnitee without the Indemnitee's prior written approval. The Indemnitee may not enter into any settlement of any such claim without the written permission of Indemnitor. The Indemnitee shall reasonably cooperate with the Indemnitor in the defense of the claim. The Indemnitee may hire its own counsel, at its own expense, to monitor the defense. In addition, the Indemnitee may elect to assume control of the defense of such claim, in which case the Indemnitor shall have no obligation to indemnify or further defend the Indemnitee with respect to such claim.

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10.3 **Insurance.** During the term of this Agreement and for so long thereafter as may be necessary, the Institute and the Sponsor each shall carry liability insurance in the type and amount appropriate and customary for the conduct and sponsorship of the Clinical Trial, respectively as per applicable regulations to cover any claims that may arise in connection with its responsibilities under this Agreement. Upon request, each Party shall provide to the other Party a certificate of such insurance or evidence of such a self-insurance plan.

10.4 The Investigator will cooperate with Meril in collection of all requisite documents and completion of required process for insurance procedure for compensation claims towards Clinical Trial Liability Policy taken by Meril.

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10.5 For clarity, the general product liability of Meril for the Study Device remains unaffected by the Clause 11.3.

10.6 In no circumstances shall any Party be liable to another Party in contract, tort (including negligence or breach of statutory duty) or otherwise howsoever arising or whatever the cause thereof, for any loss of profit, business, reputation, contracts, revenues or anticipated savings for any special, indirect or consequential damage of any nature, which arises directly or indirectly from any default on the part of any other Party.

11 Term and termination

11.1 **Term.** This Agreement shall come into effect upon the Effective Date and shall remain in force till the Study is completed and the Parties have discharged their obligations pursuant to this Agreement. The Parties expect this Agreement to expire after the day of "Site Close-out Visit"at the Institute by the Sponsor that is indicative of completion of participation of the Investigator and the Centre in the Study as well as finalization of the Study data base whichever is later; unless terminated earlier pursuant to this Clause 11.

11.2 **Sponsor Termination.** The Sponsor may terminate this Agreement (a) upon thirty (30) days' written notice to the Institute, in its sole discretion; (b) upon thirty (30) days' written notice to the Institute, for failure of the Sponsor and the Institute to agree upon a new Investigator pursuant to Clause2.3; (c) upon written notice to the Institute, if progress of enrolment at the Centre justifies such termination, in the sole discretion of the Sponsor; (d) upon written notice to the Institute, if the Parties are unable to agree on amendments to this Agreement related to amendments to the Protocol pursuant to Clause 2.9; (e) upon oral notice (promptly followed by written notice) to the Institute, if approval for the Study is not granted or is revoked by the relevant IRB; (f) upon oral notice (promptly followed by written notice) to the Institute, if any person performing activities under this Agreement is debarred, excluded or disqualified from participation in any federal health care program; or (g) upon oral notice (promptly followed by written notice) to the Institute, if the Sponsor determines that termination of the Study is necessary for the safety of the Study Subjects.

11.3 **Termination by Institute.** The Institute may terminate this Agreement (a) upon thirty (30) days' written notice to the Sponsor, for failure of the Sponsor and the Institute to agree upon a new Investigator pursuant to Section 2.3; (b) upon written notice to the Sponsor, if the Parties are unable to agree on amendments to this Agreement related to amendments to the Protocol pursuant to Section 2.9; or (c) upon oral notice (promptly followed by written notice) to the Sponsor if the Institute determines that termination of the Study is necessary for the safety of the Study Subjects.

11.4 **Termination for Material Breach.** Either Party may terminate this Agreement upon written notice to the other Party if the other Party materially breaches this Agreement and the breaching Party fails to cure the breach within thirty (30) days after receipt of written notice of the breach from the other Party.

11.5 **Procedures upon Early Termination.** If this Agreement is terminated before completion of the Study, the Institute shall cease enrolling Study Subjects immediately (or, in the case of termination by the Sponsor, as soon as the Institute has been notified of such termination), and shall cease conducting the procedures set out in the Protocol to the extent that doing so is medically permissible and appropriate. The Sponsor and the Institute shall negotiate in good faith on the subsequent treatment or transfer of the Study Subjects. In case of termination of the Study before completion, the Sponsor shall reimburse the Institute for (i) obligations incurred in accordance with the Study budget that cannot be cancelled or mitigated by the Institute using reasonable efforts, (ii) reasonable costs incurred in connection with the safe withdrawal of the Study Subjects from the Study, and (iii) mutually agreed post-termination expenses.

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11.6 **Return of Property.** Upon termination or expiration of this Agreement, the Institute shall, and shall cause the Investigator and Agents to, return to the Sponsor within thirty (30) days any unused Study Devices (is supplied by the Sponsor) except as required by law, any equipment on loan or lease from the Sponsor, and any copies of Confidential Information provided by the Sponsor that are in the possession or under the control of the Institute or the Investigator; provided, however, that the Institute may retain any copies of such Confidential Information to the extent required by applicable law. At the Sponsor's request and expense, the Institute shall dispose of the unused Study Devices and Control Devices (if supplied by the Sponsor) in accordance with Sponsor's instructions, subject to applicable law.

11.7 **Final Accounting.** The Institute shall deliver to the Sponsor, within ninety (90) days after expiration or early termination of this Agreement, a final accounting of amounts due (and reasonable supporting documentation, which requirement shall be satisfied by properly completed CRFs as to completed visits by Study Subjects), taking into account payments made and not yet made under the payment schedule, and expenses reimbursable pursuant to Clause8, from one Party to the other Party. Undisputed amounts due shall be paid within sixty (60) days thereafter.

11.8 Upon expiration or termination of this Agreement, all rights and obligations shall expire forthwith, except those rights and obligations which by their nature are intended to survive the expiration or termination of the Agreement, including Clause 3 (Confidentiality), Clause 4 (Privacy and Data protection), Clause 5 (Publication of Results), Clause 6 (Results and Intellectual Property), Clause 8 (Ownership), Clause 9 (Quality of performance - representation and warranties), Clause 10 (Liability) and Clause 12.8 (Governing Law/Jurisdiction), and each of their subparts.

12 Miscellaneous provisions

12.1 **Regulatory Approvals.** Each Party represents that it has and will maintain during the term of this Agreement all regulatory approvals required for the conduct of its respective activities in connection with the Study, and that all the Agents who perform activities under this Agreement on its behalf (including, in the case of the Institute, the Study Staff) have and will have the necessary expertise, training, qualifications, and certifications.

12.2 **Debarment.** The Institute certifies that it will not engage, directly or indirectly, any person (including the Investigator) to perform services under this Agreement if (a) that person is debarred by the applicable law or to the Institute's knowledge is threatened with debarment by a pending proceeding, action, or investigation, (b) that person is excluded from participation in any federal health care program or is the subject of an exclusion proceeding, or (c) that person is otherwise disqualified under federal or state law, or to the Institute's knowledge is threatened with such disqualification by a pending proceeding, action, or investigation, from participating in the Study. The Institute certifies that it will immediately notify the Sponsor in writing if any such debarment, exclusion, or disqualification occurs, or if any such debarment, exclusion, or disqualification proceeding, action, or investigation is commenced or, to the Institute's knowledge, is threatened, with respect to any such person.

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12.3 **No Conflicting Obligations.** The Institute represents and covenants that none of the Institute or any member of the Study Staff or none of the Agents is or will become subject to any conflicting obligations that would materially interfere with the performance of the Study or any of the Institute's other obligations under this Agreement. The Parties agree that the conduct of other clinical trials targeting the same disease or patient population as the Study does not necessarily constitute such a conflicting obligation. The Institute represents that it has a system in place to manage, eliminate, or otherwise resolve conflicts of interest. The Sponsor shall not, and shall cause its agents and contractors to refrain from, making any payments directly to Study Staff for performing the activities set out in the Protocol.

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12.4 **Independent Contractors**. Nothing contained herein shall be construed as evidence of an employment relationship between Meril and the Centre (or any personnel of the Centre including the Investigator and Agents). In performing the services hereunder, the Centre shall be deemed as an independent contractor to Meril for all purposes. Neither the Centre nor the Investigator shall have any authority to incur any liability on Meril's behalf, or to bind Meril to any obligation without the express written authorization of Meril.

12.5 **Assignment.** Neither Party may assign this Agreement without the prior written consent of the other Party, except that (a) either Party may assign this Agreement to an Affiliate, or to a third party in connection with a merger or sale of all or substantially all of its assets relating to the Study or the Study Device; and (b) the Sponsor may delegate its obligations or assign its rights under this Agreement to a contractor, provided that the Sponsor remains liable for the performance of all delegated obligations. Any Party making an assignment pursuant to this Clause 13 (other than an assignment to an Affiliate) shall provide prompt written notification to the other Party. In the case of any assignment (but not a delegation), the assignee shall assume all of the obligations of the assignor under this Agreement.

12.6 **Integration and Modification/Waiver.** This Agreement together with any exhibits hereto, constitute the entire agreement between the Parties with respect to the subject matter hereof and supersedes all prior agreements, discussions and understandings between the Parties. No amendment, modification or waiver of any term or provision of this Agreement shall be effective except by written instrument duly executed by each Party. No waiver of any breach of this Agreement shall be held to be a waiver of any other or subsequent breach.

12.7 **Force Majeure.** Noncompliance by a Party with this Agreement due to any cause beyond the reasonable control of the Party, such as war, civil commotion, destruction of production facilities and materials, fire, flood, earthquake or storm, labor disturbances, shortage of materials, failure of public utilities or common carriers (each, an event of "Force Majeure"), shall not constitute a breach of this Agreement. That Party shall be excused from performance under this Agreement to the extent and for the duration of such event of Force Majeure; provided, however, that it first notifies the other Party in writing thereof and that it uses reasonable efforts to cause such event of Force Majeure to abate.

12.8 **Governing Law/Jurisdiction.** This Agreement shall be construed and interpreted in accordance with the laws of India, without regard to its conflict of law's provisions. Any action brought to enforce or interpret this Agreement shall be brought in the courts of Mumbai, subject to appeal in the higher courts in India, and each Party hereby consents to the jurisdiction thereof.

12.9 **Severability.** If any term or provision of this Agreement is held to be invalid, unenforceable, or void by a court of competent jurisdiction, the remaining terms and provisions shall nevertheless be enforceable according to their terms.

12.10 **Counterparts.** This Agreement may be executed in one or more counterparts, which taken together, shall constitute one and the same instrument.

12.11 **Interpretation.** Unless the context of this Agreement requires otherwise, words of one gender include the other gender; words using the singular or plural number also include the plural or singular number, respectively; the terms "Clause" and "Section" refer to the specified Clause and Section of this Agreement; and the term "including" means "including, without limitation."

12.12 **Notices.** The Parties shall send notices in writing, referencing this Agreement. Notice shall be deemed given: (a) when delivered personally; (b) one (1) day after having been sent by facsimile, with a copy sent promptly by registered or certified mail, return receipt requested, postage prepaid; (c) by e-mail with a copy sent promptly by registered or certified mail, return receipt requested, postage prepaid;five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid; or (d) two (2) days after deposit with a

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nationally recognized overnight carrier, with written verification of receipt. Notice shall be given to the addressee below:

To the Institute:	**Sanjay Gandhi Postgraduate Institute of Medical Sciences** Attention: **Prof. Rakesh Kapoor** E-mail: director@sgpgi.ac.in
With a copy to:	**The Principal Investigator** Attention: **Dr. Nirmal Gupta** E-mail: drnirmalgupta@gmail.com
To the Sponsor:	**Meril Life Sciences Pvt. Ltd.** Attention: **Dr. Ashok Thakkar** E-mail: ashok.thakkar@merillife.com

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IN WITNESS WHEREOF, The Parties have duly executed this Agreement as of the date first written above.

Sponsor: Meril Life Sciences Pvt. Ltd.

Signature:

Date: 21/MAR/2018

Name: **Dr. Ashok Thakkar**

Title: **Head of Clinical Research**

Address for Notices: **Meril Life Sciences Pvt. Ltd., Bilakhia House, Muktanand Marg, Chala, Vapi-396191 Gujarat, India.**

Institute: Sanjay Gandhi Postgraduate Institute of Medical Sciences

Signature:

Date:

Name: **Prof. Rakesh Kapoor**

Director
Sanjay Gandhi Postgraduate
Institute of Medical Sciences
Lucknow-226014 (U.P) INDIA

Title: **Director SGPGI**

Address for Notices: **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow - 226014, Uttar Pradesh, India**

Investigator: Dr. Nirmal Gupta

Signature:

Date: 27/03/18

Name: **Dr. Nirmal Gupta**

Title: **Principal Investigator**

Address for Notices: **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow - 226014, Uttar Pradesh, India**

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EXHIBIT-A

Fee Schedule

Meril shall pay to the Payee (as per Clause 7 of the Agreement) following Fee subject to and in compliance with the terms and conditions of this Agreement.

Total 30,000.00 INR (Thirty Thousand Indian National Rupees) for each enrolled Research Subject will be paid to **Director, SGPGIMS, Research a/c** based on submission of the data in compliance with the terms and conditions of this Agreement. The schedule of payment will be as given in the following table.

Visit type	Amount/per Research Subject in ₹
1. Screening, Enrolment and Follow Ups	
(A) On Research Subject Screening	5,000.00
(B) Submission of completed electronic Case Report Forms ("eCRFs") (Baseline, Post Implant-Discharge,30-days follow-up)	12,000.00
(C) Submission of completed e-CRFs till and including 180-day follow up	2,000.00
(D) Submission of completed e-CRFs till and including 1-year follow up	2,000.00
(E) Submission of completed e-CRFs till and including 2-year follow up	2,000.00
(F) Submission of completed e-CRFs till and including 3-year follow up	2,000.00
(G) Submission of completed e-CRFs till and including 4-yer follow up	2,000.00
(H) Submission of completed e-CRFs till and including 5-year follow up	2,000.00
(I) Site Close Out (After Final Data Base Lock)	1,000.00
Grand Total (A-I)	**30,000.00**

- All protocol specific Lab Investigations and diagnostic procedures cost will paid as pass-through cost post generating Invoice based on original supporting bills with applicable taxes.
- Patient travel reimbursement will be paid as per actual to subject, maximum up to INR 1500/- on return clinic follow up as per the protocol specific visits for each visit depending on your distance from the Hospital/Centre.
- All payments are subject to TDS (subject to Government of India, Tax regulations) and GST as applicable.
- Reimbursement of any additional pass through cost including optional cost shall be subject to sponsor's prior approval and at actual.

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Executive Registrar
SGPGIMS Lucknow

Invoicing Instructions

Invoices in the name of "Meril Life Sciences Pvt. Ltd." shall be sent to:

Dr. Ashok Thakkar
Meril Life Sciences Pvt. Ltd.
Survey No.135/139, Bilakhia House,
Muktanand Marg ,
Chala ,Vapi – 396 191
Gujarat, India.

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Executive Registrar
SGPGIMS,Lucknow

MERIL LIFE SCIENCES PVT. LTD. VAPI

IN WITNESS WHEREOF, the Parties have duly executed this Agreement as of the date first written above.

Sponsor: Meril Life Sciences Pvt. Ltd.

Signature:

Date: 26/MAR/2018

Name: **Dr. Ashok Thakkar**

Title: **Head of Clinical Research**

Address for Notices: **Meril Life Sciences Pvt. Ltd., Bilakhia House, Survey No. 135/139, Muktanand Marg, Chala, Vapi-396191 Gujarat, India.**

Institution: Sanjay Gandhi Postgraduate Institute of Medical Sciences

Signature:

Date:

Name: **Prof. Rakesh Kapoor**

Title: **Director SGPGI**

DIRECTOR
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Address for Notices: **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow - 226014, Uttar Pradesh, India**

Investigator: Dr. Nirmal Gupta

Signature:

Date: 27/03/18

Name: **Dr. Nirmal Gupta**

Title: **Principal Investigator**

Address for Notices: **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow - 226014, Uttar Pradesh, India**

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SGPGIMS,Lucknow

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Executive Registrar
SGPGIMS,Lucknow

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SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES
Raebareli Road, Lucknow-226 014 (India)

Dr. Sanjoy Kumar Sureka
M.S., M.Ch.
Assistant Professor
Department of Urology & Renal Transplantation

To,
Faculty In charge Research (F.I.R)
S.G.P.G.I.M.S. Lucknow

Date: 09/03/2021

Ref: PAzopanib Real-world Assessment of Clinical effectiveness and safety in patients wHo have Undergone
Treatment in different sEttings in advanced renal cell carcinoma; a prospective,non-interventional, observational study.

Subject: Institute (Director) signature required on addendum to CTA.

Respected Sir,

We are running above referenced extramural research project in our department and received an addendum to our approved CTA from sponsor. This addendum is required to be signed by tripartite and for this purpose we require director signature as Institute.

I request you to kindly do the needful.

Please feel free to ask for any further information required.

Thanking You

Sincerely

(Dr. Sanjoy Kumar Sureka)
Principal Investigator

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

This First Addendum is made at Mumbai and entered into on 9th day of March, 2021 by and between;

NOVARTIS HEALTHCARE PRIVATE LIMITED, a company incorporated under the Indian Companies Act, 1956 and having its registered office at 7th floor, G Block, BKC Main Road, Bandra Kurla Complex, Bandra (East), Mumbai – 400051, Maharashtra, India (hereinafter referred to as "**Novartis**", 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;

AND

Dr. Sanjoy Kumar Sureka consulting at **Department of Urology and Renal Transplant, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow, Uttar Pradesh- 226014, India** (hereinafter referred to as "**the Investigator**", which expression shall, unless it be repugnant to the context or meaning thereof, be deemed to mean and include his/her heirs, executors, administrators and successors) and the Second Part;

AND

Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow, Uttar Pradesh- 226014, India represented by Prof. R. K. Dhiman whose designation is **Director**; 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 assigns) of the Third Part;

(Novartis, Investigator and Institution may hereinafter be individually referred to as '**Party**' and are collectively referred as '**Parties**').

WHEREAS

A. By a Affiliation Agreement for Researchers dated 23rd Feb 2018 entered into between the Parties hereto ("**Agreement**"), the Investigator and the institution have agreed to provide certain services to Novartis on the terms and conditions contained in the Agreement.

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B. Now by this first Addendum, the Parties are desirous of amending the following clause 7 on the terms and conditions herein after appearing.

This Agreement shall be effective from 02-Jul-2020 and shall remain in force until 30-June-2021 (both days inclusive) unless earlier terminated in accordance with this Section.

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Agreement read with the Prior Addendums for all intents and purposes.

2. Save and except to the extent aforesaid, all other terms and conditions of the Agreement shall continue to remain unaltered, valid and binding upon the Parties.

IN WITNESS WHEREOF, the Parties to this Addendum have caused their duly authorized representatives to enter into and execute this Addendum.

Novartis Healthcare Private Limited

By: _____

Name: Muruganathan K.

Title: Country Monitoring Head

Date: 17 Feb 2021

Sanjay Gandhi Postgraduate Institute of Medical Sciences

By: _____

Name: **Dr. Sanjoy Kumar Sureka**

Title: Investigator

Date:

By: _____

Name: **Prof. R. K. Dhiman**

Title: Institute

Date:

Prof. R. K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

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Executive Registrar
SGPGIMS,Lucknow

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Executive Registrar
SGPGIMS,Lucknow

purposes, be transferred to third parties, including other companies related to Novartis in the form of a group and their advisors and third party service providers, as well as to regulatory authorities and tax authorities, as required by applicable law or relevant stock exchange rules. You are not required to give your consent to the re-use of your personal data and your refusal may not impact the conduct of the current Trial, just further communications.

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

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

In that regard, Novartis is asking for your permission to submit your name, clinical trial site contact information, name of the clinical trial, sponsor, copy of the clinical trial agreement, and costs and fees relating to your site's retention, to a third party administrator of this database. This information will be maintained in that database for five years.

You are not required to give consent to this disclosure in order to proceed with this clinical trial. However, by doing so, you are helping to collect information on fair costs in clinical trials.

General terms of consent

I accept and agree that my personal data may be transferred to and processed in countries outside India, including the United States of America, where the level of data protection may be lower than in my country of origin. I have noted that Novartis will protect my data in this instance by entering into specific data transfer agreements, as established by the applicable privacy regulations contracts.

I am aware of my rights to access, ask for a free copy and/or request modification or deletion of my data as applicable by contacting Novartis's Data Protection Officer at [generic email address]. I also acknowledge my rights to lodge a complaint in front of the relevant Data Protection Authorities as needed.

- ☐ Yes, I hereby agree that Novartis may use my personal data for the administrative and commercial purposes described in Section 1 above..
- ☐ No, I do not give permission for Novartis to use my personal data for the administrative and commercial purposes described in Section 1 above.
- ☐ Yes, I hereby agree that Novartis may disclose my personal data in connection with the GrantPlan database.
- ☐ No, I do not give my permission to disclose my personal data in connection with the GrantPlan database.

Place and Date:

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Name: **Dr. Sanjoy Kumar Sureka**
Principal Investigator

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Act 1977 of the United States of America (***FCPA***), the Prevention of Corruption Act, 1988 and any other applicable anti-bribery and anti-corruption legislation (together the ***Applicable Anti-Corruption Legislation***).

It is the responsibility of the Trial Parties to ensure that they are familiar with, and comply with, the provisions of the Applicable Anti-Corruption Legislation. Nevertheless, the following is intended as a summary of the key principles underlying the Bribery Act and the FCPA.

(A) The Trial Parties must at all times act with integrity and honesty and comply with the highest ethical standards.

(B) The Trial Parties must not make, give, or offer any payment, gift or other benefit or advantage to any person for the purposes of:
  (i) securing any improper advantage; or
  (ii) inducing the recipient or another person to do or omit to do any act in violation of their duties or responsibilities (or for the purposes of rewarding such conduct).

  This restriction applies at all times and in all contexts. For the avoidance of any doubt, it applies both to dealings with "public officials" and to dealings with employees and agents of commercial enterprises.

(C) Nevertheless, particular care must be exercised with dealings with public officials. The Trial Parties must not make, give or offer any payment, gift or other benefit or advantage for the purposes of influencing any act or decision of a public official (or inducing such official to use their influence with another person, entity or government instrumentality or to affect or influence any act or decision of such other person, entity or government instrumentality).

(D) The term "***Public Official***" includes any person acting on behalf of any government department, agency or instrumentality or any state-owned or controlled enterprise. By way of example, this includes health care professionals employed by a state- or local municipality-run hospital or clinic, and representatives of public international organizations.

(E) The Trial Parties must not make, give or offer any payment, gift or other benefit or advantage to any person whilst knowing or suspecting that all or a portion of such money, gift, benefit or advantage will be used, whether directly or indirectly, in breach of (B) or (C) above.

(F) The Trial Parties shall make and keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Trial Parties;

(G) The Trial Parties shall devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances that –
  (i) transactions are executed in accordance with management's general or specific authorization;
  (ii) transactions are recorded as necessary
    (I) to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and
    (II) to maintain accountability for assets;
  (iii) access to assets is permitted only in accordance with management's general or specific authorization; and
  (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

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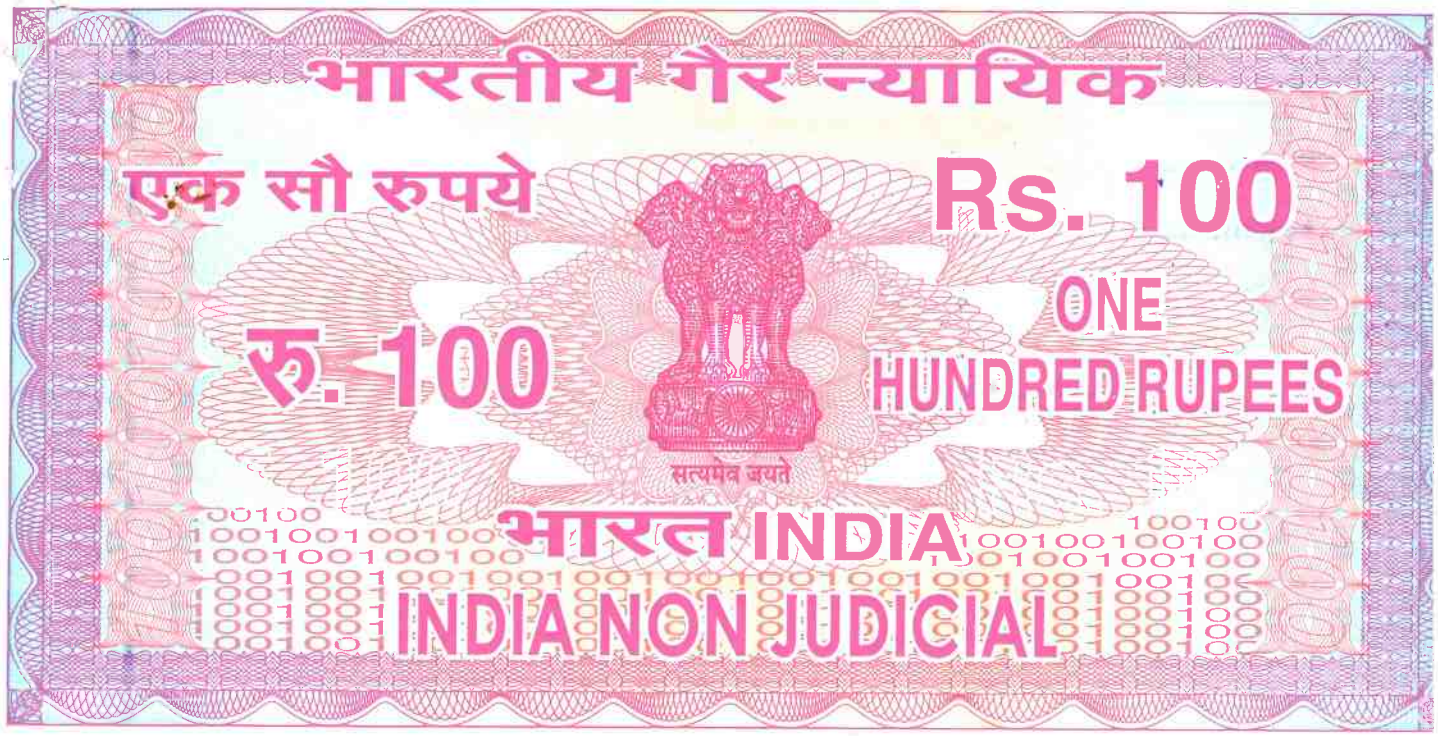

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CLINICAL TRIAL AGREEMENT

THIS AGREEMENT IS MADE AND ENTERED INTO BY AND BETWEEN:

Medclin Research Pvt. Ltd., a Company incorporated in accordance with the laws of India, under the Companies Act, 1956, having its office at Acropolis , unit 10/5 , 10th floor 1858/1,Rajdanga Main Road, Kolkata- 700107, hereafter referred to as **Clinical Research Organization(CRO)**

On the first part,

AND:

Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow 226014, Uttar Pradesh, India

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

AND:

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Dr. Piyali Bhattacharya, Consultant Paediatrician, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow 226014, Uttar Pradesh, India

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

On the second part,

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

THIS AGREEMENT RELATES TO THE FOLLOWING CLINICAL TRIAL:

A Multicentric, Randomized, Double Blind, Placebo Controlled Trial to assess the Efficacy and Safety of *Saccharomyces Boulardii CNCM-I 3799 and Bacillus Subtilis* CU – 1 *combination* For treatment of Acute Diarrhoea in Indian Children

PREAMBLE

WHEREAS, ALKEM Laboratories Ltd.is the Sponsor, as defined in the ICH GCP guidelines, of the above mentioned Clinical Trial and therefore wishes to perform this Clinical Trial;

WHEREAS, Medclin Research Pvt. Ltd. Is the CRO with Institution and the Principal Investigator are willing to organize, conduct and perform this Clinical Trial on behalf of the Sponsor;

WHEREAS, the Institution and the Principal Investigator have capable personnel and the necessary expertise to organize and perform clinical trials.

WHEREAS, the Principal Investigator is responsible for the scientific supervision and direction of the Clinical Trial and will conduct the Clinical Trial in the facilities of the Institution;

NOW THEREFORE, in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each Party), the Parties hereby agree as follows:

ARTICLE I – DEFINITIONS

For the purposes of this Agreement the following words and phrases shall have the following meanings:

- "**Additional Personnel**" means any co-investigator and/or any of Institution's contractors, employees, post-doctoral fellows, residents, demonstrators, students and/or technical staff, who may be involved in the Clinical Trial (as hereinafter defined), other than the Principal Investigator.

- **"CRO"** means Contract Research Organization; a person or an organization (commercial, academic, or other) contracted by the Sponsor, to perform one or more of a sponsor's trial-related duties and functions.

- **"Agreement"** means this Clinical Trial Agreement, all amendments and supplements to this Agreement and all schedules to this Agreement.

- "**Case Report Form**" means the form to be completed and returned to the Sponsor/CRO for each Subject participating in the Clinical Trial.

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- "**Clinical Trial**" means the clinical trial above-mentioned in the Preamble of the Agreement.

- "**Confidential Information**" means any and all information relating to the Sponsor, CRO which is of a confidential and proprietary nature, including but not limited to preclinical, clinical or formulation data, investigator's brochures, case reports, source documentation, study protocols and SOPs (as defined hereafter) as amended from time to time.

- **"Control"** means, whether used as a noun or verb, the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of a Person, whether through the ownership of voting securities, by contract or otherwise.

- **"Control Product"** means placebo to be used in the Clinical Trial in accordance with the Protocol.

- "**Enrollment Cap**" means that the Sponsor/CRO reserves the right to limit enrollment by giving written notice, or by giving notice by telephone followed by written notice, to the Institution and the Principal Investigator to cease further enrollment of Subjects in the Clinical Trial.

- **"GCP"** means:
  (i) The set of regulations established by Health Authority(ies) for conducting clinical studies including, without limitation, the set of regulations established by the CDSCO.
  (ii) The current international ethical and scientific quality standards for designing, conducting, recording and reporting clinical studies known as ICH Guidelines for Good Clinical Practice.

- "**Health Authorities**" means applicable health authorities, either governmental, regulatory or otherwise, including but not limited to the Drug Controller General of India (DCGI),

- **"ICH"** means the International Conference of Harmonization.

- "**IEC**" means the Institutional Ethics Committee responsible for review and approval of the Protocol.

- "**IND**" means an investigational new drug.

- **"Indemnitee"** means collectively the Institution, its Trustees, Officers, Directors, Agents, Additional Personnel and the Principal Investigator.

- "**Inventions**" means any inventions, discoveries, or innovations, products, processes, data, reports, results, formulations, technologies and compounds, whether patentable or not, arising directly or indirectly, in the performance of the Clinical Trial under this Agreement or using Clinical Trial funds or otherwise arising out of use of the Product.

- **"Investigational Product"** GUTGAIN ™ to be used in the Clinical Trial in accordance with the Protocol.

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- **"Person"** means an individual, partnership, joint venture, trustee, trust, corporation, unincorporated organization or other entity or a government, state or agency, or political subdivision thereof.

- **"Personal Data"** means any and all data concerning an individual participating in the Clinical Trial whether as a Subject or as an Investigator.

- **"Principal Investigator"** means the person who is named on the head of the Agreement and corresponds to the person who is named *"Investigator"* or *"Principal Investigator"* for either the entire study or a study site.

- **"Privacy Rules"** means any national and international standards of practice, establishing a category of information regarding the patients or Subjects, which may be used or disclosed to others in certain circumstances or under certain conditions.

- **"Processing"** means, in accordance with applicable rules and regulations, any operation or set of operations which is performed upon the Personal Data, whether or not by automatic means, such as collection, recording, organization, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction.

- **"Protocol"** means the last approved version of the protocol including any and all amendments, which will be considered as attached hereto upon completion, and is incorporated herein by reference.

  It is agreed that this Agreement shall be governed by the most recent version of the Protocol, and should this Agreement be executed prior to complete finalization of the Protocol, the last-dated version thereof will be considered to be incorporated by reference in place of any prior versions. In the event that there is a conflict between the terms of the Protocol and the terms of this Agreement, the terms of this Agreement will govern with respect to contract terms and conditions but the Protocol will govern with respect to the conduct of the Clinical Trial and with respect to serving the best interests of patient welfare.

- "**Public Presentation**" means, collectively or individually, drafts of abstracts and/or manuscripts for publication (including slides and texts of oral or other public presentations).

- **"Recipient"** means, collectively and individually, the Institution and/or the Principal Investigator.

- **"Related Person(s)"** means any Person(s) having a relationship with a Party whether as an employee, Additional Personnel, agent or representative.

- **"Subject"** means an individual who is selected in accordance with the terms of the Protocol to participate in the Clinical Trial.

- **"SOPs"** means the Standard Operating Procedures as amended from time to time to be used for the purpose of the Clinical Trial

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- "**Trial Product**" means collectively the Investigational Product and the Control Product.

- **"Trial Site"** means the location(s) where the Clinical Trial activities are conducted by the Institution and/or the Principal Investigator.

ARTICLE 2 – SCOPE OF WORK

The Institution and the Principal Investigator shall conduct the Clinical Trial relating to the Product in accordance with the Protocol. Creation and modification of the Protocol shall be the sole responsibility of the Sponsor.

ARTICLE 3 - CLINICAL TRIAL APPROVALS

3.1 The Principal Investigator is responsible for ensuring that the Ethics Committee is registered before starting the Clinical Trial. The Investigator is responsible to follow up and ensure updating of serious adverse events causality opinion by the Ethics Committee to Appropriate Authority, Sponsor and CRO.

3.2 The Principal Investigator shall be responsible for having the Clinical Trial documents (such as Protocol, informed consent form and / or site inform consent form, any advertisement(s) pertaining to the recruitment of Subjects in the Clinical Trial) approved by the IEC prior to the beginning of the Clinical Trial.

3.2 In the event the IEC requests that changes be made to the Protocol such as the informed consent form template, the Institution shall immediately inform Sponsor/CRO of the IEC request in detail. Any modifications to the Protocol including the informed consent form template must be approved by the Sponsor's representative, CRO and/or appropriate regulatory authority, if applicable, before being implemented by Institution.

3.3 The Institution and the Principal Investigator shall not modify the Protocol without the prior written approval of the Sponsor.

3.4 The Sponsor's representative, shall be responsible for the submission of any IND application, if applicable resulting from the Clinical Trial, and the Parties agree to fully cooperate as necessary with the Sponsor's representative, and at Sponsor's expense, in the completion and filing of the IND.

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ARTICLE 4 – ORGANIZATION OF THE CLINICAL TRIAL

4.1 The **estimated** time schedule of the Clinical Trial described in detail in the Protocol may be summarized as follows:

- Planned starting of the Subjects' recruiting process: May 2018
- Planned final report: 3 months post LSLV from all sites.

It is understood that the effective beginning of the Clinical Trial is dependent upon timely approval of key Clinical Trial documents and/or performance of preparatory

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activities by Sponsor's representative, CRO and/or third parties (e.g. IEC/IRB or Health Authority) and/or availability of the Trial Product. Thus, any delay in this approval and/or the performance of those preparatory activities and/or availability of the Trial Product may have a cascade effect on the Clinical Trial initiation. The Principal Investigator and the Institution agree that any such delay shall not entitle them to any compensation or remedy.

4.2 It is estimated that the Principal Investigator participating in this Clinical Trial will enroll a target number of Subjects of 45 Subjects in total, in approximately 50 to 180 days.

If not achieved, the Sponsor's representative/CRO might decide to reallocate the Subjects enrollment to another site and in this case, the rules set forth in section 4.2.1 of the Agreement will be applied.

For a multi-center Clinical Trial, the Sponsor's representative/CRO may amend the number of Subjects to be recruited by the Principal Investigator and in this case the rules set forth in sections 4.2.1 and/or 4.2.2 of the Agreement will be applied.

4.2.1 If in the reasonable opinion of the Sponsor/CRO, recruitment of Subjects is proceeding at the Trial Site at a rate below that required to enable the relevant timeline to be met, the Sponsor's representative/CRO may by notice to the Institution require recruitment at the Trial Site to cease and the terms of the Agreement shall relate thereafter to the number of Subjects who have been accepted for treatment in the Clinical Trial at the date of such notice; or

4.2.2 If recruitment of Subjects is proceeding at the Trial Site a rate above that required to meet the relevant timeline the Sponsor/CRO may with the agreement of the Institution increase the number of Subjects to be recruited by the Principal Investigator.

For a multi-center Clinical Trial having a competitive enrollment, the Sponsor/CRO reserves the right to request the Principal Investigator to limit recruitment of further Subjects or cease the recruitment, notably if the recruitment target for the Clinical Trial has been reached. In such event, the Sponsor's representative/CRO will inform the Principal Investigator on interrupting the recruitment of any Subject who has not yet signed the informed consent form.

The Principal Investigator shall upon receipt of a notice for stopping recruitment, stop immediately further recruitment of Subjects. Payment shall only be made according to the number of Subjects recruited up to the date of receipt of the said notice of stopping. The Sponsor's representative/CRO will neither take any responsibility, nor make any payment for the Subjects recruited after this date.

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4.3 It is agreed among the Parties that the Principal Investigator and the Additional Personnel shall attend the mandatory training session(s) organized in relation with the Clinical Trial.

The Parties agree to inform each other of the Clinical Trial performance and therefore agree to organize and to participate in meetings related thereto.

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The Principal Investigator agrees to take the necessary time to meet with any person duly appointed by the Sponsor/CRO for monitoring the Clinical Trial.

4.4 If, at any time, Institution or Principal Investigator have reason to believe that the Clinical Trial will not be initiated or completed as per the schedule initially anticipated and agreed upon by the Parties, Sponsor's representative/CRO will be advised immediately, in writing, of the reason(s) and length of additional time required to commence or complete work, and this Agreement may be terminated by Sponsor's representative/CRO as provided in Article 14 hereafter.

ARTICLE 5 - OBLIGATIONS OF THE INSTITUTION AND/OR THE PRINCIPAL INVESTIGATOR

5.1 The Institution shall apply its best efforts to retain the services of the Principal Investigator.

In the event that the Principal Investigator leaves the Institution or is otherwise unable or unwilling to continue his/her tasks as Principal Investigator, the Institution shall so inform the Sponsor/CRO by written notice immediately, and the Parties shall apply their best efforts to appoint, within a reasonable time, a mutually acceptable substitute for the resigning Principal Investigator, which replacement shall have a similar background and also knowledge of the Clinical Trial.

Any successor to the Principal Investigator must be approved, in writing, by the Sponsor/CRO and such successor shall be required to agree to all the terms and conditions of the Protocol and this Agreement and to sign each such document as evidence of such agreement (although failure to so sign will not relieve such successor from abiding with all the terms and conditions of the Protocol and this Agreement).

The Institution represents and warrants that it will not use in any capacity, in connection with any services to be performed under this Agreement, any individual who has been debarred pursuant to the notification by Medical Council of India.

The Institution agrees to immediately inform the Sponsor/CRO in writing if any person, including but not limited to the Principal Investigator, who is performing services hereunder is debarred or if any action, suit, claim, investigation or legal or administrative proceeding is pending, or to the best of the Institution's knowledge, is threatened, relating to the debarment of the Institution or any person performing services hereunder.

5.2 The Institution shall ensure that the Principal Investigator and any Additional Personnel conduct the Clinical Trial in accordance with:

(a) The Protocol and all other terms of this Agreement;

(b) All laws and regulations pertaining to the transportation, storage, use, administration and disposal of drugs, vaccines/biologicals, and the conduct of clinical investigations among which the Helsinki Declaration as amended in Edinburgh, Scotland (October 2000), including, but not limited to the Public

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Health Service Act, the Food, Drug and Cosmetic Act of India, with the Good Clinical Practice approved by the Indian Regulatory Authorities.

(c) Any and all Sponsor's/CRO's requirements, directions or instructions, including but not limited to the SOPs;

(d) Those policies, standards, procedures, conventions and techniques that are of a high, recognized and acceptable professional standard in the scientific community, such as GCP;

(e) All applicable laws and regulations.

5.3 The Institution agrees that the Subjects to be involved in the Clinical Trial will be selected pursuant to the criteria set forth in the Protocol and that they will be fully informed of the foreseeable consequences of their inclusion in the Clinical Trial and that they, or if appropriate, their parents/ Legally Acceptable Representatives having authority over them, have given written consent to their inclusion in the Clinical Trial.

Such informed consent shall be obtained by the Principal Investigator using the informed consent form template developed for the Trial Site. The Privacy Rules shall be followed in order to obtain consent from Subjects as required throughout the Clinical Trial.

5.4 The Institution and the Principal Investigator shall have the following record keeping and reporting obligations:

(i) To prepare and maintain complete and accurate written records, accounts, notes, reports and data relating to the Clinical Trial under this Agreement.

(ii) To prepare and submit to the Sponsor's representative, CRO (in a periodic and timely manner during the term of this Agreement) all raw data and other material called for in the Protocol, in the form of properly completed Case Report Forms supplied by the Sponsor, for each Subject. All Case Report Forms and the information and data stored in any electronic database shall be the exclusive property of the Sponsor.

(iii) To retain in a secure facility the essential (including but not limited to the original informed consent form signed by each Subject) and the supporting documents relating to the Clinical Trial during five (5) years. Following this retention period or at any time during this period, if the Institution or the Principal Investigator can no longer retain these elements, the Institution shall inform the Sponsor, the Parties shall discuss in good faith in order to find an alternative solution for the proper archiving of these elements in accordance with the applicable regulations. Subjects' files should be retained as per GCP requirements as defined in the Protocol and in compliance with local regulations. No document shall be destroyed without the prior written permission of the Sponsor.

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5.5 The Principal Investigator shall report any adverse experiences and adverse events observed in the Clinical Trial to the Sponsor/CRO. All adverse experience/event reports

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shall be prepared and collected by the Principal Investigator according to the procedures outlined in the Protocol.

5.6 The Institution and the Principal Investigator shall use their best efforts to complete expeditiously the Clinical Trial in accordance with the time-schedule provided for in the Protocol.

5.7 The Institution shall, on or before the signing date of this Agreement, supply the Sponsor/CRO with a complete list of its Additional Personnel who it anticipates will be involved in carrying out Institution's obligations under this Agreement, specifying the role each individual will play in carrying out these obligations. The Institution agrees to inform the Sponsor/CRO of any changes to such list and train new Additional Personnel to the specificities of the Clinical Trial.

5.8 The Institution and the Principal Investigator agree to inform the Sponsor's representative/CRO of any cooperation or collaboration they would like to undertake regarding a therapeutic/ prophylactic concept similar to the one studied according to the Protocol if such a project would compete with the Clinical Trial. The Sponsor's representative/CRO will be entitled to terminate this Agreement if such a cooperation or collaboration is deemed by the Sponsor's representative/CRO to be incompatible with its interests.

5.9 The Sponsor's representative/CRO registers all its clinical trial protocols on the web site http://ctri.nic.in. If local regulations require the Clinical Trial to be registered locally, the Institution and the Principal Investigator are in charge of doing it and informing the Sponsor. The Sponsor's representative/CRO shall support them by providing the required information.

ARTICLE 6 – TRIAL PRODUCT, EQUIPMENT AND DOCUMENT

6.1 The Trial Product, as well as the documents and the material necessary to conduct the Clinical Trial, as described in the Protocol, shall be supplied free of charge to the Institution by the Sponsor. In certain circumstances, the Sponsor's representative/CRO might instruct the Institution to purchase the Control Product and/or equipment. In such a case, the Sponsor's representative, will reimburse these expenses to the Institution at invoice value (all invoices are requested by the Sponsor's representative, CRO prior to reimbursement).

The Institution shall inform the Sponsor's representative/CRO on or before the signing date of this Agreement of the name and complete address to which the Product shall be shipped by the Sponsor.

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6.2 All the Trial Product, the document, the equipment and the material supplied pursuant to this Agreement shall remain at all times the property of the Sponsor and shall be used only and exclusively pursuant to the Agreement. It is understood that the Trial Product is provided by the Sponsor's for the sole purpose of conducting the Clinical Trial.

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THE SPONSOR'S REPRESENTATIVE MAKES NO WARRANTIES, EXPRESS OR IMPLIED, CONCERNING THE TRIAL PRODUCT OR ITS MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE, OTHER THAN FOR ITS USE IN THIS CLINICAL TRIAL.

All unused doses of Trial Product shall be promptly returned to the Sponsor's representative/CRO upon the completion of the Clinical Trial as directed by the Sponsor, or upon earlier termination of this Agreement, unless written authorization to destroy the Trial Product is given by Sponsor. If authorization to destroy unused Trial Product is previously given in writing, the Institution shall provide the Sponsor's representative/CRO with documentation as to the method of destruction. The Institution shall conform with all laws and regulations pertaining to the disposal of drugs, vaccines/biologicals during any destruction of unused quantities of the Product. Upon delivery, the Institution and the Principal Investigator shall be responsible for any improper administration, storage or handling of the Trial Product and for its use beyond its applicable expiration date.

6.3 If some products among the Investigational Product and/or Control Product were to be recalled, the Principal Investigator and the Institution commit to implement the Sponsor's instructions immediately and to quarantine the product(s) at stake.

ARTICLE 7 - AUDITS

7.1 During the Clinical Trial and for such additional period of time that the records are required to be retained by law or otherwise, it is agreed that representatives of the Sponsor/CRO may arrange with the Principal Investigator or her designee, after having duly informed the Institution respecting at least seven (7) days prior notice:

(i) To examine and audit, at regular business hours, the locations where the Clinical Trial is performed;

(ii) Subject to applicable patient confidentiality considerations, to inspect, audit, and to copy or have copied, all data and work product relating to the Clinical Trial conducted under this Agreement and to inspect and make copies of all data necessary for the Sponsor's representative/CRO to confirm that the Clinical Trial is being conducted in conformance with the Protocol and in compliance with all applicable legal and/or regulatory requirements of any and all Health Authorities; and

(iii) To meet with any person involved in the Clinical Trial's performance.

7.2 The Institution agrees to assist the Sponsor/CRO, to the extent deemed reasonable by the Sponsor/CRO, in facilitating the Sponsor's representatives' examination, inspection, auditing and copying of materials relating to the Clinical Trial and in order to enforce the rights granted to the Sponsor's representative/CRO in this Article 7.

The Principal Investigator and the Institution agree to take any action, as reasonably requested by the Sponsor/CRO to properly correct or address any deficiencies noted

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during any audit and agree to cooperate with the Sponsor's representative/CRO with respect to any action taken to address any such deficiencies.

7.3 If the need arises (or if the need be), the Institution agrees to notify Sponsor/CRO within twenty-four (24) hours in the event that a Health Authority notifies the Institution of a pending inspection/audit. In addition, the Institution will forward to Sponsor/CRO any written communication received as a result of the inspection/audit within twenty-four (24) hours of receipt of such communication and agrees to accept Sponsor's/CRO's assistance in responding to any citations. Such responses shall be made within ten (10) business days of issuance of any citations or within any earlier deadline set by the issuing Health Authority. The Institution shall also provide the Sponsor's representative/CRO with copies of any documents provided to any inspector or auditor. In the event any applicable Health Authority requests or requires any action to be taken to address any citations, the Principal Investigator and the Institution agree, after consultation with the Sponsor/CRO, to take such action as necessary to address such citations, and agree to cooperate with the Sponsor/CRO with respect to any such citation and/or action taken with respect thereto.

ARTICLE 8 - FINANCIAL PROVISIONS

The financial provisions applicable to the Agreement in consideration of the performance of the Clinical Trial are provided for in Schedule A attached hereto.

ARTICLE 9 - CONFIDENTIALITY

9.1 Before and during the course of the Clinical Trial, the Recipient may obtain, or have access to Confidential Information.

Except as expressly set forth in this Article, the Recipient shall each cause its Related Person(s) to keep the Confidential Information confidential, and the Recipient shall not disclose directly or indirectly, and shall cause its Related Persons not to disclose directly or indirectly, any Confidential Information to anyone, except that the foregoing restriction shall not apply to any information disclosed hereunder if such Confidential Information, as reasonably demonstrated by the Recipient:

(i) is generally available to the trade or public or becomes after the time of receipt by the Recipient part of the public domain, other than by reason of any breach or default by the Recipient or any of its Related Persons of a confidentiality obligation under this Agreement;

(ii) was already known to the Recipient at the time of disclosure by the Sponsor/CRO;

(iii) is disclosed to the Recipient or any of its Related Persons by a Third Party who has the right to disclose such information; or

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(iv) based on such person's good faith judgment with the advice of counsel, is otherwise required to be disclosed in compliance with applicable legal requirements to a Health Authority.

Whenever the Recipient becomes aware of any state of facts which would or might result in disclosure of Confidential Information pursuant to subparagraph (iv) above, it shall, if possible, promptly notify the Sponsor's representative/CRO prior to any such disclosure so that the Sponsor's representative/CRO may seek a protective order or other appropriate remedy and/or waive compliance with the provisions of this Agreement.

In any event, if the Recipient is unable to promptly notify the Sponsor's representative/ CRO or if such protective order or other remedy is not obtained, or if the Sponsor's representative/CRO waives compliance with the provisions of this Agreement, the Recipient will furnish only that portion of the information which its counsel directs is legally required and will exercise reasonable efforts to obtain assurance that confidential treatment will be accorded the Confidential Information.

The Sponsor's representative/CRO shall be entitled, in addition to any other right or remedy it may have, at law or in equity, to an injunction, without the posting of any bond or other security except as required by the relevant laws, enjoining or restraining the Recipient and any of its Related Persons from any violation or threatened violation of this Article.

9.2 The Recipient agrees that no Confidential Information shall:

(i) Be used in its own business except as necessary to the fulfillment of the rights and obligations of the Recipient under this Agreement;

(ii) Be disclosed, assigned, licensed, sublicensed, marketed, transferred or loaned, directly or indirectly to any third party other than to an Affiliate or a representative of the Recipient in accordance with the provisions of this Agreement, except as necessary to the fulfillment of the rights and obligations of the Parties under this Agreement;

(iii) Be used or exploited by the Recipient or any of its Related Persons for its or their respective benefit or the benefit of any other relationships with customers of such Party and its Related Persons.

(iv) Be used by the Recipient for obtaining intellectual property rights.

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Without limiting the generality of the foregoing, the Recipient agrees that, it shall not (and shall not permit any of its Related Persons) at any time to use any Confidential Information in the conduct of its business without the prior written consent of the Sponsor/CRO.

The obligations set forth in this Article shall extend to copies, if any, of Confidential Information made by the Recipient and/or its Related Persons and to documents prepared by such persons which embody or contain Confidential Information.

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9.3 The Recipient shall deal with Confidential Information so as to protect it from disclosure with a degree of care not less than that used by it in dealing with its own information intended to remain exclusively within its knowledge and shall take reasonable steps to minimize the risk of disclosure of Confidential Information which shall include, without limitation, ensuring that only their respective Related Persons who have a *bona fide* "need to know" such Confidential Information for purposes permitted or contemplated by this Agreement shall have access thereto.

The Recipient shall notify all of its Related Persons who have access to Confidential Information of its confidentiality and the care therefore required, and shall obtain from any such Related Person an agreement of confidentiality incorporating the restrictions set forth herein.

9.4 The obligations set forth in the present article shall survive the termination of this Agreement for a period of Five (5) years.

9.5 Except as otherwise agreed to by the Parties in writing, the Recipient shall (and shall cause its Related Persons to), within thirty (30) days after the termination of this Agreement, return to the Sponsor's representative/CRO or destroy all documents and tangible items then in its possession which it has received from the Sponsor's representative/CRO or its Related Persons pertaining, referring or relating to the Sponsor's Confidential Information, as well as all copies, summaries, records, descriptions, modifications, and duplications that it, or any of its Related Persons has made from the documents or tangible items received from the Sponsor's representative/CRO or Related Person; provided, however, that the Recipient may retain one copy of each document in its legal files solely to permit the Recipient to continue to comply with its obligations hereunder and, in addition, may upon notice to the Sponsor, retain in its legal files or in the office of outside legal counsel one copy of any document solely for use in any pending legal proceeding to which such document relates.

ARTICLE 10 – INVENTIONS AND PATENTS

The sole and exclusive right to any Inventions shall be the property of the Sponsor. Institution or Principal Investigator will promptly notify Sponsor's representative/CRO in writing of any such Inventions, and at Sponsor's request, and expense, Institution and Principal Investigator will cause to be assigned to Sponsor's representative/CRO all right, title, and interest in and to any such Inventions and provide reasonable assistance to obtain patents including causing the execution of any invention assignment or other documents.

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ARTICLE 11 – DATA, PUBLICATIONS, OTHER RIGHTS

In recognition of the importance of disseminating information relating to any novel or important observations or results that may arise from the Clinical Trial, and understanding that such need must be balanced with the Sponsor's obligations to maintain control over Confidential Information as well as to comply with all appropriate Health Authorities' rules and regulations, the Parties hereby agree to the following:

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11.1 The Institution and the Principal Investigator agree that all research data and results generated during the course of or as a result of the Clinical Trial shall be the property of the Sponsor. The Principal Investigator and the Institution further agree to execute any documents or undertake any further actions requested by the Sponsor's representative/ CRO to evidence transfer of title to such data.

11.2 Subject to the terms and conditions of this Agreement, the Institution and the Principal Investigator have the right to publish or publicly present their results of the Clinical Trial. The Principal Investigator and the Institution agree not to publish or publicly present any interim results of the Clinical Trial without prior review by the Sponsor, as provided below. The Principal Investigator and the Institution further agree to provide ninety (90) days written notice to the Sponsor, including a complete copy of the intended Public Presentation, prior to submission for publication or presentation to permit the Sponsor to review a Public Presentation which reports any results arising out of the Clinical Trial. The Sponsor shall have editorial rights with respect to a Public Presentation and the right to review and comment on the data analysis and presentation to ensure that:

(i) Confidential Information is protected by the provisions contained in Article 11.4 below;
(ii) The information contained in the Public Presentation are accurate; and
(iii) The Public Presentation is fairly balanced and in compliance with applicable Health Authorities' regulations.

If the Parties disagree concerning the accuracy and appropriateness of the data analysis and presentation, and/or confidentiality of Sponsor's Confidential Information, the Institution agrees to meet with Sponsor, prior to submission of a Public Presentation, for the purpose of making good faith efforts to discuss and resolve any such issues or disagreement.

In the event that the Parties cannot resolve their dispute within a period of ninety (90) days, they may refer the matter to an independent adjudicator having expertise in the field of the Clinical Trial selected jointly by them who shall decide the matter. The Parties agree to abide by the adjudicator's decision. The Principal Investigator and Institution agree not to release a Public Presentation until such time as a resolution has been reached, whether by the Parties on their own, or by the adjudicator.

11.3 To the extent that the Institution's participation in the Protocol is a part of a multi-center clinical trial, the Institution and the Principal Investigator agree that an initial Public Presentation of their results shall occur only together with the other sites unless specific written permission is obtained in advance from the Sponsor for Public Presentation of separate results. The Sponsor shall advise as to the implications of timing of any Public Presentation in the event the Clinical Trial is still in progress at sites other than the Principal Investigator's one and any institution or investigator participating in a multi-center clinical trial shall follow the Public Presentation review procedures set forth in Article 11.2 above.

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11.4 No Public Presentation shall contain any Confidential Information. Public Presentation shall be confined to new discoveries and interpretations of scientific fact. At the

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Sponsor's request, the Sponsor shall be acknowledged as one of many or as the sole financial Sponsor, as the case may be, of the Clinical Trial reported in the Public Presentation.

11.5 The Institution and the Principal Investigator shall be aware that a publication or presentation of patentable subject matter prior to filing respective patent application will jeopardize such patent rights. Therefore, if the Sponsor believes there is a patentable subject matter contained in any Public Presentation submitted for review, the Sponsor shall promptly identify such subject matter to the Institution. If the Sponsor requests and at the Sponsor's expense, the Institution and the Principal Investigator shall use their best efforts to assist the Sponsor in filing a patent application covering such subject matter prior to any publication.

Furthermore, in the event that the review of the proposed publications or other public disclosure results in a determination that potentially patentable subject matter would be disclosed, and that such disclosure would be prejudicial to perfecting Sponsor's intellectual property rights, the Principal Investigator or Institution shall delay the publication or public disclosure for an additional ninety (90) days, at Sponsor's request, to allow for filing the necessary patent applications.

ARTICLE 12 – LIABILITY, INDEMNIFICATION AND INSURANCE

12.1 In accordance with Rule 122-DAB of the Drugs & Cosmetics Rules, 1945 in the event of injury to or death of a Subject during the Study, the following shall apply:

(1) In the case of an injury occurring to the Subject, he or she shall be given free medical management as long as required or until it is proved that the injury is not related to the IP (whichever is earlier)

(2) In case the injury occurring to the Subject is related to the Study, such Subject shall also be entitled for financial compensation as determined by the Licensing Authority under the said Rules over and above the expenses incurred on the medical management of the Subject;

(3) In the case of Study related death of the Subject, his/her nominee(s) would be entitled for financial compensation as per the order of the Licensing Authority and the financial compensation will be over and above any expenses incurred on the medical management of the Subject;

(4) The expenses on medical management and financial compensation in the case of Study related injury or death of the Subject shall be borne by the Sponsor;

(5) Any injury or death of the Subject occurring in the Study due to the following reasons shall be considered as Study related injury or death and the Subject or his/her nominee(s), as the case may be will be entitled for financial compensation for such injury or death:

(a) Adverse effect of the Investigational Medicinal Product;

(b) Violation of the Protocol, scientific misconduct or negligence by the Sponsor's Representative, CRO or the Investigator, Provided that if such violation of the

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Protocol, scientific misconduct or negligence is by the Investigator, then the Investigator will be liable to reimburse to the Sponsor Representative the expenses on such medical management and financial compensation that the Sponsor's Representative shall have paid to the Subject or his/her nominee(s), as the case may be;

(c) Failure of the Investigational Medicinal Product to provide intended therapeutic effect;

(d) Use of placebo in a placebo-controlled trial;

(e) Adverse effects due to concomitant medication excluding standard care, necessitated as part of the Protocol;

(f) For injury to a child in-utero because of the participation of parent in the Study;

(g) Any clinical trial procedures involved in the Study."

(6) The Sponsor's representative/CRO shall give an undertaking along with the application for clinical trial permission to the Licensing Authority defined in clause (b) of Rule 21, to provide compensation in the case of clinical trial related injury or death for which subjects are entitled for compensation/

(7) The Sponsor's representative, CRO in case of injury or death occurring to the clinical trial subject, shall make payment for medical management of the subject and also provide financial compensation for the clinical trial related injury or death in the manner as prescribed in Appendix XII.

(8) However, the Sponsor's representative, CRO is liable to pay the medical management fee or compensation, only for those clinical trial related injury or death which happened by or before 28 day from the day of administering the product to the subject.

(9) The Sponsor's representative, CRO shall indemnify, defend and hold harmless the Indemnitee, from and against any demands, claims, actions, proceedings or costs of judgments which may be made or instituted against any of them by reason of personal injury (including death) to any person, resulting from the use of the Product in connection with the Clinical Trial.

Therefore, the Sponsor's representative, CRO shall maintain, at its sole expense, policies of liability insurance. Such insurance policies shall provide broad form contractual liability coverage for the Sponsor's indemnification under this section 12 and shall also provide product liability and clinical trials liability coverage. The minimum amounts of insurance coverage required shall not be construed to create a limit of the Sponsor's liability with respect to its indemnification under this section 12. The Sponsor's representative/CRO shall maintain the aforementioned insurance during the Clinical Trial. This obligation to maintain insurance shall survive the termination of this Agreement. The Sponsor's representative/CRO shall provide the Institution with written evidence of such insurance upon the written request of the Indemnitee.

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12.2 In the event a claim is made or an action is brought against the Institution and/or its trustees and/or its officers and/or its directors and/or its agents and/or its Additional Personnel and/or the Principal Investigator, the Institution and the Principal Investigator shall immediately report it to the Sponsor's representative/CRO and shall assist the Sponsor's representative/CRO and cooperate in the gathering of information with respect to the time, place and other circumstances of the event giving rise to the claim or action and in obtaining the names and addresses of the allegedly injured parties and available witnesses. The Principal Investigator and the Institution agree to cooperate with and to authorize the Sponsor's representative/CRO to carry out the sole management and defense of such claim or action. Neither the Principal Investigator nor the Institution, its trustees, officers or Related Persons shall compromise or settle any claim or action without the prior written approval of the Sponsor.

12.3 Notwithstanding the foregoing, the Sponsor's representative/CRO shall have no indemnification obligation or liability and the Institution and the Principal Investigator shall indemnify, defend and hold harmless the Sponsor, CRO, officers, directors, agents and employees for loss or damage resulting from:

(i) failure of the Institution or the Principal Investigator or the Additional Personnel to adhere to the terms and provisions of the Protocol or any amendments thereto (including but not limited to the Principal Investigator's and the Institution's obligations with regard to adverse event reporting procedures as set forth in this Agreement and the Protocol (and any appendix or attachment to the Protocol), or the Sponsor's written recommendations and instructions relative to the administration and use of any drug substances involved in the Clinical Trial, including but not limited to the Product, any comparative drug and any placebo;

(ii) Failure of the Institution or the Principal Investigator or the Additional Personnel to comply with any applicable Health Authorities' requirements, law, rules or regulations applicable to the performance of its obligations under this Agreement;

(iii) Failure of the Institution or the Principal Investigator or the Additional Personnel to render professional service or to conduct the Clinical Trial in accordance with GCP and current medical practice; or

(iv) Any negligent act or omission or willful misconduct by the Principal Investigator, the Institution, its trustees, officers, directors, or Related Person who rendered services under this Agreement.

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12.4 The Institution shall secure and maintain in full force and effect through the performance of the Clinical Trial (and following termination of the Clinical Trial to cover any claims arising from the Clinical Trial) insurance coverage for:

(i) Medical professional and/or medical malpractice liability (including coverage for the Principal Investigator);
(ii) General liability (including coverage for the Clinical Trial site); and
(iii) Worker's compensation coverage,

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in amounts required by applicable federal, provincial or state laws and appropriate to the conduct of Institution's business activities and the services contemplated by the Clinical Trial.

Upon request of the Sponsor, copies of certificates evidencing such insurance coverage will be made available to the Sponsor's representative/CRO and the Institution shall provide thirty (30) days' prior written notice to the Sponsor's representative/CRO in the event of cancellation or any material change in such insurance.

ARTICLE 13 - TERM

This Agreement shall become effective from the day of last signature and shall remain in full force and effect until completion of the final report of the Clinical Trial.

ARTICLE 14 – TERMINATION AND ENROLLMENT CAP

14.1 The Sponsor's representative/CRO may terminate this Agreement at any time by giving thirty (30) days written notice to the Institution. In the event thirty (30) days is determined by the Institution to be insufficient notice based upon evaluation of risks to enrolled Subject(s) then receiving the Product, the Parties will cooperate to safely withdraw Subjects from the Clinical Trial over a mutually agreeable period of time but in no event shall the Sponsor's obligation to supply the Product hereunder extend beyond a reasonable period. Notwithstanding the foregoing, in the event the Sponsor's representative/CRO believes that immediate termination is necessary due to its evaluation of risks to enrolled Subject(s), the Sponsor's representative/CRO may terminate this Agreement immediately.

The Sponsor's representative/CRO reserves the right not to perform the Clinical Trial. In such a case, the Agreement shall be considered as automatically terminated upon the Sponsor's/CRO's formal notice to both the Institution and the Principal Investigator.

14.2 Notwithstanding any other provision hereof, the Sponsor's representative/CRO shall be entitled to terminate this Agreement for any Material Breach, which shall be defined as:

(i) The Institution and/or the Principal Investigator's failure to comply with their obligations, responsibilities and the terms and conditions of this Agreement including the Protocol;

(ii) The Institution and/or the Principal Investigator's failure to comply with: (a) their obligations for keeping the Sponsor's representative/CRO informed of all necessary and relevant information in connection with the Protocol; (b) any applicable law, rule or regulation relevant to the Clinical Trial; or (c) the work to be performed under this Agreement; or

(iii) A breach by the Institution, the Principal Investigator, or their Related Persons of the confidentiality provisions of this Agreement.

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14.3 Upon termination, for any reason:

(i) The Institution shall return to the Sponsor's representative/CRO all unused materials, including but not limited to, the Product and any clinical supplies (unless written authorization to destroy them is given by the Sponsor/CRO, in which case the Institution shall comply with the applicable provisions of Article 6 hereof);

(ii) Except in the event of termination because of a Material Breach by the Institution, and unless otherwise specified in writing between the Parties, the total sums payable by the Sponsor's representative/CRO pursuant to this Agreement shall be equitably pro-rated for actual work performed in accordance with the Protocol to date of notice of termination with any unexpended portion of funds previously paid by the Sponsor's representative/CRO to the Institution being refunded to the Sponsor/CRO;

(iii) In the event of termination as a result of a Material Breach, the Parties agree to make a good faith effort to reach agreement to compensate the Institution for actual work performed in accordance with the Protocol to date of notice of termination; and

(iv) The Principal Investigator shall return to Sponsor's representative/CRO all Confidential Information (as defined in Article 9 hereof) owned or controlled by the Sponsor's representative/CRO and in the possession of the Institution or its Related Persons;

(v) The Principal Investigator must submit to the Sponsor's representative/CRO the Case Report Forms for all the work in progress as of the effective date of termination.

14.4 The termination of this Agreement shall not relieve either Party of its obligations set out in Sections 5.3, 5.4, 5.5 and Articles 6, 7, 9, 10, 11 and 12 of this Agreement

14.5 Upon receipt of notice of Enrollment Cap, the Institution and the Principal Investigator agree to enroll no further Subjects in the Clinical Trial, and the funds payable pursuant to this Agreement shall be adjusted to reflect only the number of Subjects actually enrolled and the number of visits and technical procedures actually performed prior to receipt of such notice. The Institution and the Principal Investigator, as the case may be, shall refund to Sponsor's representative/CRO any funds received in advance from Sponsor's representative/CRO that are in excess of the adjusted funding.

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ARTICLE 15 – DATA PROTECTION

15.1 It is understood among the Parties that Personal Data will be collected during the course of the Clinical Trial.

The Institution, the Principal Investigator and the Sponsor's representative/CRO agree to comply with all applicable Privacy Rules relating to such Personal Data including, if

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necessary, notification of their Processing activities under this Agreement to the supervisory authority.

The Principal Investigator and the Institution shall take any other steps requested by the Sponsor's representative/CRO in order to enable the Sponsor's representative/CRO to comply with any notification or other obligations applicable to it or its Affiliates under such laws.

Sponsor's representative/CRO represents and affirms to the Institution and the Principal Investigator that it has complied with, and will continue to comply with its obligations under the Privacy Rules applicable to the Clinical Trial.

15.2 The Principal Investigator and the Institution shall:

(a) Ensure that Personal Data collected for the purpose of the Clinical Trial will be processed only in accordance with this Agreement or as otherwise instructed in writing from time to time by the Sponsor.

(b) Ensure that Personal Data are not disclosed or transferred to any Third Party without the prior written consent of the Sponsor, except:

(i) As specifically stated in this Agreement, or

(ii) Where such disclosure or transfer is required by any applicable law, regulation or supervisory authority, in which case the Institution and Principal Investigator shall, wherever possible, notify promptly in writing (and in any event within five days of receipt) the Sponsor's representative/CRO prior to complying with any such request for disclosure or transfer and shall comply with all reasonable directions of the Sponsor's representative/CRO with respect to such disclosure or transfer.

(c) Ensure that Personal Data are accurate and, where necessary, kept updated and use best efforts to ensure that any Personal Data which are inaccurate or incomplete are erased or rectified where appropriate.

(d) Ensure that all appropriate technical and organizational measures are taken to protect Personal Data against accidental or unlawful destruction or accidental loss or alteration, or unauthorized disclosure or access and against all other unlawful forms of Processing.

(e) Notify the Sponsor's representative/CRO in a timely manner of any accidental, unlawful or unauthorized uses or disclosures of Personal Data; ensure that it refers any communication received from a Subject relating to the Subject's rights to access, modify or correct its Personal Data to the Sponsor's representative/CRO and to comply with all instructions of the Sponsor's representative/CRO before responding to such communications; comply with the provisions of this Agreement and the reasonable instructions of the Sponsor's representative/CRO to return, store or destroy the Personal Data.

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15.3 According to Privacy Rules, the Principal Investigator may request access to [his/her] Personal Data or to have [his/her] Personal Data rectified, blocked, erased or destroyed. In such case, the Principal Investigator shall send a written notice to:

Medclin Research Pvt. Ltd.
Acropolis , unit 10/5 , 10th floor
1858/1,Rajdanga Main Road,kol-107

ARTICLE 16 – NOTICES

All notices required or permitted to be given under this Agreement shall be in writing and may be effectively given if delivered personally or if sent by prepaid registered mail, or by facsimile addressed in the case of the Sponsor's representative/CRO to:

Dr. Monjori Mitra
Research Director
Medclin Research Pvt. Ltd.
Acropolis , unit 10/5 , 10th floor
1858/1,Rajdanga Main Road,kol-107

or in the case of the Institution to:

Prof. Rakesh Kapoor
Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences
Raebareli Road, Lucknow 226014, Uttar Pradesh, India

For the Principal Investigator

Dr. Piyali Bhattacharya
Consultant Paediatrician
Sanjay Gandhi Post Graduate Institute of Medical Sciences
Raebareli Road, Lucknow 226014, Uttar Pradesh, India

Any such notice shall be deemed to have been given and received when actually received. Either Party may change its address for service from time to time by notice given in accordance with the foregoing.

ARTICLE 17 - REPRESENTATION

17.1 Representations and Warranties by the Sponsor's representative/CRO: The Sponsor's representative/CRO represents and warrants to the Institution and the Principal Investigator, as of the signing date of the Agreement, and acknowledges that the Institution and the Principal Investigator are relying on such representations and warranties in entering into this Agreement, that:

(a) The Sponsor and CRO are Institutions duly organized and validly existing under the laws of India; and

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(b) The Sponsor and CRO has no commitments or agreements with any Person which interfere with or preclude the diligent and complete fulfillment of their obligations under this Agreement;

(c) The Sponsor and CRO has all necessary corporate power and authority to enter into this Agreement and to carry out its obligations under this Agreement, and the execution, performance and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement have been duly authorized by all necessary corporate action on the part of the Sponsor/CRO;

(d) This Agreement has been duly authorized, executed and delivered by the Sponsor's representative/CRO and constitutes a legal, valid and binding obligation of the Sponsor's representative/CRO enforceable in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, moratorium or similar laws, or general equitable principles, whether considered in an action at law or in equity;

(e) The Sponsor's representative/CRO shall hold harmless the Principal Investigator, the Institution, its employees and representatives against any and all liability arising out of any misrepresentation from its part.

17.2 Representations and Warranties by the Institution: The Institution represents and warrants to the Sponsor's representative/CRO and Principal Investigator, as of the signing date of the Agreement, and acknowledges that the Sponsor's representative/CRO and Principal Investigator are relying on such representations and warranties in entering into this Agreement, that:

(a) The Institution is a corporation duly incorporated and validly existing under the laws of Lucknow

(b) The Institution has no commitments or agreements with any Person which interfere with or preclude the diligent and complete fulfillment of its obligations under this Agreement;

(c) The Institution has all necessary corporate power and authority to enter into this Agreement and to carry out its obligations under this Agreement, and the execution, performance and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement have been duly authorized by all necessary corporate action on the part of the Institution;

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(d) This Agreement has been duly authorized, executed and delivered by the Institution and constitutes a legal, valid and binding obligation of the Institution enforceable in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, moratorium or similar laws, or general equitable principles, whether considered in an action at law or in equity;

(e) The Principal Investigator is an employee of the Institution.

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17.3 Representations by the Principal Investigator: The Principal Investigator represents to the Sponsor's representative/CRO and the Institution, as of the signing date of the Agreement, and acknowledges that the Sponsor's representative/CRO and the Institution are relying on such representations in entering into this Agreement, that Principal Investigator has no commitments or agreements with any Person which interfere with or preclude the diligent and complete fulfillment of her obligations under this Agreement.

ARTICLE 18 – ETHICAL CONDUCT

The Parties will conduct themselves and undertake the arrangements contemplated by this Agreement in a manner which is consistent with good business ethics and all applicable anti-bribery legislation (national and foreign), including but not limited to the OECD Convention dated 17th December 1997 on combating bribery of public officials in international business.

In particular, the Parties will not offer, promise or give any improper pecuniary or other advantage, whether directly or through intermediaries to a public official, for the benefit of that official or of a third party, for the purpose of influencing decision or actions with respect to the subject matter of this Agreement.

Failure to comply with the provisions of this Article 18 will be deemed a material breach of a material provision of this Agreement.

ARTICLE 19 - BENEFIT, ASSIGNMENT & TRANSFER

This Agreement shall benefit and be binding upon all of the Parties hereto, and their respective successors and assigns. This Agreement is concluded by the Sponsor's representative/CRO intuitu personae. Hence the Agreement may not be assigned or transferred, whether directly or indirectly, by any Party without the prior written consent of the other Party, which consent may be reasonably withheld. However, the Sponsor's representative/CRO shall be entitled to assign and transfer to one or more of its Affiliates this Agreement, without the prior written consent of the other Party, with notice thereafter to the other Party.

The Institution and the Principal Investigator shall not be allowed to subcontract totally or partially the obligations the Sponsor's representative/CRO charged them with, without the prior written consent of the Sponsor. In this latter case, the Principal Investigator and the Institution shall be fully responsible for the part of the obligations so subcontracted and warrants to the Sponsor's representative/CRO that such part of the obligations shall be rendered under conditions consistent in all respect with the terms and conditions set forth herein. For sake of clarity, such consent from the Sponsor's representative/CRO will not relieve the Institution and the Principal Investigator from any liability or obligation under this Agreement and Institution and Principal Investigator will remain liable *vis-à-vis* the Sponsor's representative/CRO for the acts, omissions, defaults or negligence of its sub-contractors.

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ARTICLE 20 - LAW

This Agreement shall be governed by and construed in accordance with the laws of the Republic of India, exclusive of its conflicts of laws principles. All and any dispute arising in connection with the interpretation or execution of this Agreement shall be settled by the competent courts of Lucknow
- India.

ARTICLE 21 - PUBLICITY

No Party shall use the name of any other Party (or the name of any of the Sponsor's divisions or Affiliates) for promotional purposes without the prior written consent of the Party whose name is proposed to be used. No news release, publicity or other public announcement, either written or oral, regarding this Agreement or performance hereunder or results arising from the Clinical Trial, shall be made by the Institution or the Principal Investigator without the prior written approval of the Sponsor.

ARTICLE 22 - INDEPENDENT CONTRACTOR

Each Party acknowledges that it is an independent contractor. For greater certainty, the relationship between Sponsor, on the one hand, and Institution and Principal Investigator, on the other hand, shall not constitute a partnership, joint venture or agency. No Party shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which will be binding on the other, without the prior consent of the other Party to do so.

ARTICLE 23 – COUNTERPARTS

This Agreement may be executed in one or more counterparts, which, together, shall constitute one and the same Agreement.

ARTICLE 24 - AGREEMENT MODIFICATIONS

The provisions of this Agreement, may not be altered, amended or modified except by written agreement signed by both Parties.
The Parties acknowledge and agree that the schedule of the present clinical trial agreement may be subject to amendments and/or update and in such a case, the last-dated version approved in written by a representative of all Parties will be considered to be incorporated therein by reference in place of any prior versions.

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47

PHARMAZZ INDIA PRIVATE LIMITED

SITE REVIEW FORM

STUDY PROTOCOL NO.: PMZ-1620/CLINICAL-2.2/2017

A. SITE DETAILS	
Site Name:	Sanjay Gandhi Post Graduate Institute of Medical Sciences
Mailing Address:	Department of Neurology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road,Lucknow-226014
Investigator's Name:	Professor Jayantee Kalita
Telephone No.: 0522-2494167	Fax No.: 0522-2668811
Mobile No.: 09450411673	Email ID: jayanteek@yahoo.com

Select a category, which describe your investigative site?

☒ Government Hospital	☐ Private Hospital	☐ Private Clinic
☐ General Practice	☐ Research Center	☐ University Hospital
☒ Medical College	☐ Others : _____	

B. FACILITIES LOCATED AT YOUR SITE? (CHECK ALL THAT APPLY)		
Emergency facility	☒ Yes ☐ No	
Number of beds	Hospital 60	ICU :12
Deep freezer ☒ -20 °C ☒ -80 °C	☒ Refrigerator	☒ X-Ray
☒ ECG Machine	☒ CT Scan/MRI	☒ Internet connection
☒ Clinical Lab	☒ Fax Machine	☒ Secure Drug Storage Area
☒ Printer & Scanner	☒ STD/ISD Phone	☒ Computer/Laptop
☒ Archival Place for 15 years		

If any other Please Specify:

What will be the mode of patient recruitment for this study?	☒ Hospital database ☒ Electronic database ☒ Site referral network ☐ Others: _____
How many trials you are handling presently as an Investigator?	Currently no
Does the investigator/site agree to allow access to all original source data/documents to sponsor and possibly regulatory authorities for all study subjects?	☒ Yes ☐ No
Availability of Separate Monitoring/Auditing space?	☒ Yes ☐ No

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46

PHARMAZZ INDIA PRIVATE LIMITED
SITE REVIEW FORM
STUDY PROTOCOL NO.: PMZ-1620/CLINICAL-2.2/2017

Do you foresee any logistical issues for conducting this study at your hospital?	☐ Yes	☒ No
Does your hospital have a Local Laboratory?	☒ Yes	☐ No
Name & Address of Laboratory: Department of Pathology, SGPGIMS, Lucknow, Raebareli, Uttar Pradesh-226014.		
Is the Laboratory Accredited?	☒ Yes	☐ No
If Yes, Please specify details of accreditation : ***National Accreditation Board for Testing and Calibration Laboratories***		
C. ETHICS COMMITTEE (EC) INSTITUTIONAL REVIEW BOARD (IRB)		
Do you have DCGI Registered Institutional Ethics Committee (IEC) or Institutional Review Board (IRB)?	☒ Yes	☐ No
If yes, Ethics Committee Name: *Institutional Ethics Committee, Sanjay Gandhi Post Graduate institute of medical sciences SGPGI Bioethics Cell room no 205 1st Floor Administrative Block Raebareli Road Lucknow -226014 Uttar Pradesh India.*		
Registration Number: **ECR/16/Inst/UP/2013/RR-16**		
Address: Sanjay Gandhi Post Graduate institute of medical sciences SGPGI Bioethics Cell room no 205 1st Floor Administrative Block Raebareli Road Lucknow -226014 Uttar Pradesh India.		
Contact Person Name: Member Secretary (Dr. Vinita Agrawal)		
Telephone No.: 0522-2494918	Fax No.: 0522-2668017	
Mobile No.:	Email ID: iec@sgpgi.ac.in	
Fees for EC submission *(if any)* INR: 25,000.00		
Payable To Director ,SGPGIMS, Lucknow		
PAN No. ***AAAJS3913IN***		
Do you have EC SOPs?	☒ Yes	☐ No
Is your EC 'Schedule Y' compliant?	☒ Yes	☐ No
Have you or your site been audited by Regulatory agency? **(If yes)** ☒ DCGI ☐ US-FDA ☐ Sponsor audit Any Other ----------	☐ Yes	☐ No
Frequency of the Ethic committee meetings: At every 3 month		
Submission timeline for EC Dossier before an EC meeting	7_Days	

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	SITE REVIEW FORM
	STUDY PROTOCOL NO.: PMZ-1620/CLINICAL-2.2/2017

Number of copies of EC Dossier required to be submitted	*Hard Copies 7* *Soft Copies 1*
Usual time length between dossier submission and EC approval	15 Day/s
Next EC meeting date	January 2018
ICF languages required for your site:	
Do you foresee any problems with your EC in relation to this study?	☐ **Yes** ☒ **No**
If Yes, Please Specify:	

D. CLINICAL TRIAL AGREEMENT/BUDGET FEASIBILITY

How many partite agreements would be required at your site?	3
Give the name of parties involved in this trial agreement: 1.Principal Investigator's Institute(SGPGIMS) 2. Pharmazz India Private Limited. 3. Patients	
What are the applicable institutional overhead charges at your Institution?	**25 %** ☐ **N/A**

E. ADDITIONAL INFORMATION/QUESTIONS

Please indicate anything further which may impact your ability to participate in this study (impending staff changes, IRB/EC approval complications, subject availability constraints, etc.)

Principal Investigator/Designee: Dr. J. KALITA Professor Dept. of Neurology SGPGIMS, Lucknow

Date: 6/12/17

Kindly provide us your updated signed and dated CV & copy of Medical Registration certificate

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	PHARMAZZ INDIA PRIVATE LIMITED (44)
	FEASIBILITY QUESTIONNAIRE
	STUDY PROTOCOL NO.: PMZ-1620/CLINICAL-2.2/2017

1. DETAILS OF PRINCIPAL INVESTIGATOR	
Investigator's Name: Professor Jayantee Kalita	
Qualification: DM	
Specialization: Neurology	
Site Name: **Department of Neurology, Sanjay Gandhi Post Graduate institute of medical sciences Raebareli Road Lucknow -226014 Uttar Pradesh India**	
Mailing Address: Department of Neurology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow, Uttar Pradesh-226014.	
Telephone No.: 0522-2494167	Fax No.: 0522-2668811
Mobile No.: 8004904630	Email ID: jayanteek@yahoo.com

2. PRIMARY CONTACT PERSON (CRC)	
Name: Professor Usha Kant Misra	
Qualification: DM	
Designation: Professor	
Experience in Clinical trial: 20 years	
Telephone No.: 0522-2494167	Fax No.: 0522-2668811
Mobile No.: 9450653685	Email ID: drukmisra@rediffmail.com
Any Site Management Organization (SMO) affiliated with your site?	☐ Yes ☒ No If yes, please mention the details. ----------

3. STUDY PARTICIPATION

After reviewing the synopsis would you be interested in participating in this study

YES ☒ **NO** ☐ If No, please check the reason and comment as applicable

Subject Recruitment ☐	Ethical Issues ☐	Study Design ☐
Insufficient Time ☐	Inclusion Criteria ☐	Exclusion Criteria ☐
Study Procedure ☐	Insufficient Staff ☐	Others ☐

Comments:

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4. INVESTIGATOR'S EXPERIENCE

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	FEASIBILITY QUESTIONNAIRE
	STUDY PROTOCOL NO.: PMZ-1620/CLINICAL-2.2/2017

a. Do you have any experience of conducting Clinical trial? (if Yes) Number of Domestic trials: 3 Number of Global trials: 4	☒ Yes ☐ No

Details of trials handled ☐ N/A

S. No.	INDICATION	PHASE	ROLE (PI/CO-I)	YEAR
1.	Intravenous autologus bone marrow-derived stem cell therapy for patients with acute ishaemic stroke: A Multi-Institutional	1	CO-PI	2006
2.	STUDY A0081063 entitled "A-13 Week Randomized, Multicenter, Double Blind & Placebo-Controlled, Parallel Group study to Evaluate the Efficacy, Safety and Tolerability of Pregabalin (150-600 mg/day) using a flexible dosing schedule in the treatment of subjects with Central Post-Stroke Pain (CPSP)" by Pfizer.	3	CO-PI	2007
3.	Intravenous autologus bone marrow-derived stem cell therapy for patients with acute ishaemic stroke: A Multi-Institutional	3	CO-PI	2008
4.	STUDY A0081046 entitled "A randomized, comparative, double-blind, parallel-group, multicenter, monotherapy, study of Pregabalin (Lyrica) and Lamotrigine (Lamictal) in patients with newly diagnosed partial seizures" Sponsored by Pfizer	3	CO-PI	2012
5.	STUDY CL3-18886-012 entitled "Prevention of cerebrovascular and cardiovascular Events of ischaemic origin with teRutroban in patients with a history of ischaemic stroke or tRansient ischaeMic stroke-The PERFORM study." Sponsored by Institue De Recherches Internationales Servier (I.R.I.S).	3	CO-PI	2012
6.	Clinical trial to assess the efficacy and safety of TNK-TPA in Acute Ischemic Stroke	3	CO-PI	2017
7.	A Prospective, Multicentric, Randomized, Double Blind, Parallel, Saline Controlled Phase II Clinical Study to Compare the Safety and Efficacy of PMZ-1620 Therapy along with Standard Supportive Care in Subjects of Acute Ischemic Stroke	3	CO-PI	2017

b. Years of clinical research experience as Principal Investigator/Sub-Investigator?	20 years
c. Do you have access to the appropriate patient population required for this study?	☒ Yes ☐ No

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d. Does the site have an adequate clinical and administrative staff to support this study (coordinators, Nurses, Phlebotomists, and other consultants)? (Please mention name and designation below)	☒ Yes ☐ No
1. Number of Nurses and ward boy:60	
e. Please mention details of Co-Investigator for this study: 1. Professor Usha Kant Misra	

5. STUDY SPECIFIC QUESTIONNAIRE

I.	How many patients of Alzheimer's disease you see in a week/month?	4/month
II.	Out of those how many patients are in the age of 45-85 yrs?	All
III.	Out of those how many patient visit the hospital who fall in mild to moderate AD condition?	50%

IV. Please give details of standard treatment/Standard of care followed by you/your site for Alzheimer's disease.

Medical	Surgical	Supportive	Other
Donepezil Mimentine Rivastigmine			

V. Which assessment procedure is used in your hospital (Please tick from the list below).

MMSE	☒
NPI Score	☒
DAD Score	☒
ADAS-Cog	☒
Geriatric Depression Scale	☐

VI. Based on the Inclusion/Exclusion criteria given in the study synopsis, provide your best estimate on subject screening/enrollment per month:

a. Estimated screening per month _4_____

b. Estimated enrollment per month 1_____

VII. Please indicate the total number of Alzheimer's patients of age group 45 to 85 years seen by you during the past 1 year	10
a. Site Load/month	4/mo
b. Investigator Load/month	
VIII. Have you conducted any clinical studies for this indication earlier?	No

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	FEASIBILITY QUESTIONNAIRE
	STUDY PROTOCOL NO.: PMZ-1620/CLINICAL-2.2/2017

IX.	Are you handling any Alzheimer's trial at present?	No
X. XI.	Are there any ongoing clinical trials for thi s indication at your site?	No
XII.	Do you think of any factors in the protocol that may limit the subject recruitment for this study at your site?	No
XIII.	Below facilities available at your site? a. CT ☒ b. MRI ☒ c. Clinical Laboratory ☒ If not, where do you refer your patients for availing above facilities (Please specify below) a. CT---------- b. MRI---------- c. Clinical Laboratory----------	
	Principal Investigator's Signature 6/12/17 Date	

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