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पंजाब PUNJAB
AS 267666

MEMORANDUM OF UNDERSTANDING

BETWEEN

CENTRAL UNIVERSITY OF PUNJAB

AND

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

1. **The Central University of Punjab,** hereinafter referred to as "CUPB" has been established through the Central Universities Act 2009 which received the assent of the President of India on 20th March 2009. Its territorial jurisdiction extends to the whole State of Punjab. This fast growing newly set up Central University at Bathinda in an important link in the recently set up chain of Central Universities created in the educationally backward areas throughout the country. This university is destined to emerge as a premier educational institution with the state of the art infrastructure to provide quality education and research in science and technology as well as humanities and social sciences.

2. **Sanjay Gandhi Postgraduate Institute of Medical Sciences** is a medical Institute under State Legislature Act, located in **Lucknow**, Uttar Pradesh. The institute is on a 550 acres (2.2 km2) residential campus at Raebareli Road, 15 km from the main city. The institute is rated amongst the top medical institutions in the country, delivering state-of-art tertiary medical care, super-specialty teaching, training and

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

research. Dedicated faculty members endeavor to provide quality education, patient care and research and strive to meet the challenges and needs of the society. The institute offers DM, MCh, MD, PhD, Post-Doctoral Fellowships (PDF) and Post-Doctoral Certificate Courses (PDCC), and Senior Residency in various specialties. The Department of Critical Care Medicine, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow hereinafter referred to as "Critical Care Medicine" was established in the year 2002 with an aim to excel inclinical services, teaching & training, as well as basic & clinical research.

This MEMORANDUM OF UNDERSTANDING (MoU) in entered into on this day of _____.

BETWEEN

The Central University of Punjab being represented by its Registrar, having its office at Bathinda, Punjab in India hereinafter referred to as the PARTY OF THE FIRST PART.

AND

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES (SGPGIMS),LUCKNOWbeing represented by its Director, having its office at Lucknow, Uttar Pradeshin India hereinafter referred to as the PARTY OF THE SECOND PART.

WITNESSETH that

WHEREAS, the Party of the First Part is an educational institution of national importance engaged in advancement of teaching and research in several branches of humanities, social sciences, science and languages. Reassuring its resolve and commitment and social responsibilities, towards the neighboring educational Institution needs of the area, adopted the Party of the Second part to help its constituents for the advancement of knowledge and creativity.

Whereas the Party of the 2nd part is a Medical Institution with a vision to provide excellent human resource throughdelivers tertiary medical care, super-specialty teaching, training and research.

WHEREAS both, Party of First Part and the Party of the Second Part with complimentary tasks have come to an understanding to promote cooperation between two organization in the field of education, research and development.

NOW, THEREFORE, IT IS HEREBY MUTUALLY AGREED BY AND BETWEEN THE PARTIES AS FOLLOWS:

1. This MoU is valid for a period of three years to promote the Innovation and research and which can be extendable.

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2. Both the parties will promote cooperation between two organization in the field of education, innovation and research in the field of Sciences, Humanities and Social Sciences.
3. Both the parties will work together to enhance the academic interchange between the two institutions to promote the teaching and research and to promote the standards.
4. The faculty and research scholars of the part one and part two will be mutually available for helping each other with the latest in the research areas. The teachers, staff and students of the institutions will have the liberty to use the facilities– Labs, library, equipment's, playground, Gymnasium, Auditorium etc. of the other party, if available, as per prescribed rules in force.
5. CUPB registered students and faculty under this MoU can use the SGPGI library and the designated laboratories for this purpose, as per prescribed rules in force.
6. The party of the First Part may allocate its students for research guidance and internships to the party of the Second Part. In all such mutually agreed instances, the faculty from First Party shall be the supervisor / guide while the faculty members from Second Party shall act as co-supervisor/co-guide. SEE IF YOU WANT TO ADD THIS
7. They can attend the seminars of the CUPB without any fee.
8. They can mutually invite faculty & research scholars to their Institutions for interaction and for guidance as per the need and availability.
9. They can apply for research funding for collaborating research project on mutually agreeable basis.
10. There will not be any financial liability on either party.
11. Ownership of findings of any joint research shall be vested in both institutions and any publications regarding the same shall only be possible after prior approval from both institutions.
12. Both institutions agree and undertake to keep confidential, at all times, any information and / or data that may be exchanged, acquired and /or shared in connection with the area of cooperation as mentioned above unless otherwise the same information already exists in the public domain.

This MOU can also serve purpose of *Rastriya Aviskaar Abhiyaan* of MHRD through inspiring and motivating the young minds, teachers, and students for research and innovation.

TERMS AND CONDITIONS

1. The MoU shall be deemed to have been automatically rescinded after the expiry of the MoU period, unless renewed for further period as per mutually agreed upon terms at a later stage. It is further agreed that

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SGPGIMS,Lucknow

following the termination of the MoU, both the parties shall refrain from carrying out the balance of the activity agreed upon in this MoU.

2. Either of the parties hitherto shall be entitled to terminate the MoU at any time with valid reasons acceptable in writings to both parties and in such case, the MoU will terminate six months after the date of written notification or date of expiry of the MoU, whichever is earlier. In case of such premature termination of the MoU, all rights and obligations of both parties shall automatically cease except for those covered by written contracts including ongoing collaborative activity that can no longer be cancelled.
3. In case of any dispute that may crop up during execution of MoU, the matter would be settled through arbitration by referring to a committee jointly appointed by both parties.

IN WITNESS WHEREOF, the authorized representatives of both parties have hereinto affixed their signature at Bathinda on the date indicated below:

Registrar
Central University of Punjab

Director
Sanjay Gandhi Postgraduate
Institute of Medical Sciences,
Lucknow.

Date:
Place:

Date:
Place:

Signed in the Presence of

Vice Chancellor
Central University of Punjab

Signed in the Presence of

Director
Sanjay Gandhi Postgraduate Institute
of Medical Sciences, Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

सत्यमेव जयते

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Certificate No.	:	IN-UP86596005778754T
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Second Party	:	Not Applicable
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Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

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MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (hereinafter called MOU) between **Sanjay Gandhi Post Graduate Institute of Medical sciences, Lucknow**, India (herein after called SGPGI) and **Deen Dayal Upadhyaya Gorakhpur University, Gorakhpur** whose address is Civil Lines, Gorakhpur (U.P.) - 273009 India (herein after called "DDUGU") entered into on this .....(day) .....(month)..... (year).

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Executive Registrar
SGPGIMS,Lucknow

Preamble:

Whereas **SGPGI** is a superspeciality hospital, established by Govt. of Uttar Pradesh, as a centre of excellence for providing medical care, education and research of high order and is chartered to function as a university under this state act.

Whereas Deen Dayal Upadhyaya Gorakhpur University (**DDUGU**) is a residential-cum-affiliating State University established in 1957 by the Uttar Pradesh State Universities Act. It is first to be established in Uttar Pradesh after Independence, playing a significant role in imparting holistic education and research to contribute meaningfully to regional and national development for the people of the Eastern region since its inception.

Whereas (**SGPGI**) and (**DDUGU**) are willing to jointly participate in the development of collaborative research, academic exchanges and to explore other avenues for possible collaboration where expertise exists and can be mentored by either or both of them and also to provide higher education opportunities for faculty, support staff and students of SGPGIMS and DDUGU. A coordinator shall be appointed on each side to monitor and ensure progress during the MOU.

Scope of MOU

This MOU will cover the joint efforts of Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, India and Deen Dayal Upadhyaya Gorakhpur University, Gorakhpur in the area of communicable and non-communicable diseases, social health awareness programs, animal model development and collaborate to promote, facilitate and implement cooperation in the following programs and activities.

Furnish full details of the work to be done:

1. **Collaborative Research Programs in specific fields of interest** - SGPGI and DDUGU will jointly identify specific fields to conduct collaborative research programs of mutual interest and benefit to both parties. It should also include technical inputs for development of protocols for collaborative projects.

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Executive Registrar
SGPGIMS,Lucknow

2. **Submission of Joint projects-** Project proposals may be jointly submitted to UGC, SERB, ICMR, DBT, UPDST or any other funding agencies for extramural funding for carrying out further studies of selected project/fields.
3. **Faculty Exchange Programs-** SGPGI and DDUGU wish to develop academic exchanges and cooperation in teaching and research in furtherance of the advancement and dissemination of learning.
4. **Student Exchange Programs-** Exchange programs for students will be explored and conducted accordingly which will be mutually beneficial for both parties.
5. **Sharing of instrumentation facilities and Joint Programs**: Sharing of Instrumentation facility for research in various human diseases and organizing jointly symposia, workshops, scientific conference, and societal health awareness programs in the areas of mutual interest.

Responsibilities of SGPGI

1. SGPGI faculty and scientists will work towards joint projects with faculty members of Departments of Zoology, Biotechnology, Microbiology and Environmental science etc. of DDUGU, on request and subject to mutual using leading research facilities developed and to be developed at SGPGI, Lucknow and DDUGU.

2. The collaborators shall initiate the work after obtaining necessary approval of the research project from Institutional Human Ethics Committee and Institutional Animal Ethics Committee of SGPGI and DDUGU respectively.

3. A student working at SGPGI, Lucknow can be registered for Ph.D. degree at DDU Gorakhpur University provided he qualifies RET and is eligible for Ph.D. registration as per the Ph.D. ordinance of the university. In that case, a faculty member of the department, in which the student is registered, will be the supervisor and the concerned faculty/scientist from SGPGI will be the co-supervisor. In all cases, Ph.D. ordinance of the university will be applicable as and when required.

4. Research students of DDUGU working overlapping areas can do relevant Pre-PhD Course at SGPGI, Lucknow and their credit shall be counted.

5. The faculty and research students of the above-mentioned departments of DDUGU shall be allowed to use library of SGPGI subject to prior permission of the Director. Faculty and Ph.D.

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Executive Registrar
SGPGIMS,Lucknow

students of SGPGI shall likewise be given the library facilities at DDUGU with prior permission of competent authority.

Responsibilities of DDUGU

1. DDUGU will registered the research students for PhD with work place in SGPGI, While registering SGPGI students for PhD degree in DDUGU, the ordinance related to PhD degree of DDUGU will be applicable.

2. DDUGU will provide the place and existing instruments for the work of collaborative projects.

3. Both parties acknowledge the importance of protection of human and animal subjects in any research activity. Matters related to the transfer of biological material should receive prior approval on each side by the competent authority according to the existing rules and regulations of each party.

4. DDUGU will agree to ensure appropriate protection of Intellectual Property Rights generated from such cooperation consistent with their respective laws, rules and regulations and other international agreements to which both parties are signatories.

Administration:

Overall responsibilities of the project will rest with Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, India & Deen Dayal Upadhyaya Gorakhpur University, Gorakhpur.

Financial Arrangements:

Funds for the projects will be distributes according to the mentioned in the applied funding agency-

1. Both parties shall take necessary financial approvals from the competent authority for fulfilling the objectives of the projects and applied for financial support from the funding agency as per utilization.

2. Both parties and their student can visit the collaborating institutes as per requirements of the project, and shall have adequate insurance coverage without any financial liability on each other.

4. Honorarium, TA/DA (if applicable) will be provided to the faculty members/scientists/technical staff of SGPGI, Lucknow and DDUGU, Gorakhpur.

5. Fellowship monitoring will be decided by the competent authority on the basis of activation of the fellowship (if candidates activate their fellowship from SGPGI, Lucknow then it is

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Executive Registrar
SGPGIMS,Lucknow

maintained by SGPGI and if activated in above mentioned departments of DDUGU then University will maintain the fellowship).

Intellectual Property rights:

1. The R & D information generated shall be shared by both the collaborating parties.
2. Any publication shall be by mutual consent of the coordinators.
3. Patents and other benefits, arising out of the project if any, shall be shared between the collaborating parties.
4. For projects identified as having a distinct potential generating know how leading to commercial applications *NRDC (National Research Development Corporation of India) guideline will be followed.

NRDC Guidelines:

1. To bring to notice of the investigator, prospective user of the technology being developed.
2. To do market research about the product and bring out a comprehensive study about the market potential for attending entrepreneur.
3. For effective coordination between the laboratory generating the know how and the entrepreneur.
4. To take such other steps as may facilitate the communication to know how.
5. NRDC will retain 40% of the royalty/permia and the remaining 60% will be sent to the institution generating the know how. The institute may decide the sharing of 40% between the institute and the project investigator team.

Duration of MOU:

This MOU will be force for the period of 05 (years from the date of its signing)

It is further agreed that the Director-SGPGI, Lucknow and Vice-Chancellor, DDUGU, Gorakhpur through periodic meetings will monitor the progress of this MOU. Any change or modification /termination as introduced/suggested by the review committee (Comprising of Director, SGPGI and Vice – Chancellor, DDUGU) will be binding to both the organizations.

Amendments to the MOU:

Amendments if any, before the authorized representative of SGPGI and DDUGU shall make the expiry of this MOU in writing after mutual agreement.

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Executive Registrar
SGPGIMS,Lucknow

Resolution of Dispute:

Any dispute or difference between the collaboration parties shall be amicably resolved by either through mutual consultation or arbitration.

Seal of parties:

In witness therof parties hereto have signed this MOU on the **day, month and year** mentioned herein before.

Parties:

Signed and delivered for and behalf of SGPGI

Signature

Date 18-10-21

Name Prof. R.C. Dhiman

Designation Director, SGPGI

Seal

Signed and delivered for and behalf of DDUGU

Signature

Date 05.10.2021

Name Prof. Ajay Singh

Designation Finance Officer

Seal

Witness

1. U C Ghosh

2.

3.

Witness

1. 5.10.2021
(Yogesh Kumar Mishra)
Estate Officer, DDUGKP
University, GKP

2. 5-10-2021
Dept. of Political Science
D.D.U Gorakhpur University

3.
(Dr. Sushil Kumar)
Assistant Professor
Dept. of Zoology
D.D.U. Gorakhpur University

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Memorandum of Understanding (MOU)

FOR FACILITATING

COLLOBORATIVE SERVICES,TRAINING, EDUCATION AND RESEARCH

Between

Himalayan Institute of Medical Sciences, SRHU,

Dehradun

And

Sanjay Gandhi Post Graduate Institute of Medical Sciences

Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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Principal

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

MEMORANDUM OF UNDERSTANDING (MOU)

This Memorandum of Understanding (MoU) is entered into on this **18th day of September 2021.**

This memorandum of understanding (MOU) is for cooperation in health services, education, training, research and for developing a collaborative arrangement, whereby the Institutions may participate in collaborative teaching, training, research and other agreed activities to further enhance relationship between two Institutions.

This MOU is entered between:

Himalayan Institute of Medical Sciences (HIMS), a constituent medical college of Swami Rama Himalayan University (SRHU) a University established under section 2(f) of UGC Act and enacted vide Uttarakhand Act No. 12 of 2013 having its registered office at Swami Ram Nagar, P.O. Jolly Grant, Dehradun, Uttarakhand, India, 248140, (herein after referred as "HIMS Dehradun"), through its **Principal**, which expression shall, unless repugnant to the context, include its successor, administrators, assigns or legal representatives.

And

Sanjay Gandhi Post Graduate Institute of Medical Sciences situated at Raebareli Road, Lucknow-226014, India (herein after referred as "SGPGI Lucknow"), (The Institute shall be a body corporate and shall function as University established under UP Act. no. 30 of 1983, dated October 13, 1983. Acting through **Director**, which expression shall, unless repugnant to the context, include its successor, administrators, assigns or legal representatives.

Both institutions state that they:

Recognize the value of academic interchange and lively engagement in an national & international scholarly community by members of academic and research institutions.
Discern the significance and importance of collaboration in the pursuit of national & international cooperation and awareness by each institute's interest in and need for establishing and sustaining such cooperative ties.
Confirm the significance of the furthering of knowledge and the creative role of the national & international scholarly communication and collaboration in the development and dissemination of learning and research.

Hence, in the spirit of promoting exchanges between them in all pertinent area of health education, research, and service, both the institutions **agree as follows:**

A. General Objectives

i. To exchange information, articles, reports and teaching materials in order to support the educational programs of each institution in the field of the Professional Competencies (particularly the areas of Communication, Skills, Ethics, Professionalism).

ii. To strengthen and encourage communication and collaboration in education and research between members of the two institutions, particularly with respect to the Professional Competencies.

iii. To stimulate contacts between investigators in health science from the two institutions.

iv. To develop academic projects such as collaborative research, teaching, technical cooperative, evaluation and publication. The human and technical resources which will contribute in designing and operating the program shall be specified from each institution.

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Executive Registrar
SGPGIMS,Lucknow

v. To promote bilateral co-operation in scientific research and education in different faculties involving:
   a. Teaching and exchange of scientific researchers
   b. Organizing lectures, seminars and scientific meetings
   c. Development of projects of common interest
   d. Visits of faculty and students for the mutual benefits of both institutions
   e. Co-operation in conduct of research (except finances).

B. Scholar Exchange and Education Collaboration

i. To develop learning opportunities through courses, seminars workshops, and other means from both institutions to pursue activities related to scholars' academic program, particularly with respect to the development of a Professional Competencies.

ii. To facilitate visit by medical students between institutions vice versa who will assist with the roll-out of the Professional Competencies, as well as participating in clinical electives. In addition, to facilitate visits by students from other related disciplines like nursing.

iii. To facilitate the exchange of health science faculty members and visiting scholars dedicated to participating in teaching and research.

iv. In all cases, the exchange of faculty members and visiting scholars will occur within the regulation of each institution and will take place on an individual basis.

C. Legal Conditions

i. This MOU is a statement of intent and in no way intended to create legal or binding obligation on either Institutions and serves only as a record of the institutions' current intention to enhance the relationship of the Institution going forward. This MoU does not create legally enforceable rights claim, interest, duty, or obligation in favour of either of the party as against other party.

ii All co-operation is on self-finance basis and none of the institutions is obliged to support each other financially for the purpose of this MOU.

iii. The Institutions agree to designate the following person as administrative focal point for any administrative aspects for this MOU:

a) For **HIMS, Dehradun**
Professor Mushtaq Ahmad
Principal
Email: Principal.hims@srhu.edu.in
Ph: 0135-2471220

b) For: **SGPGI Lucknow**
Professor RK Dhiman
Director
Email: director@sgpgi.ac.in
Ph: 0522-2494001/2494129

iv. All students and faculty exchanges will be approved at the departmental and faculty level through the appropriate mechanisms as per defined procedures.

v. For the purpose of coordinating visits, correspondence and projects, exchange visitors will communicate with a counterpart in the institutions where cooperative research or teaching occurs.

Himalayan Institute of Medical Sciences
Principal

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

vi. Before any particular cooperative project or program is initiated, all financial detail shall be negotiated specially allocation to effect by administration authorities. Notwithstanding anything contained in this MOU, each institution will remain responsible for their own initiative in level of finance.

vii. Cooperative projects requiring financial support shall not be initiated in the expectation of support by either institution before such funding has been explicitly agreed to and committed by written consent and a further agreement would be required.

viii. This MOU shall come into effect for a period of five (05) years upon the signature of both parties and shall be renewed with their mutual consent and signature. It may be extended by written agreement of both partners.

ix. In case of any dispute or difference relating to this MOU, both parties agree to resolve the same through mediation before going to arbitration or litigation.

x. Either party may terminate this MOU with six months advance written notice to the other party. Competent courts in Uttarakhand shall have exclusive jurisdiction.

xi. Both parties of this MOU agree to act in good faith and in a spirit of mutual understanding and accommodation to facilitate achievement of goals set under this MOU.

In witness thereof, the parties herein have appended their respective signatures the day and the year above stated:

Signed For and on behalf of **Himalayan Institute of Medical Sciences**, a constituent medical college of SRHU, Dehradun (Uttarakhand), INDIA - 248140	Signed For and on behalf of **Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow** INDIA-226014
Authorized Representative:	Authorised Representative:
Signature:	Signature: .....
Seal:	Seal:
Name: Prof. Mushtaq Ahmad Designation: Principal	Name: Prof. RK Dhiman Designation: Director
Date.....	Date.....
Witness 1:	Witness 1: UC Ghosh
Witness 2:	Witness 2:

DR. GIRISH GUPTA
PROFESSOR & HEAD
DEPARTMENT OF NEONATOLOGY
REGISTRATION NO. 40084

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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Second Party	:	Not Applicable
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Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

ZAKIR HUSSAIN
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MEMORANDOM OF UNDERSTANDING

This agreement is made on ..20th..... day of September....2021

Between

BABASAHEB BHIMRAO AMBEDKAR UNIVERSITY, LUCKNOW

AND

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

on

ACADEMIC AND RESEARCH COLLABORATION AND COOPERATION

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS Lucknow

Statutory Alert:
1. The authenticity of this Stamp certificate should be verified at 'www.shcilestamp.com' or using e-Stamp Mobile App of Stock Holding. Any discrepancy in the details on this Certificate and as available on the website / Mobile App renders it invalid.

All disputes and differences concerning the validity, scope, meaning construction or effect of this MoU or any dispute or disagreement between the parties hereto as to any matter relating to this memorandum which cannot be settled by mutual discussion shall be settle by arbitration by 2 (two) arbitrators, appointed by each parties, in case of difference of opinion between the said two arbitrators to an umpire, who shall be appointed by arbitrators, and any such decision is binding on the parties.

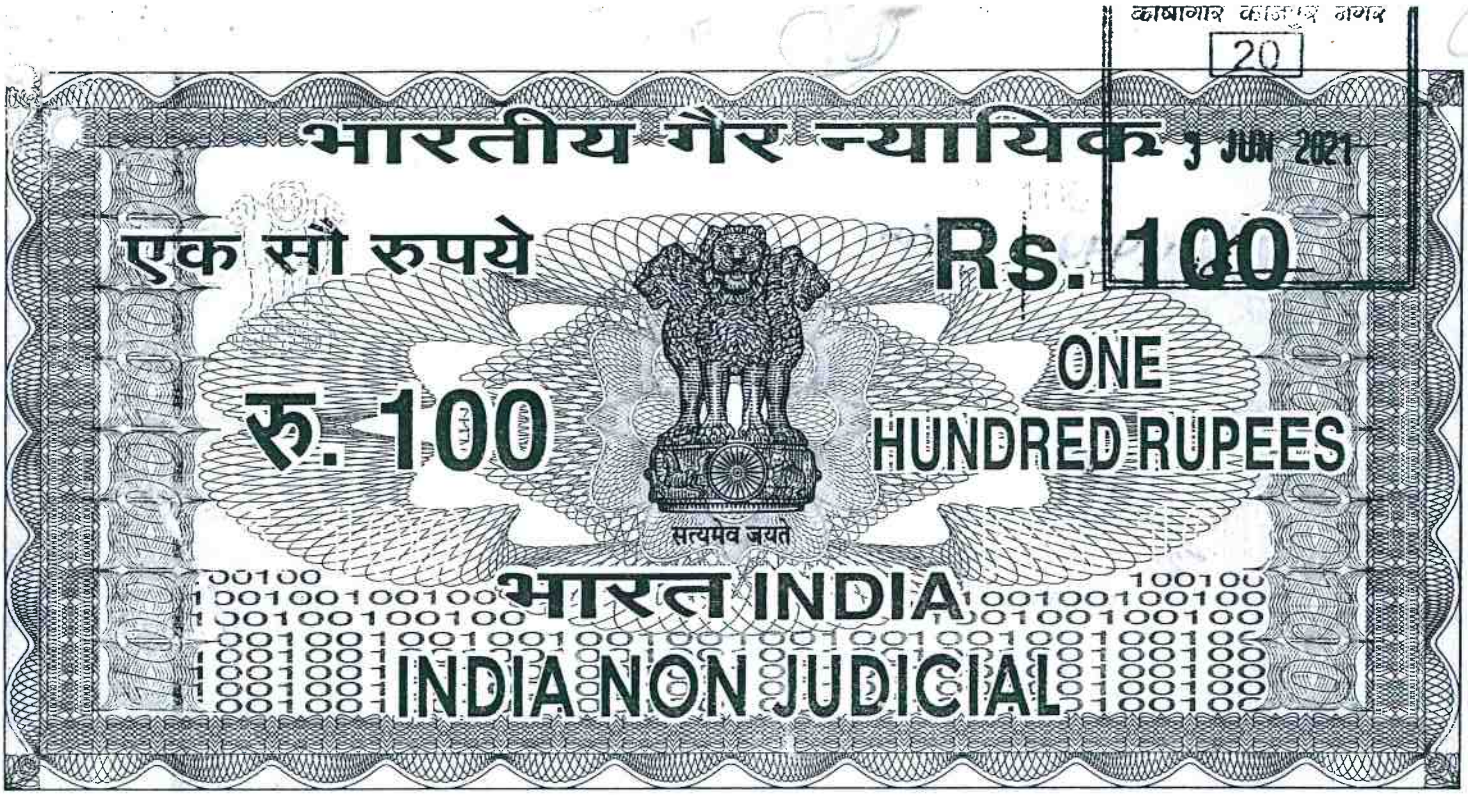
9. The Memorandum of Understanding will be initially for three years in continuation of previous MoU& reviewed thereafter for continuation.

(Dr. R. K. Diman)
Director
SGPGIMS
Raebareli Road
Lucknow

S.G.P.G.I.M. Lucknow (U.P.) India Director

(Prof. Victor Babu)
Registrar
B.B.A. University
Raebareli Road
Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow



उत्तर प्रदेश UTTAR PRADESH FU 356031

Memorandum of Understanding for Research Collaboration

Between

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

And

Indian Institute of Technology Kanpur

This Memorandum of Understanding ("MoU") is effective as of the 29-06-2021 ("Effective Date") by and between **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow (SGPGIMS)** having its office at **Lucknow, Uttar Pradesh,** hereinafter referred to as **SGPGI** which term shall unless is repugnant to the context include its successors, representatives, administrators and permitted assigns of the FIRST PART,

And

Indian Institute of Technology Kanpur, is a body corporate incorporated under the Institutes of Technology Act, 1961 and having its office at P.O. IIT Kanpur, Kalyanpur Kanpur, Uttar Pradesh-208016, India, is a research and educational institution of national importance, hereinafter referred to as "IITK" which term shall unless is repugnant to the context include its successors, representatives, administrators and permitted assigns of the SECOND PART,

Prof. R. K. DHIMAN
Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences
LUCKNOW-226 014, INDIA

DEAN R&D OFFICE
I.I.T. KANPUR

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

The aforesaid institutions are hereinafter referred to individually as the Party and collectively as the Parties.

Introduction

IITK is one of the premier institutes to provide meaningful education, to conduct original research of the highest standard and to provide leadership in technological innovation for the industrial growth of the country. IITK imparts and undertakes cutting-edge research in various areas of science, engineering, design, management, and humanities.

Whereas the SGPGIMS, Lucknow is tertiary care hospital and deemed to be medical university established under State of Uttar Pradesh Act engaged in super specialty medical education & training besides carrying out high level of medical research relevance to society. It has been engaged in Information Technology application research and deployment for over two decades and has established a "School of Telemedicine & Biomedical Informatics" in its campus which has been recognized as a National Resource Center by Ministries of Electronics & Information Technology (MeitY) and Ministry of Health & Family Welfare (MOH&FW), Govt. of India.

The faculty member(s) of IITK involved in this MoU or in any project specific agreement will receive/disclose Confidential Information on behalf of IITK. He / She / They will execute the obligations of non-disclosure of Confidential Information received from **SGPGI**.

The Parties wish to work in the areas of **Telemedicine and Robotics**. The degree of mutual interest is so great that considerable advantage may be gained from their pursuit on a collaborative basis.

NOW THEREFORE IN CONSIDERATION OF THE MUTUAL COVENANTS, CONTAINED HEREIN, THE PARTIES HERETO AGREE AS FOLLOWS.

1. Object:

Both the Parties agree to collaborative in the area of Telemedicine and Robotics with the goal of setting up a center of excellence at IIT Kanpur as given the Annexure. These activities will be carried out in the research areas of mutual interest, on a basis of equality and reciprocity.

The Parties shall seek to promote:

(i) Collaboration in research and development, and consultancy studies in the field of mutual interest,

(iii) The exchange of academic materials and publications,

(iii) Undertaking joint research, submission of joint proposal.

(iv) SGPGI will share the data on which IITK researchers will develop data analytics

(v) SGPGI and IITK will jointly set up many health care kiosks that will give rise to new model of smart health care through the creation of an eco-system - data analytics developed by IITK and medical experts from SGPGI within 5G framework.

(vi) The development of a customized telemedicine system in the Indian context will be a short term goal that will be demonstrated with the help of Government health-care system.

The Parties will work out a specific plan for any activity mentioned above; and mutually discuss the detailed arrangements for collaboration. The terms and conditions for such activity such as

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Sanjay Gandhi Post Graduate
Institute of Medical Sciences

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SGPGIMS,Lucknow

deliverables, funding, developers, intellectual property will be specified in a separate project specific agreement.

2. Intellectual Property Rights:

Ownership of any background intellectual property (including but not limited to confidential information, know-how, patents, copyrights, design rights, rights relating to computer software, and any other industrial or intellectual property rights) shall remain with the Party owning it.

Ownership of any intellectual property (including but not limited to confidential information, know-how, patents, copyrights, design rights, rights relating to computer software, and any other industrial or intellectual property rights) developed during the course of this MoU shall be decided through a separate project specific agreement.

3. Effective date, duration, termination of the MoU:

The MoU shall be effective from the effective date and shall remain in force for a period of Ten (10) years. The Party may extend the term in writing. The MoU may be terminated by either Party by giving a written notice of 60 days to the other Party, mentioning sufficient cause for such termination. However, both the Parties will ensure that the provisions of this MoU shall continue to apply to all activities in progress until their completion. Clauses 3, 5, 6, 7, 8, 9 and 10 shall survive the termination or expiration of this MoU.

4. Confidentiality:

a. Confidential information includes all communication of information disclosed in documentary or tangible form between the Parties, including oral, written and machine-readable form, pertaining to the above which is indicated as confidential. In the case of such information disclosed orally or visually, the Disclosing Party shall confirm in writing the fact and general nature of each disclosure within (30) days after it is made.

b. Confidential information includes information:

1. Disclosed by or on behalf of the Disclosing Party to the Receiving Party,
2. Otherwise learned or ascertained by the Receiving Party from inspection and/or evaluation of sample(s) identified by the Disclosing Party as confidential and provided to the Receiving Party by or on behalf of the Disclosing Party (sample(s)) and/or,
3. Otherwise learned or ascertained by the Receiving Party from the Disclosing Party.

c. The Receiving Party will not disclose confidential information of the Disclosing Party to any other person and use at least the same degree of care to maintain the Information confidential as Receiving Party uses in maintaining as confidential its own confidential Information, but always at least a reasonable degree of care; due diligence will be taken by both the Parties in maintenance of confidential information.

d. The Receiving Party will use the confidential information only for the above mentioned purpose.

e. The Receiving Party will restrict disclosure of the confidential information of the Disclosing Party solely to those employees, subsidiaries, parent and affiliated companies of Receiving Party having a need to know such Information in order to accomplish the purpose stated above.

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f. This MoU imposes no obligations on Receiving Party with respect to any portion of the confidential information received from Disclosing Party which:

1. was known to Receiving Party prior to disclosure by Disclosing Party,
2. is lawfully obtained by Receiving Party from a third party under no obligation of confidentiality,
3. is or becomes generally known or publicly available other than by unauthorized disclosure,
4. is independently developed by Receiving Party,
5. is disclosed by Disclosing Party to a third party without a duty of confidentiality on the third party.
6. is required by law or decree.

g. The confidential information shall remain the sole property of the Disclosing Party.

h. The obligation of non-disclosure of confidential information shall survive for 3 years after expiry/termination of this MoU.

5. No Liability:

Neither Party, nor any of their affiliates nor their or their affiliates respective directors, officers, employees, subcontractors or agents shall be liable to the other Party for any special, incidental, indirect or consequential damages (including, but not limited to, contract, negligence and tort liability) in connection with or arising out of this MoU.

6. Publicity:

Neither Party shall use the name of the other Party or its employees in any advertisement, press release or publicity with reference to this MoU without prior written approval of the other Party, except for necessary governmental disclosures.

7. Independent Contractors:

For the purposes of this MoU, the Parties hereto are independent contractors and nothing contained in this MoU shall be construed to place them in the relationship of partners, principal and agent, employer/employee or joint ventures.

8. Assignment:

This MoU shall not be assigned by either Party without the prior written consent of the other, to any third party. In case of any such assignment, the party taking up the assignment shall succeed to the rights, benefits, titles, duties, interest and obligations and liabilities of the Party making such an assignment under the MoU.

9. Amendment:

Any amendment or variation to this MoU shall be made by a written MoU between the Parties.

10. Arbitration and Governing Law:

This MoU shall be constructed, governed, interpreted and applied in accordance with the laws of India and the courts of Kanpur shall have the exclusive jurisdiction.

The Parties shall attempt in good faith to resolve promptly any dispute arising out of or relating to this MoU by negotiation. If the matter cannot be resolved in the normal course of business, within ten (10) days after the dispute arises, any interested Party shall give the other Party written notice of any such dispute not resolved, after which the dispute shall be referred to the Director, IITK and **Director, SPGCI** who will jointly resolve the dispute in a spirit of independence, mutual respect, and shared

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responsibility. In case an amicable settlement of any disputes arising out of or relating to this MoU is not achieved within thirty (30) days after written notice is received, such dispute shall be referred to arbitration under the Rules of Arbitration and Conciliation Act, 1996 (as amended from time to time), by one (1) sole arbitrator appointed in accordance with said Rules. The seat of the arbitration shall be Kanpur. The arbitration shall be conducted in the English language and the award shall be final and binding upon the Parties. Each Party shall bear its own costs of the arbitration unless the arbitrator otherwise directs.

In witness thereof, the Parties hereto have signed this MoU on the Effective Date mentioned hereinbefore.

For and on behalf of **SGPGI**

Signature

Name Prof R. K. Dhiman

Designation Director

Date S.G.P.G.I.M.S., Lucknow

Witness:

For and on behalf of **IITK**

Signature

अधिष्ठाता
DEAN
अनुसंधान एवं विकास
Research & Development
आई॰ आई॰ टी॰ कानपुर
I. I. T. KANPUR

Name: Prof. A. R. Harish

Designation: Dean of Research and Development

Date:

Witness: Prof. Laxmidhar Behera

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Annexure

Center of Excellence in Telemedicine and Robotics

Telemedicine

The World Health Organization has defined telemedicine as: "The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities"

Four critical elements of an effective telemedicine systems are: 1. It's purpose is to provide clinical support. 2. It is intended to overcome geographical barriers, connecting doctors, health workers and patients who are not in the same physical location. 3. It involves the use of various types of information communication technology such as IoT devices, Sensors, Cloud and Internet. More importantly to create the telepresence of the doctor for a patient in a remote corner without creating any emotional barrier. 4. Its goal is to improve health outcomes.

In India context, we have situations where a child falling sick at night with no doctor and medicine around, a pregnant lady needs regular home check ups, elders and chronic patients need regular check ups for symptoms monitoring or village residents want a second opinion for better healthcare. Although many proof of concepts are already existing, acceptance by users through a proper business model needs following challenges to be sorted out:

1. One such challenge is a complex of human and cultural factors. Some patients and health care-workers resist adopting service models that differ from traditional approaches or indigenous practices, while others lack ICT literacy to use telemedicine approaches effectively.
2. Demonstrating solid business cases to convince policy-makers to embrace and invest in telemedicine.
3. As public and private sectors engage in closer collaboration and become increasingly interdependent in telemedicine, care must be taken to ensure that telemedicine will be deployed intelligently to maximize health services and optimal quality and guarantee that for-profit endeavours do not deprive citizens access to fundamental public health services. Issues pertaining to confidentiality, dignity, and privacy are of ethical concern with respect to the use of ICTs in telemedicine. It is imperative that telemedicine be implemented equitably and to the highest ethical standards, to maintain the dignity of all individuals and ensure that differences in education, language, geographic location, physical and mental ability, age, and sex will not lead to marginalization of care.

Objectives of this CoE

1. Develop cost effective telemedicine systems for different segments considering Indian rural sectors. Liaise with district level administrators for the field testing of the technology.
2. Introduce advance features such as telepresence doctors using concepts such as Avatar.
3. Liaise with start ups, Government and hospital to create a proper business model.

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Robotics in Health Care

Given COVID 2019 situation and beyond, we are going to see pervasiveness of robotics devices for health care. In health care situations, we need robots that can insulate health workers from the patients. We need telepresence robotics that can help nurses and doctors to provide care to patients without creating any emotional barrier. However, these robots need to work along with the humans. They must understand humans through interfaces such as voice, gesture, Brain Computer Interface, and haptics. These robots in some situations must learn to express humanly emotions as well. Such collaborative robots with human in the loop has following two distinct advantages:

1. These robots take guidance from the humans in complex and unknown situations. With human in the loop, we do not have to build fully autonomous systems and hence the effective cost of these devices will drastically come down. Simultaneously these devices can behave even smarter as they would embody human cognition.

2. There is a need to internalize the science of cognition. Robots are active agents that are more amenable to experimentally validate such studies.

Objectives CoE

1. Research in cognitive robotics involving multi-modal human-robot interactions will be given emphasis. The research problems will be identified by having collaborations with some of the renowned medical colleges and hospitals.
2. Robotic Nurse, Brain-wave controlled smart wheel chair, Companion Robots for elderly care, Rehabilitation robots, Robot assisted remote care for injured soldiers in remote location, will be some of the pet projects that will be implemented in this center leading to prototypes at the level of TRL 7.

Robotic Nurse

During a hospital stay, patients interact with nurses the most. They draw blood, check your vital signs, monitor your condition and take care of your hygiene if needed. What if we could design robotic systems with associated intelligence which can assist doctors to provide critical treatments to patients or can be deployed inside the hospital wards to replace health personnel? Such a technology would definitely revolutionize the applications of the modern robots and it would also open up new avenues in health-care application: the robot will be able to help the doctor to maintain social distance from the patients or doctor's assistant in real time; the robots can be deployed in the hospital ward to perform the tasks which are typically done by the nurses or can be used as tele-presence of the doctor to provide the consultation to the patient. However, successful execution of these tasks demands highly intelligent behavior from the robots, which are quite difficult to achieve with the current computational capabilities, numerical algorithms and commercially available robotic systems.
This project aims to solve these problems 1) by designing the necessary algorithms for robots, which will be useful to handle the challenges faced in this dynamic environment, 2) by developing intelligent motion planning, 3D localization / navigation for desired task execution and 3) by designing necessary grippers/hardware which are sometimes task specific. Robotic nurses will help carry this burden of a nurse while being monitored by the nurse/doctor. They will be designed to be able to carry out repetitive and monotonous tasks being guided remotely by the Nurse/Doctor. Using Avatar platform,

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they can express their care and empathy while effectively insulating health care professionals from the patients.

Brain Wave Controlled Wheel Chair (BCW)

Stroke patients and motor neuron patients are faced with a life quality devoid of autonomy, ease of communication and social interaction and entertainment. A person with lower limb disability is forced to use a wheelchair. In a traditional wheelchair the user spends time in a seated position most of the time. This gives rise to many physical as well as mental health related issues such as painful lesions on parts of the body, accumulation of pressure points leading to pressure sores, reduced blood circulation, and high dependence on other people for basic needs. We propose solutions to this problem by providing sensitive, flexible, easily calibratable mechanisms in the wheelchair to aid the MND subject to stand. This research work is aimed at developing brain computer interface (BCI) based human machine interface (HMI) that will enable these patients independently to perform their daily activities i.e. moving in a wheelchair to drink coffee and read a book etc. Last, but not the least it will also lead to activity dependent brain plasticity of the patients. The objective is to build a "cost-effective robotic wheelchair with bio-signal enabled control for motor neuron and stroke patients including elderly care". MND patients are not able to use devices like joysticks or buttons. Our goal is to develop a system usable in hospitals and homes with little hardware changes, which can help these people regain maneuverability. A proper brain computer interface system involves pre-processing EEG signal as these types of bio-signals are embedded in a kind of unknown stochastic noise of non-stationary type as well as classification of these processed signals. Algorithm based on recurrent quantum neural network has got significant attention from the researchers worldwide. Besides working on motor-imagery based deciphering EEG signal, hybrid models consisting of P300, SSVEP and MI needs to be developed to create a robust BCI system.

Cognitive Imitation Learning and Tele-Presence Mobile Manipulation.

Humans are gifted with the ability to adapt in uncertain and dynamic situations while performing a complex task using the a priori basic skills with little or no knowledge of the situations. They generalize and perform novel motions based on their previously learned motor skills. In contrast, current robots can only work efficiently in structured environments separated from humans and are limited to a small number of predefined tasks. The task is hard coded by a human expert after careful analysis of a robot's workspace. Thus, robots are still not able to adapt their skills to novel situations or to learn new motor tasks in real time. Issac Asimov envisioned robots as companions in the domestic environment, workers in automated commerce industries and soldiers in war. The solution to this problem is to learn new motor skills autonomously using prior learned basic skills and improve them over time. This poses an interesting scientific problem: can the robot observe humans doing such tasks and then imitate? Additionally, can we program the robot to exploit the knowledge of its own embodiment and dynamically adapt to moving obstacles, or people working in the same workspace? In this context, learning motor skills through human demonstrations needs to leverage prior information about the objects being picked, robot's movement capabilities and exploit abstract representation of the task that allows generalizing the learnt skill to novel situations. The robotic arm systems with a mobile base considered in this proposal has several redundant degrees of freedom and is equipped with depth-sensing camera to operate in an unstructured environment as well as distinctly identify, reach and manipulate different objects. Using these demonstrator platforms, our objective is to increase robustness and adaptability of autonomous solutions to robotic applications by addressing the following scientific goals:

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1. Represent the human demonstrations in a scalable, alternate relational space, that will allow us to transfer the task to heterogeneous robots robustly
2. Exploit offline computation to achieve fast, robust and collision-free motion planning in a dynamically changing environment
3. Enable robots to acquire visual servoing capabilities to reach any target and manipulate different objects
4. Equip the sensing system to visually perceive its unstructured workspace repeatedly and robustly
5. Write software that will allow us to learn, and transfer these skills across various robotic platforms, minimizing the platform-specific setup
6. In the context of various complex robotic automation, our techniques will be validated through mock-ups. We will use metrics such as success rate, accuracy, amount of demonstration data needed, motion power efficiency and runtime speed.

Most past work on robotic imitation learning has focused on having a robot literally copy/duplicate the human demonstrator's actions without any deeper "understanding" of the demonstrator's goals and intentions. In this context, the primary overall goal of this research project is to create and critically evaluate a general-purpose neurocognitive architecture for imitation learning by a semi-autonomous system. These learned skills shall be transferred to teleoperated robot using transfer learning framework.

Telepresence and Teleaction System for Robot Assisted Dentistry

In recent times, telepresence and teleaction (TPTA) systems have gained a lot of attention in the research community because of its many applications in various fields. TPTA systems allow a user to be present and active in a remote environment. Telemedicine (i.e., tele-diagnostics as well as tele-surgery) is one of its main applications. In hospitals, nurses typically spend a substantial amount of time with the patients to fulfil various needs such as, giving medicines or foods, checking vitals of the patients or responding to other requests from the patients. Also, the doctors are required to visit each patient to check their test reports, understand their complaints and symptoms while interacting personally with them. This poses risks to the nurses/health workers/doctors while treating patients with contagious diseases such as COVID-19 infection which has become a pandemic in present days. This kind of risk can be mitigated by introducing tele-presence robots between patients and health workers/doctors and thereby keeping the presence of the health personnel in the isolation ward at minimum level.

A typical telemedicine system (i.e., TPTA system) will consist of a human system interface connected to an operator, a communication medium, and /tele-robot as shown in Fig. WP3.1.1. The human system interface has input devices for position and orientation sensing, and output devices for displaying multiple modalities (i.e., vision, auditory, haptics, etc.). An operator is connected with the human system interface and commands the position/velocity to the teleoperator while observing the remote environment through the multi-modal feedback. The communication medium is used to transport the multimedia streams bidirectionally. Such TPTA systems will be developed for dentistry and will be further extended to other healthcare applications.

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CLINICAL REGISTRY AGREEMENT
(SITE)

This Tri-Partite Agreement ("the Agreement") is made on this 26th Day of Jul, 2022 ("Effective Date") at New Delhi.

Protocol Title : SHOCK/TL/R-2021-01: A Prospective, Observational, Single Arm, Multicenter Registry to evaluate clinical outcomes of the Shockwave Coronary Intravascular Lithotripsy (IVL) followed by stent implantation in Calcified Coronary Arteries in Real World Indian Patient Population.

Medical Research Asia Pacific Pvt. Ltd. Faridabad

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SGPGIMS,Lucknow

Statutory Alert:
1. The authenticity of this Stamp certificate should be verified at 'www.shcilestamp.com' or using e-Stamp Mobile App of Stock Holding. Any discrepancy in the details on this Certificate and as available on the website / Mobile App 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.

(44)

BY AND BETWEEN

Translumina Therapeutics LLP, having its Registered Office at, Ground Floor, Metro Tower, Local Shopping Complex, MOR Land, New Rajinder Nagar, New Delhi – 110060, India, Phone: 91-11- 2874 (hereinafter referred to as **"Sponsor")** have delegated the above mentioned registry **to CRO viz. JSS Medical Research Asia Pacific Pvt. Ltd.**

Sponsor has contracted JSS Medical Research Asia Pacific Private Limited, having its registered office at corporate Head Office at Tower 2 ,1st South wing Floor, L & T Business Park, 6th Floor, Vatika Mindscapes, (Tower B), Plot 12/4, Sector 27D, Delhi Mathura Road, Near Saraj Khwaja Metro Station ,Faridabad-121003, as CRO (Hereinafter referred to as "**CRO**") to coordinate and/or perform activities on behalf of the Sponsor, required for the conduct of the Registry and for the purposes of this Agreement of the **FirstPart**

AND

Sanjay Gandhi Post Gradute Institute of Medical Sciences, New PMSSY Rd, Raibareli Rd, Lucknow, Uttar Pradesh 226014 (hereinafter referred to as **"Institution or site"),** which expression shall, unless repugnant to the context or meaning thereof shall be deemed to mean and include its affiliates and permitted assigns), **of the Second Part**

AND

Dr. Aditya Kapoor, DM (Cardiology) working as a Professor & Head (Cardiology) at Sanjay Gandhi Post Gradute Institute of Medical Sciences, New PMSSY Rd, Raibareli Rd, Lucknow, Uttar Pradesh 226014 (hereinafter referred to as "**Site Investigator")** which expression shall, unless repugnant to context or meaning thereof shall be deemed to mean and include its successors and assigns **of the Third Part**

The CRO, Institution and Site Investigator are henceforth referred to individually as and collectively as "Parties".

AND WHEREAS, the Institution represents and warrants that it is equipped to undertake the Registry along with the Purpose as envisaged in this Agreement and accordingly has the requisite experience and expertise for the above said.

Now, therefore, in consideration of the premises and the mutual promises and covenants expressed herein, Sponsor represented through its Lead Principal Investigator and/or CRO, the Site and/or the Site Investigator, hereby agrees to conduct the Registry on the following terms and conditions.

1. RULES FOR INTERPRETING THIS AGREEMENT

Headings are for convenience only, and do not affect interpretation. The following rules also apply in interpreting this Agreement, except where the context makes it clear that a rule is not intended to apply.

(a) reference to any statute, regulation, proclamation, ordinance, by-law, or guideline includes all statutes, regulations, proclamations, ordinances, by-laws or guidelines varying, consolidating or replacing them and a reference to a statute includes all regulations, proclamations, ordinances, by-laws or guidelines issued under that statute.

(b) Words importing the singular include the plural and vice versa and reference to one gender includes all genders.

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(c) a reference to a document or agreement including this Agreement includes a reference to that document or agreement as amended, supplemented, varied, or replaced from time to time.

(d) Where a word or phrase is given particular meaning, other parts of the speech or grammatical forms of that word or phrase have corresponding meanings.

(e) The whole and/or part of a recital or annexure forms part of this Agreement; and

(f) A reference to an individual or person includes a corporation, partnership, joint venture, association, authority, state or government and vice versa.

2. CONDUCT OF THE REGISTRY

2.1 The Site Investigator shall conduct the Registry at the Site according to the Registry protocol, the applicable laws and regulations of India, this Agreement, IRB/ IEC approved written instructions of CRO with respect to the Registry and terms of approval of the IRB/IEC ("**Institution Review Board/ Institutional Ethics Committee**").

2.2 The protocol will be considered final following approval by the IRB/IEC. Any amendments in the Protocol may be carried out by the Site Investigator only after written consent of assigned CRO on behalf of lead investigator or as recommended by IRB/IEC.

2.3 In the event of a participant's medical emergency, the site Investigator, in all his prudence and due diligence deems it absolutely necessary, may, to that extent, cause and/or effectuate improvisations to the Protocol. The Site Investigator must immediately thereafter notify, in writing, the Sponsor, CRO, IRB/IEC of the above said subject to the terms and conditions of this Agreement and as per the regulatory timelines or as mentioned in the respective EC SOP.

2.4 Site Investigator shall fully comply with the SAE reporting provisions of the Protocol and all applicable Regulations and shall keep the IRB/IEC notified of the same.

2.5 The Site Investigator/Site will ensure that Eligible Patients (as per registry protocol) sign the written patient information sheet and informed consent form as provided by the CRO and approved and cleared by the respective IRB/IEC. The Site Investigator/Site will maintain a signed original of the consent form along with Patient's records in site master file.

2.6 Site Investigator shall maintain a Site master file which shall include all details about the conduct of the Registry including without limitation approvals of the IRB/IEC, final approved Protocol, consent forms, amendments to the above, correspondence, log of all site visits. Such Site master file will be maintained and retained as per ICH GCP requirements and all applicable Regulations. Site Investigator will, at CRO cost, retain the Site trial master and all Registry records in appropriate storage conditions, either at the Site or at a third-party location for a period of 2 years after Site Closeout. Site Investigator will contact CRO at least thirty (30) days before the planned destruction of any or all the Site master file, at which time CRO may request Site Investigator to deliver such records to CRO or its designee at Sponsor's cost. Site Investigator will notify lead investigator through CRO (if during the term of this Agreement) promptly in writing of any accidental loss or destruction of Registry records.

3. COVENANTS OF THE PARTIES

3.1 The Site and the Site Investigator undertake this Registry in furtherance of their goal of seeking data collection and to evaluate clinical outcomes of the Shockwave Coronary Intravascular Lithotripsy (IVL) C2 Coronary Catheter System in Calcified Coronary Arteries in Real World Indian Population and furthering their task and objectives as a research site and medical interventional center.

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3.2 Each Party warrants that it has power and authority to enter into and perform this Agreement and the Registry and services contemplated by this Agreement and its entry into, and performance of this Agreement and the acts contemplated by it, do not constitute a breach of any obligation or default of any other agreement/arrangement by which it is bound or of any applicable law, regulation or policy.

3.3 Each Party warrants that the person executing this Agreement on its behalf is duly authorized to do so and that nothing contained herein conflicts with any of the provisions of the Memorandum and Articles of Association or similar or other documents relating to the incorporation or of the rules and regulations governing the party.

3.4 That without prejudice to the terms and conditions of this Agreement, the Sponsor and/or CRO have in no manner whatsoever any vested interest/right in the results arising out of or in connection with the Registry.

3.5 It is agreed and understood that funding of the Registry in furtherance to the Purpose of this Agreement, by the Sponsor, is in no manner whatsoever, an act of guarantee with regard to the nature and extent of the outcome of the research registry.

3.6 The Site/ Site Investigator warrant that they have obtained all internal consents and approvals to carry out the Registry at the Site as per the Protocol.

3.7 The Site/ Site Investigator shall ensure that in the event of a temporary absence of the Site Investigator, a duly nominated and authorized substitute in the capacity of a 'Sub-Site Investigator' shall perform the functions of the Site Investigator. Further that during the period of such temporary absence of the Site Investigator, all obligations and representations of the Site Investigator under this Agreement shall continue to vest in the Site Investigator. That further such nomination/authorization will be done with the prior written approval of the Sponsor and/or CRO. If however a permanent substitution (replacement of site investigator) is required it will be notified to Sponsor and/or CRO who shall send a written approval only after consulting with the Investigator, otherwise the Registry will be suspended, till a replacement is found.

3.8 No Party hereto shall use the name of another Party hereto or the Sponsor either expressly or by implication in any news or publicity release, policy recommendation or commercial purpose without the express written approval of that Party or the Sponsor, as the case may be. Nothing herein shall be construed as a prohibition on the publication rights of the Sponsor/CRO.

4. MONITORING AND REPORTING

4.1 As per the Protocol, Site/ Site Investigator shall report any SAE suffered by a Patient during the Registry, whether or not causally related to the registry or Patient's participation in the Registry, promptly (within 48 hours) to CRO describing the circumstances under which the SAE occurred, and the remedies applied. Site/ Site Investigator shall follow-up such immediate report by sending a written report to Sponsor.

4.2 If in the medical judgment of the Site Investigator alternatives on or deviations from the Protocol are required due to a medical emergency, the alternatives and / or deviations and reasons for their use, will be documented and be forwarded to CRO at the earliest possible occasion following the occurrence of any such event, within two (02) days.

4.3 The Site/ Site Investigator shall notify CRO promptly if any Regulatory Authority requests permission to inspect the Site/ Site Investigator facilities, records regarding the Registry and shall permit such Regulatory Authority to conduct such inspection in accordance with and to the extent as permissible in law.. If the inspection occurs than the Site/ Site Investigator shall provide CRO with all materials, correspondence, statements, forms and records received from or exchanged with the Regulatory Authorities.

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4.4 Qualified personnel from the CRO (or their representatives) may call on Site periodically at any time during any working day convenient to all parties concerned to monitor and/or audit the Registry and ask procedural questions, inspect records and documents, which the Site/ Site Investigator will provide access to. Institution will make Registry records available for the CRO, only as far as permitted under the Protocol and in accordance with internal standard operating policies of the Institution and the requirements made by the IRB/IEC.

Furthermore, such records can only be made available as far as permitted and/or required by applicable Regulations including but not limited to the legislation regarding the privacy of persons and the protection of personal data.

4.5 If in accordance with Regulations, the facilities at the Site are determined as being inadequate for the purposes of the Registry or not as per the Protocol, and the Site/ Site Investigator do not remedy such inadequacies upon notice to them from either Sponsor, then Sponsor may in its discretion terminate this Agreement or refuse to commence or continue the Registry.

5. RECORDING AND PUBLICATION OF RESULTS

5.1 It is understood by all the Parties that the final report of the Registry is a scientific report. The report and analysis required to be submitted as per Regulations will be drafted by and under the full responsibility of Sponsor.

5.2 Site/ Site Investigator will report the findings of the Registry to CRO in the form of Registry reports, to be submitted to CRO at such stages or intervals as set out in the Protocol (including for instance the progress and the number of included patients) and/or as further agreed between the Parties.

5.3 The Parties acknowledge that Sponsor shall have the right to publish and present the results of the Registry. Sponsor shall take into account that these results represent a joint effort among Sponsor, lead investigator of registry, the Site and Site Investigator. Nothing in such publications shall contain any confidential information/material related to the Parties. unless otherwise agreed in writing by abd between the Parties. Sponsor shall mention the Site Investigator of the Site in a footnote in the manuscript as a member of the Registry.

5.4 The Site Investigator/Site shall not publish and present the results of the Registry unless approved or consented by the sponsor and steering committee members.

5.5 Sponsor shall retain ownership of all original CRFs, data, analyses and reports that result from the Registry.

6. INTELLECTUAL PROPERTY RIGHTS

6.1 All rights, title and interest including, but not limited to, all Intellectual Property Rights of any nature whatsoever in the Registry, and all materials, data, reports and information connected thereto shall remain the sole and exclusive property of Sponsor and Site/ Site Investigator shall take all reasonable steps to protect such rights and intellectual property as and when required by the Sponsor and or CRO.

6.2 Any information, inventions or discoveries (whether patentable, copyrightable or not), innovations, communications and reports (collectively, "Inventions") conceived, reduced to practice, made or developed by Site/ Site Investigator as a result of conducting the Registry shall be promptly disclosed to Sponsor and shall be the sole property of Sponsor.

6.3 All data supplied by Sponsor/ lead investigator/CRO to the Site and Site Investigator, and all data generated in the conduction of the Registry, (collectively, "Data") shall be and remain the absolute and exclusive property of Sponsor. All copy rights and other rights of intellectual and industrial property with regard to the Data shall be vested in Sponsor.

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6.4 Site/ Site Investigator hereby assign to Sponsor all of their rights, title and interest in and to the Inventions and Data and further agree, upon request by Sponsor and at Sponsor's expense, to execute such documents and to take such other actions as Sponsor deems necessary or appropriate to affect such assignment and to obtain patent or other proprietary protection in Sponsor's name covering any of the foregoing.

7. FEE AND COMPENSATION

7.1 In consideration for the Registry, the Site will be paid fee/compensation in accordance with the approved payment rates detailed in the budget proposal attached hereto as **Exhibit B** and in accordance with the payment milestones mentioned therein (the "Payment Schedule"). The consideration mentioned under Exhibit B is the total consideration and includes the consideration for purchase of any equipment, infrastructure, admin overheads or hiring of any manpower required, if any, in connection with the Registry. The Payment Schedule may be modified only upon the prior written consent of Sponsor. Non-emergency additional tests or services (tests or services not required by the Protocol or performed in excess of Protocol requirements) shall not be compensated hereunder unless the written consent of Sponsor has been obtained prior to the administration of such tests or services.

7.2 In the event of Site Investigator recruiting more or less than minimum number of eligible patients, the consideration for the services will be pro-rated according to the actual number of Eligible Patients enrolled as per the agreed per patient fee which further will be limited on actual work done say number of visits completed by an enrolled patient.

7.3 Upon completion or termination of the Registry, the Site/ Site Investigator agrees to provide written acknowledgement to the CRO that all work requested under this Agreement has been completed and all monies due have been received. In any event, acceptance of payments as "final" constitutes such acknowledgement.

7.4 Sponsor further agrees to reimburse the Site for the actual cost of diagnostic procedures and medical treatment necessary to treat a Patient injury related to the Registry, subject to adjudication by clinical events committee and confirmation that the event is a device related injury or death. Patient injury means harm or loss that occurs to an individual as a result of participation in research, which would not occur otherwise in standard clinical practice, irrespective of the manner in which it has occurred, and is only limited to adverse events and serious adverse events related to the subject's participation in the registry. There is no provision for medical management and /or compensation for events including serious events or death which are listed in the Instructions for Use, however, reasonable financial support will be provided to the Site and Site Investigator for medical management and compensation for the device related injury or death as awarded by the IEC as per applicable laws and regulations, subject to adjudication by clinical events committee and confirmation that the event is a device related injury or death.

8. TERM AND TERMINATION

8.1 The Registry will be deemed to be concluded on the day when the final and complete report of the Registry is sent by the Site Investigator to the CRO.

8.2 The Parties have agreed that all reasonable efforts will be made to complete the Registry within the mutually agreed period, unless agreed otherwise explicitly between Parties.

8.3 The Registry and this Agreement may be terminated by prior written notice of 30 (thirty) days from Sponsor to Site/ Site Investigator, for any of following reasons but not limited to these:

a. Notification by Sponsor to terminate the Registry.
b. Notification by an IRB/IEC to terminate the Registry with relevant report.

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c. Determination by Sponsor that Site Investigator is not performing the Registry as required in the Protocol.
d. Failure of the Site Investigator/ Site to provide access to any and all original medical records necessary to verify entries on Registry CRF's
e. Failure of Site Investigator/Site to comply with all Regulations
f. Unauthorized replacement of Site Investigator.
g. CRFs provided to Site Investigator for use in the registry, are not completed and forwarded to CRO, within the timelines prescribed in the Protocol.
h. Failure of Site Investigator/Site to enroll patients

Immediately upon receipt of a notice of termination, Site Investigator shall cease entering new patients into the Registry, cease conducting procedures to the extent medically permissible on the existing subjects already entered into the Registry and shall initiate the process of their safe withdrawal from the Registry as per the prevailing medical standard and Site Investigator's medical judgment.

8.4 The Registry may be suspended by written notice from Site/ Site Investigator to CRO, with immediate effect, if in the Site Investigator's reasonable medical opinion for such suspension is necessary to protect patient safety. Promptly after CRO's receipt of such notice, representatives of the Parties and CRO shall meet (in person or via teleconference) to discuss in good faith Site Investigator's concerns and an appropriate resolution to such concerns, which may include mutual termination of the Registry and this Agreement upon discussion with the Sponsor.

8.5 The Registry and this Agreement may be terminated by a prior written notice of 30 (thirty) days from the Site/ Site Investigator to CRO if CRO commits any material breach of this Agreement which it does not remedy within 30 days of receipt of written notice from the Site/ Site Investigator specifying the breach and requiring remedy; provided that Site/ Site Investigator shall not be entitled to serve such notice of termination until (i) Site/ Site Investigator has notified Sponsor in writing that CRO has failed to remedy the specified breach within such 30 day period and (ii) either the breach has been remedied or this Agreement has been assigned to Sponsor within 30 days of Sponsor's receipt of such notice from Site/ Site Investigator.

8.6 In the event of termination, any funds not due but already paid shall be returned to Sponsor by the Site.

8.7 Upon completion or termination of the Registry," **Director SGPGI Research Account**" (Payee name) agrees to provide written acknowledgement to CRO that all work requested under this Agreement has been completed and all pending payments have been received. In any event, acceptance of the payments as "final" constitutes such acknowledgement. At the time of termination, a detailed account of work completed by site as per clause 8.3 will be prepared and any balance payment to be made to the site, will be done by sponsor. In case, site has received excess money that amount shall be remitted by the Institution to the Sponsor.

9. INDEMNITY AND INSURANCE

9.1 Sponsor shall indemnify, defend and hold harmless the Site Investigator, Institution, Directors, Co-investigator, Coordinators & ethics committee, from and against any third party loss, claim, cost (including reasonable attorney fees) or demand (collectively, "Claims") arising out of or in connection with (i) the administration of the Registry in accordance with the Protocol at the Site including an injury to a Patient arising from the use of the Registry Material in the Registry; (ii) any breach of this Agreement by Sponsor or its employees or agents, or (iii) any breach by Sponsor of any representation, warranties or covenants herein, except to the extent the same is

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caused by the gross negligence or willful misconduct of Site Investigator; however, that any such liability, loss, or damage resulting from (1) a failure to adhere to the terms of the protocol, or this Agreement or IRB/ IEC approved written instructions of the Sponsor's with respect to the Registry (2) failure to obtain the Patients' informed consent (3) failure to comply with any applicable governmental requirements; or (4) negligence or willful malfeasance by the Site, the Site Investigator or associated staff is excluded from this Agreement to indemnify and hold harmless.

It is hereby clarified that the Site/ Site Investigator's aggregate liability under this Agreement (whether under contract, tort or otherwise) shall be limited to the amount of consideration actually received by the Site under this Agreement.

The Site and the Site Investigator agree to notify Sponsor as soon as they become aware of a claim or action as to which Sponsor has indemnification obligations under this Agreement and to cooperate with and to authorize Sponsor to carry out the sole management and defense of such claim or action. Sponsor agrees, at its own expense, to provide attorneys to defend against any such claim or action, whether or not such claim or action is rightfully brought or filed. Neither the Site, Site Investigator nor associated staff shall compromise or settle any claim or action without the prior written approval of Sponsor.

10. CONFIDENTIALITY

10.1 In handling a Patient's medical records, the Site/ Site Investigator and associated staff shall hold in strict confidence the identity of the patient, and shall comply fully with any and all Regulations regarding the confidentiality of such records and data protection.

10.2 The Site/ Site Investigator shall be responsible for effecting and maintaining all registrations for the processing of personal data that are required by Regulations, including under the Drugs and Cosmetics Rules 1945. Site Investigator hereby consents for CRO and CRO's affiliates to collect and/or otherwise process personal data provided by or relating to Site Investigator for purposes of sharing such personal data with Regulatory Authorities and for any use by CRO and its affiliates. Site Investigator agrees that CRO and CRO's affiliates may transfer such personal data to CRO's facilities, and to Regulatory Authorities, if asked by authority in future.

10.3 The Site/ Site Investigator acknowledge and agree that all information disclosed to them by or on behalf of Sponsor or developed by the Site or Site Investigator in connection with the Registry is the proprietary information of Sponsor and shall be deemed to be Sponsor's Confidential Information and each undertakes to Sponsor, for its own benefit and for the benefit of Sponsor, that it will ensure that such information is kept confidential, for a period of 05 (five) years even after expiry or termination of this Agreement and is not disclosed to any third party without prior written consent of Sponsor. The Site/ Site Investigator will hold in strictest confidence and will not directly or indirectly, disclose, reveal, report, use, lecture, broadcast, transfer, disseminate in any form, upon or publish any Confidential Information of CRO or Sponsor.

10.4 The Site/ Site Investigator shall limit access to the Confidential Information of Sponsor to their officers, directors and employees (collectively "Representatives") who require access to such Confidential Information in order to effectuate the purposes of this Agreement. The Site/ Site Investigator agrees and shall obligate their Representatives to agree, that they will use the same degree of care and discretion as they use to protect their own Confidential Information.

10.5 The Site/ Site Investigator shall use the Confidential Information of Sponsor only for the purpose of fulfilling their obligations under this Agreement. The Site/ Site Investigator shall not be entitled

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to use any of the results or data, or any other information, resulting from or related to the Registry for own research or other purposes, nor shall the Site Investigator be involved in such research, without having obtained the prior written consent of Sponsor.

10.6 Excluded from the above confidentiality obligations shall be information which, may be demonstrated by the Site/ Site Investigator to the reasonable satisfaction of Sponsor, as the case may be:

(i) was already in possession of the Site/ Site Investigator at the time of disclosure or acquisition in connection with the Registry;

(ii) was at the time of such disclosure or acquisition already in the public domain or subsequently enters the public domain without default on the part of the Site/ Site Investigator; or

(iii) was received from a third party, who does not owe an obligation of confidentiality to the Sponsor.

10.7 Consent shall be deemed to have been given by Sponsor to the following disclosures of their respective Confidential Information:

(i) Disclosure of such Confidential Information to employees or consultants of the Site/ Site Investigator provided that the Site/ Site Investigator ensures that such employees or consultants are bound by obligations of confidentiality no less strict than those set out herein and that they require the information disclosed for the purposes of the Registry;

(ii) Disclosure of such information to the extent required by law or by any Regulatory Authority, provided that Sponsor, as the case may be, is informed of such requirements and in so far as practicable, the Site/ Site Investigator arranges for the disclosure to be made in confidence.

11. RESEARCH DELIVERABLES

In this undertaking the Site Investigator agrees to perform the work required by this Agreement (more specifically as defined under **Exhibit A** attached herewith) and the Site Investigator has fully understood the service deliverables under this Agreement. Site Investigator representing that he is duly authorized by the Ethics Committee of the Institution to do so, agrees to make reasonable endeavors to enroll minimum 25 Patients or such higher numbers as agreed upon with Sponsor from time to time to meet the patient selection criteria described in the Protocol. Site Investigator acknowledges that enrollment for the Registry is competitive, and that the enrollment period may be terminated at any time. The estimated registry duration is 24 months including pre-& post registry period and extended follow up (telephonic) is 1 month and 365 days for OCT sub study group subjects.

12. GENERAL PROVISIONS

12.1 Notices: Unless otherwise provided herein, any notice required or permitted to be given hereunder shall be in writing and faxed/emailed, mailed by registered mail, or delivered by hand to the party to whom such correspondence is required or permitted to be given hereunder at the addresses set out above (or such other address as a party may designate by notice in writing).If delivered by registered mail, any such correspondence shall be deemed to have been delivered after three business days from dispatch, and if delivered by hand, any such correspondence shall be deemed to have been delivered on receipt, and if faxed, any such correspondence shall be deemed to have been delivered immediately upon successful facsimile/email transmission.

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12.2 **Governing law**: This Agreement, and any disputes arising hereunder, shall be governed by and interpreted in accordance with the **laws of India** and the PARTIES submit to the exclusive jurisdiction of the courts of **Lucknow.**

12.3 **Entire Agreement**: This Agreement sets forth the entire Agreement and understanding of the Parties relating to the subject matter hereof, and supersedes all prior agreements, arrangements and understandings, written or oral, between the Parties.

12.4 **Severability**: If any provision of this Agreement shall be held invalid, illegal or unenforceable, such provision shall be enforced to the maximum extent permitted by law and in compliance with the Parties' intent, and the remaining provisions shall not be affected or impaired.

12.5 **Amendments, Waivers**: This Agreement may be amended, modified, superseded, cancelled, renewed or extended, and the terms or covenants hereof may be waived, only by a written instrument (which identifies this Agreement and states the plan or intent to modify) executed by all Parties hereto, or in the case of a waiver, by the Party waiving compliance.

12.6 **Assignment**: Site/ Site Investigator may not assign this Agreement to any party and may not subcontract any of their obligations under this Agreement, unless prior written consent for the same has been obtained from CRO

12.7 **Survival**: Notwithstanding the termination of this Agreement, obligations which have accrued or have application beyond the term including without limitation those relating to confidentiality, intellectual property, publications, indemnification and enforcement of Parties' rights, shall survive the expiration or earlier termination of this Agreement.

12.8 **Relationship of the Parties**: The Parties agree that Site/ Site Investigator shall their respective roles and obligations as memoralised under the terms of this Agreement perform services hereunder as an independent contractor, and not as an agent, retaining control over and responsibility for its own operations and personnel. Site/ Site Investigator shall not, and will ensure that its Representatives shall not, represent themselves to be the agents, employees, partners or joint ventures of Sponsor and shall not otherwise cause Sponsor to be liable under any contract or otherwise.

12.9 **Attachments**: **Exhibits A & B** form an integral and substantial part of this Agreement.

12.10 **Force Majeure**: Except CRO on behalf of sponsor's obligation to make payment to the Site in accordance with Exhibit B, no Party hereto shall be liable for damages or have the right to cancel this Agreement for any delay or default in performing its obligations hereunder, if such delay or default is caused by conditions beyond its control, including but not limited to natural disasters, acts of God, government restrictions/policy, laws, wars, terrorist acts, or insurrections. Whichever of Site/ Site Investigator and CRO is affected by such circumstances (the "Affected Party") shall promptly notify the other (the "Non-Affected Party") in writing when such circumstances cause a delay or failure in performance ("a Delay"). In the event of a Delay lasting for four (4) weeks or more the Non-Affected Party shall have the right to terminate this Agreement by notice of 30 (thirty) days in writing to the Affected Party.

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IN WITNESS WHEREOF the parties hereto have accepted and executed this Agreement as of the day and year first set above. This Agreement has been executed in **Triplicate**; each party having received one original.

ACCEPTED AND AGREED:

SITE INVESTIGATOR:

Name: Dr. Aditya Kapoor

Date: 3/Aug/2022

Title: Professor & Head

INSTITUTION:

Name: Prof. R.K. DHIMAN, Director, Sanjay Gandhi Post Graduate Institute of Medical Sciences, LUCKNOW-226 014, INDIA

Date: 01.09.2022

Title: -

CRO

Name: Mr. Kishor Kumar

JSS Medical Research Asia Pacific Pvt. Ltd. Faridabad

Date: 26th July'2022

Title: Chief Financial Officer

JSS Medical Research Asia Pacific Pvt. Ltd. Faridabad

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Executive Registrar
SGPGIMS,Lucknow

EXHIBIT – A

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LIST OF SERVICES

1. Scientific clearance for conduction of registry at investigator site (if applicable)
2. Ec approval of registry documents like protocol, informed consent document etc.
3. Identification of eligible patients for the registry
4. Obtaining of informed consent process
5. Treat registry participants as hospital standard of care & adequate follow up
6. Collection of complete medical history of the patients
7. Recording of physical examination – signs and symptoms of all the patients and other related information on source / e-CRF
8. Reporting of adverse events and serious adverse events reporting as per regulatory/ec sop -timelines
9. Writing the patient registry summary-completion of source documentation
10. Supporting and coordinate with CRO's/ sponsor monitor to monitor the registry
11. Supporting and coordinate with CRO's/ sponsor auditor for the registry audit.
12. Supporting and coordinate with CRO's/ sponsor for registry closeout at end of the registry

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EXHIBIT – B

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BUDGET AND PAYMENT SUMMARY:

COMPETITIVE ENROLLMENT OF 25 PARTICIPANTS IN THE REGISTRY.

BUDGET AND PAYMENT SCHEDULE:

Registry Financial Grant: Per patients enrolled and upon COMPLETION (INR) = ₹ 15000 as per the following:

(SUMMARY)	
Description	**Amount Rs. (Excl. TDS & GST)**
TOTAL PER PATIENT REGISTRY GRANT IN INR	
Investigator/ CRC Fees per patient inclusive Investigation/Laboratory costs	₹ 15,000/ participant (Includes PI fee, CRC fee and Institute Overhead)
REGISTRY GRANT PAYMENTS & MILESTONES	
Schedule Registry grants release milestones	**Milestone & registry Grant amounts**
Upon initiation of Shock India Registry site	Investigator and CRC Fees per Patient inclusive Laboratory Costs
Screening & Enrolment (pre procedure)	₹ 15000 / patient
Index Procedure	
Post Procedure (Discharge)	
1 Month clinic FU/ Telephonic Call	
1 year clinic FU/ Telephonic Call for first 100 patients with OCT imaging	
CRC fee for data entry into eCRF and other registry related work	

Note:

- As Per sponsor request, archival of the documents will be at third party outside vendor, hence archival fee will not be applicable for this registry.
- TDS if applicable, will be deducted at prevailing applicable percentage rates.
- GST is NIL on Investigation/Laboratory Costs.
- GST @ 18% if applicable, as per prescribed rates.

* Laboratory tests (Hemoglobin, Platelet, Serum creatinine and CK-MB, 2D ECHO, 12 Lead ECG) if done, as part of the standard of care prior to the registry screening date, will be considered as valid for the registry and will not be compensated for.

* Similarly, all investigations required as part of the registry follow up, and if done as part of the standard of care will be considered as valid and will not be compensated for.

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A. PAYMENT TERMS:

All payments are based on enrolled patients' actual registry visits (Registry visits are as defined in the protocol scheduled visits). The total payment will be dependent on the total number of patient visits which are captured in the CRF, and source data verification based.

All payments under this Agreement shall be subject to deduction of tax at source, wherever applicable and, as per applicable Indian laws, for which if required, a TDS certificate will be issued by the CRO on behalf of sponsor to the Site/ Site Investigator within the time permissible under applicable laws.

B. DISCONTINUED OR EARLY TERMINATION PAYMENTS:

No payment will be made in the event of a failure to follow the registry procedure as defined by the protocol, except where such failures are beyond the reasonable control of the Site. Reimbursement will not be provided for patients who enter the registry but fail to meet all the inclusion and exclusion criteria. Reimbursement for discontinued or early termination patients will be prorated based on the number of confirmed completed visits.

C. IRB/EC PAYMENT:

IRB/EC costs will be reimbursed on a pass-through basis and are not included in the attached budget. The nature of this registry being purely academic, CRO on behalf of sponsor will not pay for any EC renewal fees.

D. PAYEE INFORMATION

The parties agree that the payee designated below is the proper payee for this Agreement, and that payments under this Agreement will be made only to the following payee (the "Payee").

Payments will be issued by the CRO within 30 (thirty) days from the date of receipt of invoice from the Payee according to visits completed, as verified by the registry monitor in the electronic data captured tool E-CRF records. Payments will be made by cheque / wire transfer in favor of this agreement payee details.

PAYEE NAME:	Director SGPGI Research Account
PAYEE ADDRESS:	Sanjay Gandhi Post Graduate Institute of Medical Sciences, Rae Bareli Road, Lucknow, UP-226014, India
PAYEE ACCOUNT NUMBER	10095237491
BRANCH ADDRESS	State Bank of India, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Rae Bareli Road, Lucknow, UP- 226014, India
IFSC CODE	SBIN0007789
PERMANENT ACCOUNT (PAN) OF PAYEE	AAAJS3913N
(GST NO), if applicable	09AAAJS3913N2ZN

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Executive Registrar
SGPGIMS,Lucknow



महाराष्ट्र MAHARASHTRA ◑ 2021 ◑ BH 103139

कोषागार कार्यालय ठाणे

जिल्हा कोषागार कार्यालय, ठाणे
10 JAN 2022
मुद्रांक प्रमुख लिपीक / लिपीक

NOVARTIS HEALTHCARE PRIVATE LIMITED (First Part)

AND

Dr. Sanjeev (Second Part)

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences (Third Part)

K. Mayanatha

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement ("**Agreement**") is entered into as of *[__ _____ 22_]* ("**Effective Date**") between **Novartis Healthcare Private Limited,** a company incorporated under the provisions of the Companies Act, 1956, and having its registered office at Inspire BKC, Part of 601 & 701, Bandra Kurla Complex, Bandra (East), Mumbai – 400 051, Maharashtra, India (hereinafter referred to as "**Novartis**" which expression shall unless repugnant to meaning or context mean and include its successors and assigns) of the FIRST PART;

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences, located at ***Lucknow*** ("**Institution**") registered under state legislature Act, 1983 and having its address at Raebareli road, Lucknow 226014 which expression shall mean and include its successors and assigns of the SECOND PART;

AND

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

Novartis, Institution and Principal Investigator are hereinafter individually referred to as the "**Party**" and jointly as the "**Parties**". For the purposes of this Agreement, "**Affiliate(s)**" shall mean any entity which directly or indirectly controls, is controlled by or is under common control of Novartis.

RECITALS:

WHEREAS, Novartis is to perform a clinical trial (hereinafter the "Trial) to evaluate the following drug: **Crizanlizumab, SEG101** (hereafter the "Trial Drug") in accordance with a protocol entitled "***An Indian Multi-centric Phase IV study to assess the safety of Crizanlizumab with or without hydroxyurea therapy in sickle cell disease patients with vaso-occlusive crises', Protocol No-CSEG101A2403"*** and its potential subsequent amendments (hereinafter collectively the "Protocol").

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

WHEREAS the Principal Investigator is an employee of the Institution,

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

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

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

CONFORMANCE WITH LAW AND ACCEPTED PRACTICE

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

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

NOVARTIS HEALTHCARE Pvt Ltd.

By: V. Muruganthan

Name: Muruganthan K.

Title: Country Monitoring Head

Date: 27 Jan 2022

Sanjay Gandhi Post Graduate Institute of Medical Sciences

By: Verma

Name: _____

Title: _____

Date: 11/2/22

PRINCIPAL INVESTIGATOR

Sanjeev

Dr. SANJEEV
Associate Professor
Department of Hematology
S.G.P.G.I.M.S., Lucknow
U.P.-226014

By: _____

Name: Dr. Sanjeev

Title: Principal Investigator

Date: 17/02/2022

Bajpai

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

INDIA NON JUDICIAL

Government of National Capital Territory of Delhi

सत्यमेव जयते

₹100

e-Stamp

Certificate No.	:	IN-DL05054049809906U
Certificate Issued Date	:	16-Mar-2022 01:32 PM
Account Reference	:	IMPACC (IV)/ dl700603/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL70060398783511234109U
Purchased by	:	DATT MEDIPRODUCTS PVT LTD
Description of Document	:	Article 5 General Agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	DATT MEDIPRODUCTS PVT LTD
Second Party	:	DIRECTOR SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES AND PROF GYAN CHAND SGPGIMS
Stamp Duty Paid By	:	DATT MEDIPRODUCTS PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

सत्यमेव जयते

₹100

Please write or type below this line IN-DL05054049809906U

This non-judicial stamp paper forms an integral part of clinical trial agreement (CTA) executed between Datt Mediproducts Pvt. Ltd., Director (SGPGIMS) & Prof. Gyan Chand, Dept. of Endocrine Surgery, SGPGIMS Lucknow

Siddharth Pandey

(Principal Investigator) (Institute/Hospital) (Sponsor)

DATT MEDIPRODUCTS PVT. LTD. New Delhi

Clinical Trial Agreement

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Statutory Alert:

1. The authenticity of this Stamp certificate should be verified at 'www.shcilestamp.com' or using e-Stamp Mobile App of Stock Holding. Any discrepancy in the details on this Certificate and as available on the website / Mobile App 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.

Certificate No.: IN-DL050540498099O6U

CLINICAL TRIAL AGREEMENT

Clinical Investigation Plan/Protocol Title:	A randomized, open label, single centre Post Market Surveillance Study to evaluate the efficacy and safety of a new antimicrobial wound dressing (VELVERT) compared to standard dressing (SD) in the treatment of Diabetic foot ulcer.
Clinical Investigation Plan/Protocol Number:	**Protocol No.: DMPL/CIP-02-2020/CT/VV; Version No.: 1.0, Date: 03-Sep-2020**
Date of Agreement:	17-Mar-2022
SPONSOR	
Name:	Datt Mediproducts Pvt. Ltd.
Address:	**Registered office:** Gazraj Chambers, 2B, Second Floor, 86 B/2, Topsia Road (South), Kolkata, 700046. **Corporate office:** 56, Community Center, East of Kailash, D Block, New Delhi, Delhi 110065.
PRINCIPAL INVESTIGATOR	
Name:	Prof. Dr. Gyan Chand
Address:	Department of Endocrine Surgery, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli road, Lucknow,226014, Uttar Pradesh.
INSTITUTION	
Name:	Prof. R K Dhiman
Address:	Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raibareli Road, Lucknow- 226014, Uttar Pradesh, India.

(Principal Investigator) (Institute/Hospital) (Sponsor)

Siddharth Pandey

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Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

This Clinical Trial Agreement ("Agreement" is made between **DATT MEDIPRODUCTS PRIVATE LIMITED**, (hereinafter referred to as **"SPONSOR")** a company incorporated under the COMPANIES ACT 1956, having registered office at **Gajraj Chambers, 2B, second floor, 86 B/2, Topsia Road (South), Kolkata 700046** and corporate office at **56, Community Center, East of Kailash, New Delhi – 110065**, on the First Party.

AND

Director, SGPGIMS (hereinafter referred to as "Investigation Site"), which is located at Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raibareli Road, Lucknow- 226014, Uttar Pradesh, India., on the Second Party.

AND

Prof. Gyan Chand, whose designation is **"Professor"** at **Department of Endocrine Surgery, Sanjay Gandhi Post Graduate Institute of Medical Sciences,** (herein after referred to as "Principal Investigator" (PI), which expression shall, unless it be repugnant to the context or meaning thereof, be deemed to mean and include his/her heirs, executers, administrators and successors) of the Third Party;

Sponsor, Principal Investigator (PI) and Institution shall individually be referred as **"Party"** and collectively as "Parties".

RECITALS:

WHEREAS,

A. SPONSOR, is inter-alia, engaged in the business of manufacturing and marketing of medical device along with research, product development & clinical research,
B. The **INVESTIGATOR** is engaged in the treatment of subjects with potential exposure to the indication intended for treatment, at an Institution/hospital;
C. The **INSTITUTION** is the facility where the clinical trials and study will be conducted ethically and as per the approved Clinical Investigation Plan/protocol;
D. **SPONSOR** is willing to engage the **Principal Investigator** and **Institution** to conduct the clinical trial and the study on non-exclusive basis and Institution and **Principal INVESTIGATOR** are willing to carry out the study on the terms set out in this Agreement.
E. The purpose of this **AGREEMENT** is to agree on terms and conditions, as well as procedures, according to which the clinical trials and the study will be conducted, and on the division of duties and responsibilities between the parties conducting the said trials/study.
F. The **SPONSOR** is desirous of conducting the study as per **IEC** approved protocol.

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G. The clinical trials/study will be initiated at the site only after an approval from the registered ethics committee of the institute.

H. On the faith and strength of the aforesaid representations and warranties, the **SPONSOR** has agreed to appoint the institution and Investigator for the conduct and supervision of the clinical trial/study in accordance with the approved **Clinical Investigation Plan/protocol,** subject to the terms and conditions hereinafter appearing.

NOW THEREFORE, the Parties agree as follows:

1. DEFINITIONS:

1.1 "Adverse Event (AE)" means any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product (see the ICH-GCP Guidance page-2 section-1.2) for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

1.2 "Affiliate" means with respect to an entity, any entity that directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such entity. "Control" and, with correlative meanings, the terms "controlled by" and "under common control with" mean (a) the power to direct the management or policies of an entity, whether through ownership of voting securities or by contract relating to voting rights or corporate governance, resolution, regulation or otherwise, or (b) to own 50% or more of the outstanding voting securities or other ownership interest of such entity. "Entity" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision, department or agency of a government.

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1.3 **"Applicable law"** means the Drugs & Cosmetics Act, 1940, Drugs & Cosmetics Rules, 1945 with its amendments and any other law or rules for the time being in force in India.

1.4 **"Case Report form"** means a printed, optical or electronic document or database designed to record subject information.

1.5 **"Confidential information"** means any or all data or information whether oral, written or in electronic form disclosed by sponsor and its affiliates to Principal Investigator and/or to the Institution, including – **i.** all information collected in the course of, resulting from, or arising directly from the study; **ii.** Clinical Investigation Plan/protocol, Investigator's Brochure, study materials and Investigational Product, business plans, sales or marketing methods; **iii.** Information, ideas, concepts, IPR, technical and operational information, scientific or technical processes or techniques, product composition or details owned by the sponsor and its affiliates; **iv.** Know-how, methodology, trade secrets, sequences and structure of the study; and v. Information concerning the business affairs or clients and its affiliates.

1.6 **"Fees"** shall mean the milestone payments agreed by the parties of the study.

1.7 **"Force Majeure Event"** shall mean circumstances beyond reasonable control of a party, including but not limited to, change in government policy, fire, flood, epidemic, act of God, war and riot;

1.8 **"GCP"** means good clinical practices guidelines issued by the Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services, Govt. of India and under applicable Laws;

1.9 **"GLP"** shall mean good laboratory practices guidelines issued by the Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services, Govt. of India and under applicable Laws;

1.10 "ICH-GCP" shall mean International Conference of Harmonization of Technical Requirements for Pharmaceuticals for Human Use – Good Clinical Practice Guidelines, is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of Human subjects;

1.11 "IEC" shall mean Institutional Ethics Committee of the Institution;

1.12 "Investigational Product" shall mean an allogenic cell based wound dressing (VELVERT), which will use, as how it will be used.

1.13 "IPR" shall mean patent, copyright, trademark, service mark, service name, trade name, interned domain name, brand name, trade dress, label, logo, know-how, technical and non-technical information, trade secret, formulae, technique, sketch

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drawing, model, invention, design, specifications, processes, apparatus, equipment, database, research, experimental work, development, study materials and Investigational Product and all the confidential or proprietary information obtained by the Principal Investigator and Institution from the Sponsor or generated or created by Principal Investigator and Institution as a direct or sole result of performing clinical trial/study under this agreement, including, without limitation results of the clinical trial/study, data generated, confidential proprietary, commercial, scientific, medical or technical information.

1.14 **"Party"** shall individually mean sponsor or Principal Investigator or Institution.

1.15 **"Parties"** shall collectively mean Sponsor, Principal Investigator and Institution.

1.16 **"Clinical Investigation Plan/protocol"** shall mean a document that states the background, objectives, rationale, design, methodology and statistical considerations of the study.

1.17 **"Regulatory Authorities"** means the Drugs Controller General (India), Directorate General of Health Services, Ministry of Health and family Welfare, Drug Advisory Committee and relevant government authority having jurisdiction under applicable Laws.

1.18 **"Representative"** shall mean the employees, directors and officers of a party.

1.19 **"Serious Adverse Event"** means an untoward medical occurrence that leads to,— (i) a death; or (ii) a serious deterioration in the health of the subject that either- (A) resulted in a life-threatening illness or injury; or (B) resulted in a permanent impairment of a body structure or a body function; or (C) required in-patient hospitalization or prolongation of existing hospitalization; or (D) resulted in medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure or a body function; or (iii) foetal distress, foetal death or a congenital abnormality or birth defect;

1.20 **"Study site"** shall mean the Institution facility (Department of Endocrine Surgery), Located at Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow– Uttar Pradesh, India.

"Clinical trial/Study" means the clinical trial/study (A randomized, open label, single centre Post Market Surveillance Study to evaluate the efficacy and safety of a new antimicrobial wound dressing (VELVERT) compared to standard dressing (SD) in the treatment of Diabetic foot ulcer.

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1.21) to be conducted on eligible subjects by the Principal Investigator and Institution to test the Safety and Efficacy of the study device.

1.22 Study completion occurs when the final **Clinical Study Report (CSR)** is signed by the Principal Investigator and Institution and Sponsor. Data generated in the clinical trial/study has been locked and provide to Sponsor, including a copy of approval letter of IEC acknowledgment of final report.

1.23 Study Material means Medical Device VELVERT).

1.24 Subject means patient enrolled in said study.

2. SCOPE AND CONDUCT OF THE STUDY:

2.1 Sponsor hereby engages the Principal Investigator and Institution to conduct the Clinical trial/study on non-exclusive basis.

2.2 Institution agrees to provide all the facilities to the Principal Investigator and confirms that the study shall be conducted at the study site under the direction of Principal Investigator.

2.3 Principal Investigator shall conduct the study in accordance with the Clinical Investigation Plan/protocol, GCP, Regulatory Authority requirements including ICH-GCP, institution standard Operating procedures and other applicable laws.

2.4 Institution shall perform the Clinical Trial/Study under the direct supervision and control of Principal Investigator. If Principal Investigator is unwilling or unable to perform the study, Institution shall refer alternative Investigator to Sponsor as replacement of Principal Investigator and based on Sponsor's written approval, such Investigator shall be engaged as Principal Investigator for the clinical trial/study. If a mutually acceptable Principal Investigator is not referred by the Institution, then the study may be continued with **Prof. Gyan Chand** until the Sponsor suspends or terminates the study or till completion of the study.

2.5 Sponsor will not accept the study until relevant milestones are achieved as identified in the Clinical Investigation Plan/protocol. In the event of any actual or anticipated failure by Site to perform the Clinical Trial/Study in strict compliance with the standards specified in the Clinical Investigation Plan/protocol or otherwise described in this Agreement for any reason other than Sponsor's acts or omissions, Sponsor shall be entitled to, at it's sole option, require the Principal Investigator and Institution to re-perform the relevant milestone in the study without any additional cost to the Sponsor within timelines specified by the Sponsor

3. SUBJECT RECRUITMENT:

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3.1 Principal Investigator shall enroll the Subjects in the study after IEC approval.

3.2 Principal Investigator shall ensure that all Subjects comply with Clinical Investigation Plan/protocol.

3.3 It shall be the responsibility of the Institution and Principal Investigator to notify Sponsor and IEC of any significant deviation from Clinical Investigation Plan/protocol and/or Applicable and Regulatory Authority guidelines including without limitation to Serious Adverse Events within Forty-eight (48) Hours.

3.4 Principal Investigator and Institution shall enroll **100 patients at site. If additional subjects are enrolled or less subjects are enrolled then, it should be communicated with sponsor.**, additional Subjects may be recruited only upon Sponsor's prior written consent.

3.5 Principal Investigator and Institution agrees that Sponsor can limit or stop Subject inclusion in the Study at any time for any reasons. If Sponsor limits Subject inclusion in the Study, milestone Fees under the payment schedule shall be paid by Sponsor based on the milestones achieved by the Principal Investigator and Institution as defined in Annexure - I. Should there be no Subject enrollment or there is no Study kick-off by Principal Investigator and Institution in accordance with the Agreement, entire milestone Fees paid by Sponsor shall be refunded immediately.

3.6 If a Subject suffers with any Study related injury, Principal Investigator and Institution shall notify Sponsor within 24 hours, however, Principal Investigator and Institution shall be responsible to provide complete medical treatment to the Subject. Sponsor will bear actual medical expenses incurred by the Principal Investigator and Institution for the Subject as a result of any study related injury. In case of death of Subject due to Study related injury, Principal Investigator and Institution shall immediately notify the Sponsor and Sponsor will pay the financial compensation as a result of Study related death as provided under Regulatory Authority guidelines and Applicable Law.

4. RESPOSNIBILITIES OF PARTIES:

4.1 PRINCIPAL INVESTIGATOR & INSTITUTION:

4.1.1 Principal Investigator and Institution shall be responsible to conduct the said Study at the Study Site.

4.1.2 Principal Investigator and Institution shall not subcontract the Study to any third party, except with prior written consent of Siddharth Pandey.

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4.1.3 Principal Investigator and Institution shall provide preliminary and final detailed reports to Sponsor as per the timelines specified in the Protocol.

4.1.4 Principal Investigator and Institution shall be responsible to provide daily updates in respect of Serious Adverse Events, milestones pending, completed and safety issues.

4.1.5 Principal Investigator and Institution agrees that the Investigational Product and Study Materials are owned by Sponsor and all unused Investigational Product and Study Materials shall be returned to Sponsor on Study Completion. However, Institution is responsible to maintain full and accurate records for the use of Investigational Product and Study Materials in the Study.

4.1.6 Principal Investigator and Institution shall be responsible to notify Sponsor and IEC if there is a requirement for change in Clinical Investigation Plan/Protocol. Principal Investigator shall carry out the modifications and/or amendments in the Clinical Investigation Plan/Protocol based on the approval of IEC and Sponsor.

4.1.7 Principal Investigator and Institution agrees that Sponsor can monitor the Clinical Trial/Study and advise Principal Investigator and Institution on cessation of the Clinical Trial/Study or withdrawal of Investigational Product and Study Materials for safety reasons.

4.1.8 Principal Investigator and Institution shall maintain all Study Materials, including copies of signed consent forms, Case Report Forms, Protocol and information relating to Investigational Product and Study Materials in safe custody always locked.

4.2 PRINCIPAL INVESTIGATOR:

4.2.1 Principal Investigator thoroughly familiarizes him/herself with the appropriate use study materials/Investigational Product (**VELVERT**) and described in Clinical Investigation Plan/Protocol, Informed Consent Documents and Case Report Form.

4.2.2 Principal Investigator shall be responsible to coordinate with the research staff and Institution and deliver all reports, data, statement and deliverables of the Clinical Trial/Study to the Sponsor.

4.3 INSTITUTION:

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4.3.1 Institution is responsible to ensure that Principal Investigator is conducting the study under this agreement is not debarred by the Regulatory Authority or under applicable laws.

4.3.2 If Principal Investigator leaves the Institution or otherwise ceases to be available, then the Institution must consult with the Sponsor and use reasonable endeavors to nominate as soon as possible, a replacement reasonably accepted to both parties; and the Sponsor many require recruitment into the study by the Institution to cease, or move the study to a different study site.

4.3.3 The Institution shall be responsible for ensuring sufficient, appropriate and necessary facilities, equipment and resources for the conduct of the trials/Study, and all other resources reasonably required to complete the Study and that no other than legal obligations or commitments of the Institution cause unreasonable damage to or delay in conducting the said trial/Study as set forth in this agreement.

4.3.4 Institution will ensure that the Study is subject to the continuing oversight of the Principal Investigator and IEC throughout the Study Completion.

4.3.5 Institution shall be responsible to retain archival records of the Study including the original or a copy of al Subject consent forms in conformance with applicable regulations for a minimum free storage period of **fifteen (15) years.**

4.3.6 Institution shall notify Sponsor before destroying any Study Materials and retain the Study Materials for such longer period as reasonably required by the Sponsor at the mutually agreed costs after completion of free storage period of **fifteen (15) years.**

4.4 SPONSOR:

4.4.1 Sponsor will provide study materials to the Principal Investigator and Institution for the purpose of conducting the Clinical Trial/Study.

4.4.2 Sponsor will share relevant information of study materials and Investigational Product with Principal Investigator and Institution.

5. REGULATORY AUTHORITY:

5.1 Principal Investigator and Institution shall obtain IEC approval and Sponsor will obtain regulatory authority clearance under applicable law as specified in Clinical Investigation Plan/Protocol.

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5.2 If Principal Investigator and Institution fails to obtain the IEC approval within the agreed timelines stated in the Clinical Investigation Plan/Protocol, Sponsor shall at its sole option, immediately suspend or terminate the Clinical Trial/Study and terminate this Agreement as per Section 13 Principal Investigator and Institution shall notify sponsor within twenty-four (24) hours upon receipt of written communication from Regulatory Authority inspection or inquiry related to the Clinical Trial/Study.

5.3 Principal Investigator and Institution shall cooperate with Sponsor from time to time in inquiry, investigation, audit or proceedings of Regulatory Authority without additional cost to Sponsor.

6. REPRESENTATION & WARRANTIES:

6.1 Parties represent and warrant that they are authorized to execute this agreement and that the terms of this agreement are not in violation of any contract to which they are a party.

6.2 Principal Investigator and Institution represents and warrants that they have relevant skill, experience, expertise, regulatory approvals/licenses and facilities to conduct the Clinical Trials/Study as required by Sponsor from time to time.

6.3 Institution represents and warrants that the processes and clinical tools used by Principal Investigator to perform the Study herein does not infringe any Intellectual Property Rights including patent, copyright, trade secret, industrial rights or other proprietary right of any third party.

6.4 Institution warrants that Principal Investigator, and all Representatives deputed for performing the Study shall possess relevant skills and qualifications and the Clinical Trial/Study shall be rendered in a professional and workmanlike manner.

6.5 Principal Investigator and Institution shall diligently and timely respond to all queries and requests of Sponsor.

6.6 Principal Investigator and Institution shall comply with all Applicable laws including data privacy, confidentiality and data security policies from time-to-time.

7. INTELLECTUAL PROPERTY:

7.1 All rights, title and interests resulting from the said Clinical Trials/Study, Study Materials and Investigational Product including IPR whether created, developed, generated, modified or improved by Principal Investigator and/or Institution shall be the exclusive property of Sponsor. Principal Investigator and Institution agrees that Sponsor owns the right, title and interest in any inventions, designs, discoveries, improvements, developments, innovations and works of authorship

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produced as a result of the Study. Principal Investigator and Institution shall irrevocably transfer and assign all rights, title and interest in IPR in favor of Sponsor.

7.2 Principal Investigator and Institution shall not use the Confidential Information and IPR and/or data generated from the study directly or indirectly for any purpose other than the Clinical Trial/Study.

7.3 Principal Investigator and Institution agrees that all inventions, data, works, discoveries, technology and innovations or improvements in relation to the study and IPR, whether or not subject to any protection by statute which are conceived of, made, reduced to practice, created, written, designed or developed, authored or made by Principal Investigator and/or Institution either alone or in combination, in the course of the performance of study under this Agreement including modifications or improvements to any proprietary technology, information or materials provided by Sponsor to Principal Investigator and Institution shall be the exclusive property of Sponsor. The Inventions are to be promptly reported to Sponsor. Sponsor is free to use the results of the Clinical Trial/Study without any further communication to Principal Investigator and Institution.

7.4 Principal Investigator and Institution agrees to cooperate with Sponsor and its nominees to obtain patents or register copyrights in any and all countries for the inventions and IPR and to execute all documents for use in applying for and obtaining such protection thereon as Sponsor may desire, together with assignments thereof to confirm Sponsor's ownership. In the event that any improvements, innovations or developments do not qualify to be work for hire, Principal Investigator and Institution herby irrevocably transfers, assigns and conveys, all rights, title and interest in such improvements or developments to Sponsor free from all encumbrances and agrees to execute and shall cause it's representative to execute, all necessary documents in favor of Sponsor.

8. FEES:

8.1 Principal Investigator and Institution shall submit any invoice to the Sponsor for conducting the said Clinical Trial/Study. Principal Investigator and Institution agrees that the payment made by Sponsor for conducting the Clinical Trial/Study is fair as mutually agreed by the parties as per **Annexure I.**

8.2 Principal Investigator consideration of the Clinical Trial/Study, Sponsor will pay the Fees/ charges to the Institute on completion of relevant milestones as specified in **Annexure I**.

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8.3 Institute shall submit to Sponsor the invoices for Clinical Trial/Study completed till the relevant milestones. All invoices shall be approved by the Sponsor representative. Principal Investigator shall give supportive documents upon successful completion of deliverables within the agreed timelines. Sponsor will make payments against undisputed invoices within thirty (30) business days from the date of receipt of invoice. If there is any discrepancy in the invoice submitted by the Institute, Sponsor will notify Institute within fifteen (15) business days from the date of receipt of such invoice and withhold disputed invoice amounts until resolved by the Parties. However, pending resolution of any dispute under this Agreement, Principal Investigator and Institution shall proceed diligently with its performance of Clinical Trial/Study and complete the Clinical Trial/Study during dispute proceeding, unless otherwise instructed by the Sponsor.

8.4 All payments made by Sponsor to Institute shall be subject to tax deduction at source, service tax and payments, other applicable taxes as per their applicable rates, shall be paid extra by Sponsor.

8.5 Institute has provided NEFT/RTGS/wire transfer details to the Sponsor for processing the payments and subject to undisputed invoices, payment will be processed by the Sponsor.

All invoices to be sent to:

SPONSOR:	Datt Mediproducts Private Limited
BILLING ADDRESS:	Datt Mediproducts Private Limited, 56, Community Center, East of Kailash, New Delhi – 110065, India
ATTENTION OF:	Dr. Rajan Datt
TELEPHONE:	+91 – (11) 47191777
EMAIL:	lifescience@dattmedi.com

All invoices will be sent to the Sponsor via email and the electronic version of the invoices will be considered as the original and hard copies of the invoices will be shared by Institute on above address.

9. PUBLICATION:

9.1 Principal Investigator and Institution shall not, without prior written consent of the Sponsor, report or publish or make available the data, results or any report of the

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Clinical Trial/Study conducted under this Agreement to any third party or in any journal, book, magazine etc.

9.2 Accordingly, Study results may be published in medical journals or presented at a public forum such as conferences only after Sponsor's written consent and Sponsor has determined that such publication will not compromise IPR issues and/or confidentiality issues associated with the Clinical Trial/Study and approved or consented in writing that the Principal Investigator and Institution may publish or report the data, results or any report of the Clinical Trial/Study.

The Principal Investigator and Institution shall declare that Sponsor has provided her/him with funding for the Study whenever she/he writes or speaks in public about a matter that is the subject of this Agreement or about any other issue relating to Sponsor.

9.3 In all publications, the Sponsor's support of the Study shall be acknowledged. The Study will be clinically and statistically evaluated collaboratively by the Sponsor, Principal Investigator and on behalf of Institution and manuscript shall be prepared for submission to a peer-reviewed journal, subject to written approval of Sponsor.

9.4 Authorship credits shall, upon mutual consent between the Institution and the Sponsor, shall be decided considering all those participating in the Study program. The Sponsor may freely use, copy and disseminate any manuscript following its publication in a journal without further obligation to the Principal Investigator & Institution or disclosure. All communications in relation to the Clinical Trial/Study such as press release or responses to inquiries from media should receive prior written approval from the Sponsor.

10. CONFIDENTIALITY:

10.1 Principal Investigator and Institution agrees that CONFIDENTIAL information shall be used only for rendering the services. Principal Investigator and Institution shall keep CONFIDENTIAL information strictly confidential, protect from unauthorized use, reproduction, access and damage or destruction and employ the same degree of care as it would employ to protect its own confidential Information.

10.2 Principal Investigator and Institution shall limit disclosure of Confidential Information only to its Representatives who necessarily require access to render the Services, provided that –

(a) Principal Investigator and Institution first require each of them to agree in writing, either as a condition of their service to Principal Investigator and Institution or in order to obtain Confidential Information, to be bound by terms

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and conditions substantially similar to those terms and conditions applicable to Principal Investigator and Institution under this Agreement, and

(b) Principal Investigator and Institution shall maintain a record of Confidential Information disclosed to the Representatives and such record shall contain the name, designation of the Representatives and details of Confidential Information disclosed, which shall be made available to Sponsor upon request. However, Principal Investigator and Institution shall, under all circumstances, continue to be liable as a principal party.

10.3 In the event Principal Investigator and Institution becomes legally compelled by government or judicial process to disclose any Confidential Information, Principal Investigator and Institution will provide prior written notice thereof to Sponsor before making any disclosures, to enable Sponsor to seek protective order or other appropriate remedy to minimize disclosure and Principal Investigator and Institution shall disclose only such portion of Confidential Information absolutely necessary in the opinion of its legal counsel to comply with the process.

10.4 All Confidential Information is provided **"as is"**, without any warranty, express, implied or otherwise, regarding its accuracy or performance and in no event shall Sponsor be liable to Principal Investigator and Institution for disclosure of Confidential Information under this Agreement.

10.5 Upon the first written request of Sponsor at any time during the term or immediately upon expiry or earlier termination of the Agreement, Principal Investigator and Institution shall return **within fifteen (15) days** all Confidential Information to Sponsor, by registered mail/courier of international repute, and/or destroy such Confidential Information as per the directions and instructions of Sponsor and provide written certification to Sponsor. Principal Investigator and Institution may, however, retain one copy of such Confidential Information in its legal archives solely for legal compliance purposes, under strict obligations of confidentiality as stated in this Agreement.

10.6 All obligations contained in the Agreement shall however survive the expiry or early termination of this Agreement and the Parties shall always remain bound by the same.

11. INDEMNITY:

Sponsor shall assume responsibility for injuries to third parties caused in the course of carrying out the Trial according to the Applicable Laws, this Agreement and the Protocol, provided that:

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11.1 The Institution, the Principal Investigator, the Institution's employees and collaborators (hereinafter collectively "the Indemnitees" or each an "Indemnitee") shall have been free of wrongful conduct or omission, negligence, and wilful misconduct in the conduct of the Trial and in their obligations under this Agreement and the Protocol, and shall not have failed to follow the instructions or recommendations of Datt Mediproducts Pvt. Ltd.;

11.2 The Indemnitee refrains from making any admission of liability or any attempt to settle any claim without Sponsor consent;

11.3 The Trial Drug causing the injury was given by the Principal Investigator in accordance with the Protocol;

11.4 An adequate causal relationship is proven between the use of the Trial Drug and the appearance of injury;

11.5 Sponsor is immediately informed of the claim and all pertinent information relating thereto (but in any case, within ten (10) days after the Indemnitee shall have received notice thereof);

11.6 The Indemnitee provide such information and assistance to Sponsor in connection with such claim as is reasonably requested by Sponsor and its representatives;

11.7 Sponsor is permitted to handle and control such claim in its sole discretion.

11.8 An Indemnitee seeking indemnification shall take all reasonable steps to mitigate the amount of any claim for indemnification; and

11.9 The indemnity will not inure to the benefit of any Indemnitee's insurer, by subrogation or otherwise. The provisions of this Section constitute the Indemnitees' sole and exclusive remedy against Datt Mediproducts Pvt. Ltd. in respect of all claims.

12. TERM:

This agreement shall commence from the effective date and shall be valid for a period of Two (02) Years or on Clinical Trial/Study completion or unless sooner terminated by Sponsor in accordance with section 13, whichever is applicable. Parties may renew this Agreement upon mutually agreed terms & conditions.

13. TERMINATION:

13.1 Sponsor shall be entitled to terminate this Agreement in the following circumstances:

13.2 Without cause at any time by giving seven (7) days' prior written notice to the Principal Investigator and/or Institution.

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13.3 In the event of breach by Principal Investigator and Institution that is not cured within thirty (30) days from the date of written notice by Sponsor.

13.4 Immediately, if Principal Investigator and Institution fails to obtain ethics committee clearance.

13.5 Immediately, if Institution becomes insolvent or files for bankruptcy.

13.6 In the event of change of control of Institution, unless Sponsor decides otherwise, in which case, the acquiring entity undertakes in writing to assume all liabilities and responsibilities of Institution under this Agreement.

13.7 If this Agreement is terminated by Sponsor and/or Principal Investigator, Institution:

13.8 If Sponsor terminate the study: Fees for successful completion of Study till the date of termination as per the relevant milestone shall be paid by Sponsor.

13.9 If Principal Investigator/Institution terminate the study: Principal Investigator and Institution shall be liable to reimburse the Fees and expenses to Sponsor as a result of Sponsor retaining third party contractor to complete the Study.

13.10 Should Sponsor retain a third party for completion of the Study, then Principal Investigator and Institution shall provide transition services to such third party within the timelines specified by Sponsor without any costs thereon.

13.11

13.12

13.13 INSURANCE:

13.14 Sponsor shall secure and maintain in full force and effect throughout the performance of the Study, insurance coverage from a reputed insurance company to cover its obligations including the Principal Investigator and Representatives and all the claims arising out of Subjects injury and/or death.

14. NOTICE:

14.1 Any notice given under this Agreement shall be in writing and signed by or on behalf of party giving it and may be served by delivering it personally or sending it by pre-paid recorded delivery or registered post or by email or fax to the address and for the attention of the relevant **Party.** Any changes in address shall be notified by a **Party** to the other.

14.2 Any such notices be deemed to have been received;
-If delivered personally at the time of delivery;

Siddharth Pandey

(Principal Investigator) (Institute/Hospital) (Sponsor)

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-In the case of registered airmail, pre-paid recorded delivery or registered post-upon receipt;
-In the case of fax, at the time of transmission

The addresses, Email IDs and fax number of **Parties** for the purpose of any written notice is as follows:

FOR SPONSOR	FOR PRINCIPAL INVESTIGATOR
DATT MEDIPRODUCTS PRIVATE LIMITED 56, COMMUNITY CENTER, EAST OF KAILASH, NEW DELHI – 110065, INDIA TELEPHONE: +91 (11) 47191777 EMAIL: lifescience@dattmedi.com	**Dr. GYAN CHAND.** DEPARTMENT OF ENDOCRINE SURGERY, SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW.

14.3 This agreement and the Parties rights and obligations hereunder shall be governed by and interpreted in accordance with the laws of India.

14.4 All disputes arising under this Agreement shall be mutually settled by the Parties within **thirty (30) days**, failing which, shall be finally resolved by arbitration under the Rules as per Lucknow Court by one/sole arbitrator appointed in accordance with its Rules. The language of the arbitration proceedings shall be Hindi/English. The place of arbitration shall be at Lucknow and verdict passed by the arbitrator shall be final and binding on the Parties.

15. GENERAL PROVISION:

15.1 The relationship between Sponsor is Institute is of independent contractor.

15.2 A Party shall be excused from performing its obligations under this Agreement to the extent its performance is delayed or prevented by a Force Majeure Event provided that the affected **Party** promptly notifies the other of the occurrence of Force **Majeure Event.**

15.3 Principal Investigator and Institution shall not assign this Agreement to any person without prior written consent of Sponsor.

15.4 Any waiver by a **Party** of any provisions of this Agreement shall not operate or De construed as a waiver of any subsequent breach of such provision or any other provision hereof by such Party.

(Principal Investigator) (Institute/Hospital) (Sponsor)

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15.5 The invalidity or unenforceability of any provision of this Agreement shall not in any way affect, impair or render unenforceable this Agreement or any other provision contained herein, which shall remain in full force and effect.

15.6 No amendment to this agreement shall be valid unless mutually agreed in writing and executed by the parties.

15.7 This Agreement represents the entire engagement between parties and supersedes all prior negotiations, understanding the agreements, written or oral, relating to the subject matter herein.

In Witness, whereof, the Parties herby sign and execute this Agreement as of Effective Date.

FOR SPONSOR:

Signature: Siddharth Pandey

Name: Dr Siddharth Pandey

Title: Vice president & RND Head

Address: Datt Mediproducts Pvt. Ltd., 56, Community Center, East of Kailash, New Delhi – 110065, India

FOR SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES:

Signature: _____

Name: Prof. R K Dhiman Prof. R.K. DHIMAN Director Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226 014 (INDIA)

Title: Director

Address: Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raibareli Road, Lucknow- 226014, Uttar Pradesh, India.

FOR PRINCIPAL INVESTIGATOR:

Signature: _____

Name: Dr. Gyan Chand Dr. Gyan Chand Professor Dept. of Endocrine Surgeon S.G.P.G.I. M.S., Lucknow

Title: Professor

Address: Department of Endocrine Surgery, Sanjay Gandhi Post Graduate Institute of Medical Sciences,

Siddharth Pandey

(Principal Investigator) (Institute/Hospital) (Sponsor)

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ANNEXURE I

Study Title:
A randomized, open label, single centre Post Market Surveillance Study to evaluate the efficacy and safety of a new antimicrobial wound dressing (VELVERT) compared to standard dressing (SD) in the treatment of Diabetic foot ulcer.

Fixed cost as investigators includes both investigators Principal and Co-Investigator fee: Datt Mediproducts Pvt. Ltd. will pay maximum up to INR 700/ per visit upon achieving the milestones listed below.
Clinical research coordinator shall be provided by the sponsor and cost of the same shall be borne by the sponsor.

1. **Payment Milestones**

As per monthly invoice generated by site. Invoice will be clear by sponsor within 30 days of receipt of invoice.

2. **Allocated study budget** (B)

Particulars	Per visit	Cost Per subject
Investigators Fee	INR 700/	**INR 10,500/-**
Institutional charges @ 25% of total Budget	-	*25% Institutional overhead*
Grand Total	-	

3. **Bank details for payment transfer:**

Beneficiary Name	Director SGPGI Research Account
Bank Name	State Bank of India
Bank Address	Sanjay Gandhi PGIMS, Rae Bareli Road, Lucknow, Uttar Pradesh, India 226014
Account No.	10095237491
Account Type	Current
NEFT/ IFC / RTGS code	IFSC code. SBIN0007789

Siddharth Pandey

(Principal Investigator) (Institute/Hospital) (Sponsor)

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महाराष्ट्र MAHARASHTRA ◑ 2021 ◑ BG 124182

उप कोषागार कार्यालय कल्याण

उप कोषागार अधिकारी कल्याण

29 JUN 2022

Novartis Healthcare Private Limited (FIRST PART)

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences (SECOND PART)

AND

Dr. Jayantee Kalita (THIRD PART)

V. Jayanthi

Kalita

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement ("**Agreement**") is entered into as of [22 NOV 2022] ("**Effective Date**") between **Novartis Healthcare Private Limited,** a company incorporated under the provisions of the Companies Act, 1956, and having its registered office at Inspire BKC, Part of 601 & 701, Bandra Kurla Complex, Bandra (East), Mumbai – 400 051, Maharashtra, India (hereinafter referred to as "**Novartis**" which expression shall unless repugnant to meaning or context mean and include its successors and assigns) of the FIRST PART;

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences, located at ***Uttar Pradesh*** ("**Institution**") registered under the provision of the State Legislature Act and having its address at Raebareli road, lucknow-226014, Uttar Pradesh, India which expression shall mean and include its successors and assigns of the SECOND PART;

AND

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

Novartis, Institution and Principal Investigator are hereinafter individually referred to as the "**Party**" and jointly as the "**Parties**". For the purposes of this Agreement, "**Affiliate(s)**" shall mean any entity which directly or indirectly controls, is controlled by or is under common control of Novartis.

RECITALS:

WHEREAS, Novartis is to perform a clinical trial (hereinafter the "Trial) to evaluate the following drug **LOU064/remibrutinib** (hereafter the "Trial Drug") in accordance with a protocol entitled **"A randomized, double-blind, double-dummy, parallel-group study, comparing the efficacy and safety of remibrutinib versus teriflunomide in participants with relapsing multiple sclerosis, followed by extended treatment with open-label remibrutinib.", CLOU064C12301"** and its potential subsequent amendments (hereinafter collectively the "Protocol").

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

WHEREAS the Principal Investigator is an employee of the Institution,

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

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

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1. **CONFORMANCE WITH LAW AND ACCEPTED PRACTICE**

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

(a) the Protocol;

(b) Good Clinical Practice (GCP) including the International Conference for Harmonization (ICH) GCP;

(c) the Declaration of Helsinki of the World Medical Association, "Ethical Principles for Medical Research Involving Human Subjects";

(d) any applicable direction received from a Regulatory Authority (like Drug Controller General of India) or Ethics Committee with jurisdiction over the Trial;

(e) any "**Applicable Law(s)**" being hereinafter defined as: all regional, federal, state, and local directives, laws rules including but not limited to New Drugs and Clinical Trials Rules 2019, any data protection laws and rules relating to the privacy, security, confidentiality and/or integrity of Personal Data that are applicable to the operations, services or products of Institution, Principal Investigator and Novartis, regulations, orders, published guidelines, operating procedures applicable to the Trial and/or the Parties including but not limited to, legislation applicable to clinical studies, the Parties, medical treatment, disclosures of transfers of value and the processing of personal and medical data;

(f) Comply with all guidelines provided to it by Novartis from time to time including but not limited to the Applicable Anti-Corruption Legislations (as set out in Annex 3) and Novartis Professional Practice Policy.

and all written instructions given by Novartis.

all, as amended from time to time.

The Institution shall ensure that the Principal Investigator and the Institution's employees and other persons involved in the Trial will 1) adhere to all Applicable Laws, 2) comply with all obligations set forth in this Agreement, 3) fully understand and adhere to the Protocol.

2. PROTOCOL

2.1 A copy of the Protocol has previously been furnished to the Institution and the Principal Investigator and receipt thereof is hereby acknowledged by the Institution and the Principal Investigator. The Parties agree that the Protocol, including any subsequent amendments and the Annexes form an integral part of this Agreement.

2.2 Institution and Principal Investigator shall perform the Trial in accordance with the Protocol, all Applicable Laws, the identified timelines and the terms and conditions of this Agreement. Institution and Principal Investigator shall not start the Trial without prior approval of the appropriate Ethics Committee and/or Regulatory Authority.

2.3 Novartis may at any time amend the Protocol by written notice to Principal Investigator and Institution. Such amendments, whether or not substantial, may require the approval of the Ethics Committee and/or the Regulatory Authority before implementation.

2.4 No financial adjustments shall be made due to such amendments, unless the Parties hereto amend this Agreement accordingly.

3. APPROVALS

The Trial shall not start until:

(a) all the necessary approvals of the relevant Regulatory Authority and the competent Ethics Committee have been obtained in writing by the Principal Investigator/or Novartis. Relevant approvals from the Ethics Committees shall be forwarded to Novartis as they are obtained;

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

(c) the Informed Consent Form as defined in Section 5.3 (d) provided by Novartis, has been approved by the Principal Investigator and/or, as applicable, by the Ethics Committee.

4. TERM OF THIS AGREEMENT

4.1 This Agreement shall be effective upon signature by both Parties and shall expire upon receipt and acceptance by Novartis of the work product specified in the Protocol.

4.2 The following provisions shall survive the termination or expiry of this Agreement: Section 11 (Intellectual Property), Section 12 (Publication), Section 14 (Confidentiality)

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understood to survive the termination or expiry of this Agreement, including compliance with Applicable Laws.

The Institution shall not be able to replace the Principal Investigator with another Principal Investigator without the prior written consent of Novartis. The Institution shall inform Novartis in writing within five (5) business days if the Principal Investigator is unable or unwilling to continue to perform its duties as Principal Investigator and shall provide reasonable assistance in finding a replacement acceptable to Novartis. Enrolment of new trial subjects (hereinafter "Trial Subjects"), shall be put on hold until the new Principal Investigator has been appointed. The Institution acknowledges that Novartis will continue to make payments for Trial Subjects already enrolled by the prior Principal Investigator, but shall not shall make payments for new Trial Subjects.

During the selection process of the new Principal Investigator, Novartis shall agree immediately with the Institution to appoint an ad interim Principal Investigator in order to continue to perform the Trial Subjects visits according to Protocol.

If a replacement is unable to be found within thirty (30) days after notification, Novartis may terminate this Agreement. If the Principal Investigator ceases to be affiliated with the Institution, Novartis shall have the right to transfer the conduct of the Trial from the Institution to the Principal Investigator's new practice, and the Institution agrees to fully cooperate with Novartis and the Principal Investigator in the transition of such responsibilities, including assisting with the transfer of any subject medical records.

5. PERFORMANCE OF THE TRIAL

Principal Investigator shall be responsible for the performance of the Trial, in particular for the following:

The Principal Investigator may appoint individuals and investigational staff as they may deem appropriate as sub-investigator (the "Sub-Investigators") to assist in the conduct of the Trial, (collectively " the Trial Staff").

All Sub-Investigators and investigational staff will be adequately qualified, timely appointed and an updated list will be maintained by the Principal Investigator. Principal Investigator shall be responsible for leading such team of Sub-Investigators and investigational staff, who, in all respects, shall be bound by the same terms and conditions as the Principal Investigator under this Agreement. The Principal Investigator shall provide Novartis with an up-to-date signed CV of him/her and of all key investigational staff members as well as all other relevant document establishing qualification, experience. He/ She shall document and oversee the duties delegated to the staff, ensuring only qualified and trained staff members are involved in the Trial. The Principal Investigator shall be responsible for the conduct of the Trial in its entirety and for the rights, safety and well-being of the Trial Subjects.

5.1 Trial Site

The Trial shall be conducted at the premises of Institution: (hereinafter the "**Trial Site**").

5.2 Use of Trial Drug:

Novartis shall provide the Trial Drug in sufficient quantity to conduct the Trial. For purposes of this Agreement only, the Trial Drug shall be supplied to Institution free of charge. In all events, the Trial Drug shall remain the sole property of Novartis.

The Principal Investigator shall

(a) ensure the safe receipt, handling, storage, use and administration of the Trial Drug and take all reasonable measures to ensure that it is kept secure, in agreement with GCP, the Protocol and any applicable guidelines;

(b) make a written declaration revealing whether or not the Principal Investigator has any possible economic or other interests in connection with the conduct of the Trial and the Trial Drug and – if so – what his/her interests are and shall submit such written declaration to Novartis.

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

(d) shall not make the Trial Drug available to any third party other than as specified in the

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

(f) cooperate with the Novartis Monitors and observe the instructions given by them;

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

5.3 **Trial Subject consent and entry into Trial:**

Before entering a Trial Subject into the Trial, the Principal Investigator shall:

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

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

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

(d) ensure that, before his /her participation in the Trial, each Trial Subject and/or as the case may be her/his legal representative has given his or her Informed Consent by signing a consent form ("Informed Consent Form" or "ICF") in the form provided by Novartis, in accordance with the Protocol and without the undue influence or coercion of any person directly involved in the Trial, and in accordance with Applicable Laws.;

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

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

(g) comply with the procedures described in the Protocol in relation to that Trial Subject.

5.4 **Trial Subject Recruitment**

Principal Investigator has estimated that he/she can recruit the number of Trial Subjects as specified in Annex 1. This target of recruitment can be increased only upon written agreement of Novartis. In addition, Novartis may establish a threshold number of Trial Subjects and rate of accrual of Trial Subjects (1 subject screening per month) to allow for appropriate monitoring of the Trial, and will communicate this information to the Principal Investigator. The Principal Investigator undertakes to comply with these limitations and conditions for further recruitment at the Trial Site as required by Novartis.

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

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

5.5 **Recordkeeping**

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

(a) Preparation and maintenance of complete, accurately written and electronic records,

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disposition of the Trial Drug and all supportive documentation and data for each Trial Subject of this Trial (hereinafter "Records");

(b) Preparation and maintenance of the Investigator Site File (hereinafter "the ISF") and, in particular, ongoing filing of all relevant Trial-related original documents in the ISF;

(c) Maintenance of a copy of all documents related to this Trial for the longer of at least a) fifteen (15) years after the Trial is completed or discontinued by Novartis, b) or longer as required by Applicable Laws. Maintenance of all documents and other Records generated in the Trial in safe keeping for such period as is required by any applicable regulations, and in any event for 15 years following termination of the Trial. If Novartis has any legal reasons to wish to access the documents for a longer period than described above, Novartis shall notify the Institution accordingly before the end of such period. In the event of the insolvency or bankruptcy of Institution, Institution agrees to promptly transmit all copies of such records to Novartis in accordance with Novartis' written instructions at Novartis' expense.

(d) Meet with a representative of Novartis to discuss the progress of the Trial; and notification to Novartis immediately upon discovering any significant violations of the Protocol.

(e) Safely keeping the hospital records of Trial Subjects in a known and accessible location during the period defined here-above.

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

(g) Be responsible for making any necessary applications for registration under the data protection legislation in connection with data obtained under this Agreement.

5.6 **Reporting**:

The Principal Investigator shall, and shall ensure that any co-investigator involved in the conduct of the Trial shall, on reasonable notice

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

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

(c) In accordance with the procedure set out in the Protocol: Completion of a Case Report Form for each Trial Subject; review and signing of each of the Case Report Forms to ensure and confirm their accuracy and completeness, ensuring errors are corrected upon identification; and prompt submission of the Case Report Forms to Novartis following their completion,

(d) Cooperation with Novartis in all their efforts to monitor the Trial and to support Novartis in all matters of data collection, verification and discrepancy resolution

(e) Immediately or at latest within two (2) days of the occurrence, inform Novartis upon discovering any violations of the Protocol, or breaches or potential breaches of the Applicable Laws.

5.7 **Reporting of Safety Information**:

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

The Institution and the Principal Investigator shall also ensure that any person involved in the conduct of the Trial shall:

(a) Immediately and not later than within 24 hours report to Novartis according to the procedure set out in the Protocol, any new safety findings on the Trial Drug, including

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risk-benefit ratio of the Trial Drug. The Principal Investigator shall follow up such immediate reports and provide the additional information in a detailed, written manner to Novartis in accordance with the Protocol;

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

(c) Cooperate with and supply any further information required by Novartis and/or any relevant Ethics Committee or Regulatory Authority with jurisdiction over the Trial; and

(d) Report to Novartis any emergency that requires to that requires to unblind the patient in in the event of double-blind studies and to document and notify Novartis of the date and reason for the emergency situation.

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

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

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

5.8 Items supplied by Novartis

Novartis shall provide directly or indirectly the Principal Investigator and/or the Institution with all necessary information, documents, study equipments (as set out in Annex 1) and materials, including but not limited to:

(a) the Investigator Brochure (IB)

(b) the Protocol,

(c) the CRF/e-CRF

(d) The Trial Drug

6. LIABILITY-INDEMNIFICATION

Novartis shall assume responsibility for injuries to third parties caused in the course of carrying out the Trial according to the Applicable Laws, this Agreement and the Protocol, provided that:

(a) The Institution, the Principal Investigator, the Institution's employees and collaborators (hereinafter collectively "the Indemnitees" or each an "Indemnitee") shall have been free of wrongful conduct or omission, negligence, and wilful misconduct in the conduct of the Trial and in their obligations under this Agreement and the Protocol, and shall not have failed to follow the instructions or recommendations of Novartis;

(b) The Indemnitee refrains from making any admission of liability or any attempt to settle any claim without Novartis' consent;

(c) The Trial Drug causing the injury was given by the Principal Investigator in accordance with the Protocol;

(d) an adequate causal relationship is proven between the use of the Trial Drug and the appearance of injury;

(e) Novartis is immediately informed of the claim and all pertinent information relating thereto (but in any case within ten (10) days after the Indemnitee shall have received notice thereof);

(f) The Indemnitee provide such information and assistance to Novartis in connection with such claim as is reasonably requested by Novartis and its representatives;

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(g) Novartis is permitted to handle and control such claim in its sole discretion.

(h) An Indemnitee seeking indemnification shall take all reasonable steps to mitigate the amount of any claim for indemnification; and

(i) The indemnity will not inure to the benefit of any Indemnitee's insurer, by subrogation or otherwise. The provisions of this Section constitute the Indemnitees' sole and exclusive remedy against Novartis in respect of all claims.

7. INSURANCE

The PI of Institution warrants that it has appropriate and adequate professional indemnity insurance to cover claims or damages for which it shall be liable under this Agreement. The Institution shall provide evidence of its insurance upon request by Novartis.

Novartis warrants that it has insurance for the Trial Subjects included in the Trial in place at Trial start as per the Applicable Laws.

8. COMPENSATION

8.1 In consideration for the Institution's satisfactory performance of the Trial according to this Agreement and the Protocol, the Institution and Investigator agrees to Payment Schedule attached hereto as Annex 1.

8.2 Novartis reserves the right to terminate the Agreement immediately if no Trial Subjects have been recruited at the Trial Site within 90 days after the Site Initiation Visit (SIV).

8.3 Fees for the Trial Subjects not completing the Trial will be paid to the Institution on a prorated basis according to the number of completed Trial assessment as per Protocol. All payment will be made for subject visits according to the Payment Schedule referred in Annex 1. Reimbursement for expenses related to screening failures will be made according to the Payment Schedule in Annex 1.

8.4 The Institution shall send the invoices to:

Novartis Healthcare Private Limited

GDO Trial Monitoring, India

6 & 7 floor, Inspire BKC, G Block,

BKC Main Road,

Bandra Kurla Complex , Bandra (East),

Mumbai – 400051

8.5 Each invoice shall specify the Trial Code. Novartis shall make payments into the account indicated by the Institution within 60 (sixty) days of receipt of an invoice from the Institution.

8.6 Novartis shall give its prior express written approval regarding any additional costs or expenses not foreseen in the Payment Schedule or Annex 1. Any costs or expenses incurred without this prior written approval shall be borne by the Institution.

8.7 Each Party represents and warrants to the others that the payment of the fees related to the conduct of the Trial (including payments to subcontractors, consultants, or other agents working on behalf of the Institution/the Principal Investigator or as part of the Institution's and/or Principal Investigator's services to Novartis, as applicable) (i) represents the fair market value for the conduct of the Trial, (ii) has not been determined in any manner that takes into account the volume or value of any referrals, reimbursements or business between the Institution and/or the Principal Investigator and Novartis, and (iii) is not offered or provided, in whole or in part, with the intent of, directly or indirectly, implicitly or explicitly, influencing or encouraging the recipient to purchase, prescribe, refer, sell, arrange for the purchase or sale, or recommend favorable formulary placement of a Novartis product or as a reward for past behaviour.

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9. EQUIPMENT

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

9.2 If Novartis, or its designee, provides the Institution and/or Investigator with Equipment for the purpose of this Trial, the Institution and Investigator agree that neither Novartis nor its designee shall be responsible to (i) insure the Equipment against any damages caused to or by the Equipment, and (ii) do the maintenance of the Equipment during the term of the Trial. The Institution and/or Investigator agree that the Equipment shall remain in the same condition during the Trial, with the exception of ordinary depreciation.

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

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

10. TERMINATION

(a) Termination by Novartis. Novartis, in its sole discretion, shall have the right to terminate with immediate effect the conduct of the Trial at any time and give notice to the Institution 07 days before the termination of the trial .Upon receipt of the notice to terminate the Trial, the Institution and the Principal Investigator shall immediately take all reasonable steps to cease conduct of the Trial at the Institution as soon as reasonably possible and to protect the wellbeing of Trial Subjects.

(b) Termination by the Institution. The Institution shall have the right to terminate the conduct of the Trial upon a thirty (30) days prior written notice if necessary to protect the wellbeing of Trial Subjects.

(c) Termination due to unavailability of the Principal Investigator. In addition, either Party may terminate this Agreement with immediate effect by written notice to the respective other Party if the Principal Investigator is no longer available or terminates his or her relationship with the Institution, and a suitable replacement cannot, after reasonable efforts by the Institution, be found that is agreeable to Novartis as described in Section 5.

(d) Termination for Breach etc. Either Party may terminate this Agreement with immediate effect by written notice to the other in the event that (i) the other Party commits a material breach of this Agreement which (if remediable) is not remedied within thirty (30) days of a written notice from the non-defaulting party; or (ii) the other party becomes insolvent.

Any violation of the good clinical practices, the Applicable Anti-Corruption Legislations (as set out in Annex 3), or data protection provisions under the Applicable Laws shall be deemed to be a material breach of this Agreement.

(e) Respective Obligations in the Event of Early Termination. In the event that the conduct of the Trial at the Institution is terminated prior to its completion other than by Novartis under Section 10 Novartis shall pay to the Institution the remuneration detailed in this Agreement for the milestones which have been duly achieved to the date of termination and all non-cancellable expenses previously approved by Novartis. In the event of early termination for any reason, the Institution shall provide all such assistance as Novartis shall reasonably require in order to ensure an efficient handover of the conduct of the Trial to a third party and with due regard for the welfare of the Trial Subjects.

(f) Return of Documents and Material. Upon termination of this Agreement for any reason the Institution shall and shall procure that the Principal Investigator shall return to Novartis all documents, Trial results and material used, generated or referred to in the course of the Trial, and the Institution and the Principal Investigator hereby irrevocably waive any ownership interest or intellectual rights worthy of protection of any of the above.

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The Agreement shall be terminated in writing by registered mail with acknowledgement of receipt. The termination of this Agreement by e-mail communication shall be excluded.

11. INTELLECTUAL PROPERTY

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

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

11.3 The Institution also agrees to, and to cause its employees and collaborators and the Principal Investigator to, execute promptly all documents and take all such other action as may reasonably be requested by Novartis to permit Novartis to obtain the benefit of its rights under this Agreement. This includes without limitation taking all necessary steps for the transfer of ownership of all data, information, documents, inventions and discoveries to Novartis in accordance with this Agreement, and assisting Novartis in the preparation and prosecution of patent applications. The Institution shall be solely responsible for all payments due to the Principal Investigator and/or the Institution's employees and/or collaborators according to the applicable law for any inventions transferred to Novartis. The fees under Section 8 and Annex 1 shall be deemed to include consideration for such payments by the Institution.

12. TAXES AND SOCIAL SECURITY CONTRIBUTIONS

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

13. PUBLICATION

13.1 Novartis recognizes the Institution's interest in making publications and presentations relating to the Trial in journals, at meetings or otherwise, and Novartis shall therefore permit such publications and presentations, provided however that the Institution shall provide to Novartis any proposed presentation (oral or written) at least 15 (fifteen) working days and any other proposed publication at least 45 (forty-five) working days, for its review prior to being disclosed or submitted to anyone who is not employed by the Institution and not under an obligation of non-disclosure and non-use at least substantially identical to that imposed on the Principal Investigator by this Agreement, and provided that Novartis shall have the right to require amendments to any such proposed presentation or publication on reasonable grounds including without limitation:

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

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

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

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

13.2 The list of persons to be designated as primary or secondary author of any publication relating to the Trial shall be determined by mutual agreement.

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

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

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13.5 Any such publication or disclosure must comply with all Applicable Laws and must be limited to scientific findings. Such publications or disclosures must, in particular, not constitute promotion under the Applicable Laws.

13.6 Subject to any copyright rights owned by the applicable publisher, Novartis and its agents may use, refer to and disseminate reprints of scientific, medical and other published articles which disclose the name of the Institution and/or the Principal Investigator.

13.7 Novartis and its agents may use the Institution and the Principal Investigator contact details and Trial status in Trial specific newsletters and on the worldwide web for the purpose of conducting this Trial. Newsletters may be distributed to all participating sites and postings to the worldwide web are for the purpose of providing information to potential Trial Subjects regarding the Trial giving them the ability to contact participating sites.

13.8 Neither the Institution nor the Principal Investigator shall disclose the existence of this Agreement or its association with Novartis, or use the name of Novartis or its agents in any press release, article or other method of communication, without the express prior written approval of the party whose name is the subject of the potential disclosure. Provided, however, that in order for the Institution to satisfy its reporting obligations, they may identify Novartis as the Trial sponsor and disclose the amount of funding received for the Trial, but it shall not include in any such report any information that identifies any product by name or the therapeutic area(s) involved in the Trial, except as otherwise required by the Applicable Laws. The Institution, the Principal Investigator and investigational staff shall not use the name of Novartis or its agents or any information that identifies the Trial Drug or Trial in any social media.

14. CONFIDENTIALITY

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

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

14.3 Upon termination or expiry of this Agreement, the Institution shall destroy or return to Novartis, as per Novartis' request, all documents, samples and material containing or relating to Information, except for one copy of Information which is to be retained in the confidential files of the Institution for record purposes only. If requested by Novartis, such destruction shall be promptly confirmed in writing by the Institution to Novartis.

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

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

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

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

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15. DATA PRIVACY

15.1 Provisions on the collection and processing of data by the Institution and the Principal Investigator.

(a) The collection and processing of Research Data (meaning any data, including personal data concerning the Trial Subjects (such as gender, age, health status, etc) and the Trial Staff shall be performed in compliance with this Agreement and as indicated in the Protocol, the Informed Consent Form and any written instructions issued by Novartis. Research Data collected by the Institution in the Case Report Form shall be processed by the Institution only for the purpose of the performance of this Agreement. However, the Institution may use the data collected in the course of the Trial for the Trial Subject's treatment purposes.

(b) Processing of Research Data shall be performed by the Principal Investigator, Trial Staff and other authorized persons on the need to know basis. The Institution shall be responsible for managing access to the Research Data provided the details in the Institution's possession or control.

(c) The Institution shall ensure Trial Staff processing Research Data have appropriate skills and training to handle personal data and maintain its confidentiality.

(d) Research Data must be kept confidential. It shall not be disclosed or transferred to any third party without prior written approval of Novartis. In case such disclosure includes personal data, the third party receiving the data must have a valid ground under Applicable Law to receive and process such data. Research Data may be disclosed where required by Applicable Law or when requested by a data protection authority.

(e) The Institution shall implement appropriate administrative, technical and physical security measures to protect personal data using current industry best practices taking into consideration the state of the art of applicable technologies.

(f) The Institution shall comply with any instructions regarding the coding of Research Data issued at any time by Novartis in accordance with Applicable Laws and best practice.

(g) The Institution shall maintain procedures to detect and respond to a personal data breach, as defined under Applicable Law, including breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed. The Institution shall notify Novartis of any personal data breach, related to the processing of the Research Data, without undue delay, but no later than twenty-four (24) hours of discovery of such breach. The Institution and Novartis shall reasonably cooperate to remediate a personal data breach and liaise with each other before reporting a personal data breach to the relevant authority.

15.2 Information to Data Subjects. The Institution and the Principal Investigator shall provide Trial Subjects, in accordance with the Applicable Laws, with an Informed Consent to participate in the Trial approved by the sponsor Novartis and the relevant Ethics Committee. Such Informed Consent shall be signed prior to Trial Subject's participation in the Trial. The Institution and/or the Principal Investigator shall timely inform Novartis when a Subject withdraws consent or opposes the use of his/her personal data, as per Applicable Law. The parties agree to collaborate in the context of Trial Subjects' individual requests.

15.3 Trial Staff Personal Data. Prior to and during the course of the Trial, the Principal Investigator and Trial Staff may be required to provide personal data which falls within the scope of the Applicable Laws and/or is needed for the implementation of the Agreement. The Institution and the Principal Investigator agree to inform Trial Staff that their personal data will be processed by Novartis and are responsible for sharing an appropriate privacy notice with such staff members following the framework attached as Annex 4.

15.4 Transfer of data. Novartis may transfer personal data to other affiliates of the Novartis group of companies and their respective agents worldwide. Novartis and its affiliates and respective agents will apply adequate privacy safeguards to protect such personal data. Personal data may also be disclosed as required by individual competent authorities or Applicable Laws, for example to report serious adverse events and comply with drug safety laws and regulations.

15.5 Retention of data. Personal data will be kept only for the period necessary to fulfil the purposes of the collection unless a longer retention period is required or permitted by Applicable Laws

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16. **NOTICES**

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

17. **ASSIGNMENT**

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

18. **SUBCONTRACTING**

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

Whenever a subcontractor is appointed and approved by Novartis, the Principal Investigator shall be responsible for the oversight of the subcontractor's personnel as part of the Trial Staff.

19. **SEVERABILITY**

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

20. **WAIVER**

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

21. **ENTIRE AGREEMENT**

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

22. **DEBARMENT OF INSTITUTION/PRINCIPAL INVESTIGATOR OR OTHER RESTRICTIONS FROM THE COMPETENT AUTHORITIES**

(a) **Debarment**. The Institution and the Principal Investigator certify that they are not debarred or more generally under a prohibition under the relevant Applicable Laws to perform their activities. They certify that they will not use in any capacity the services of any person debarred (or otherwise under a prohibition to perform their activity) with respect to services to be performed under this Agreement. During the term of this Agreement and for three (3) years after its termination, the Institution and the Principal Investigator will notify Novartis promptly if this certification needs to be amended in light of new information. Principal Investigator also certifies that he/she does not have a revoked or suspended medical license or applicable certification.

(b) **Investigations, Inquiries, Warnings or Enforcement Actions Related to Conduct of Clinical Research**. The Institution and the Principal Investigator certify that they are not the subject of any past or pending governmental or regulatory investigation, inquiry, warning, or enforcement action (collectively, "**Competent Authority Action**") related to its conduct of clinical research that has not been disclosed to Novartis. The Institution and the Principal Investigator will notify Novartis promptly if it receives notice of or becomes the subject of any Competent Authority Action regarding its compliance with ethical, scientific, or regulatory standards for the conduct of clinical research, if the Competent Authority Action relates to events or activities that occurred prior to or during the period in which the Trial was conducted.

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23. CONFLICT OF INTEREST AND FINANCIAL DISCLOSURE

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

23.2 As the case may be, the Institution and the Principal Investigator shall ensure that the Principal Investigator and all Sub-Investigators involved in the Trial provide Novartis or its designee with the appropriate financial disclosures required by the U.S. Food and Drug Administration under 21 CFR Part 54, on such forms as Novartis or its designee may supply or approve. During the term of this Agreement and one (1) year following its expiration or earlier termination, the Institution and the Principal Investigator agree to assist the Sponsor or its designee in obtaining updated forms.

24. TRANSPARENCY/DISCLOSURE

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

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

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

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

24.3 It shall be assessed locally if the Provision 24.3 below is required and that it does not contradict with Local Regulations on Data Privacy. The provisions shall be adapted as needed to ensure consistency with Local Regulations on Data Privacy. This term is mandatory for clinical studies that have sites in China as they have to be registered in the "Drug Clinical Trial Registry", and this registration includes investigator's personal data. Please inform clinicaltrial.cn@novartis.com if this term could not be included due to Local Regulations on Data Privacy so that individual consent request could be administered.

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

25. AUDITS AND INSPECTIONS

(a) Audit by Novartis and Records. The Institution shall grant access to its premises periodically as frequently as required for the proper performance and oversight of the Trial site in order to proceed with any and all monitoring activities required for the Trial. In addition, the Institution shall permit Novartis and its agents, during normal business hours and at mutually agreeable times, to inspect and make abstracts of records and reports collected and generated by the Institution and the Principal Investigator in the course of conducting the Trial and to inspect the facilities at which the Trial is conducted to verify compliance with this Agreement, the Protocol, Applicable Laws and the accuracy of information provided in connection with the Trial. The Institution shall ensure that the

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during an audit in order to discuss such records and reports and to resolve any questions relating to such records and reports. At the request of Novartis or its agents, the Institution and the Principal Investigator shall immediately correct any errors or omissions in such records and reports.

(b) Cooperation during Audit by Novartis. The Institution shall cooperate, and shall cause the Principal Investigator and the staff to cooperate, with Novartis and its contractors and agents in the event of any internal audits, upon reasonable notice and during normal business hours. The Institution shall furthermore make available to Novartis and its contractors and agents (for examination and duplication) all documentation, data and information relating to the Trial. Trial Subject medical records will be made available where appropriate for the purpose of source document verification procedures as part of the audit. The Institution also shall make the Principal Investigator and staff available to Novartis and its contractors and agents to explain and discuss such documentation, data and information. For the avoidance of doubt audits shall be supported at no cost by the Principal Investigator and investigational staff.

(c) Inspection by Competent Authority. The Institution and the Principal Investigator acknowledge that the Trial is subject to inspections by regulatory agencies worldwide, and that such inspections may also occur after completion of the Trial. In the event the Institution or the Principal Investigator receives notice that the Institution shall be the subject of an investigation or audit by any competent authority or Ethics Committee, as applicable, in relation to the Trial, it shall notify Novartis immediately within twenty four (24) hours the latest and shall obtain approval for Novartis or its agents to be present at the inspection or otherwise keep Novartis timely and constantly informed of the progress. In the event the Institution or the Principal Investigator does not receive prior notice of said inspection, it shall notify Novartis as soon as practicable after receiving knowledge of said inspection. Institution shall provide Novartis with copies of any reports or information issued by the authority and Institution's proposed and final response. The Institution will promptly forward to Novartis copies of any inspection findings that the Institution receives from a competent authority or Ethics Committee, as applicable, in relation to the Trial. The Institution will provide Novartis with an opportunity to prospectively review any Institution responses to competent authority inspections in regard to the Trial.

(d) The Institution, the Principal Investigator and the staff shall cooperate with the relevant competent authorities or Ethics Committee, as applicable and comply with the legitimate requirements of an inspection. This also includes the making available (for examination and duplication) of documentation, data and information relating to the Trial. Subject medical records shall be made available where required for source document verification procedures as part of the inspection. The Institution also shall make the Principal Investigator and other staff available to the relevant competent authority to explain and discuss such documentation, data and information.

26. JURISDICTION, APPLICABLE LAW, AND DISPUTE RESOLUTION.

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

In the event of dispute arising under the agreement, the parties shall be resolve the dispute in good faith through mutual consultation. In case the dispute is not resolved within 7 days, the parties agree that the competent courts of Lucknow India shall have jurisdiction to decide any dispute related to this agreement.

27. PRECEDENCE

To the extent that there may be any inconsistency between this Agreement and the Protocol, the Protocol shall take precedence in relation with trial procedures.

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

NOVARTIS HEALTHCARE Pvt Ltd.

By: _____

Name: **Murugananthan K.**

Title: Country Monitoring Head

Date: 22 NOV 2022

Sanjay Gandhi Post Graduate Institute of Medical Science

By: _____

Name: Prof R.K Diman

Title: Director

Date: _____

Prof. R.K. DHIMAN
Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences
LUCKNOW-226 014, INDIA

PRINCIPAL INVESTIGATOR

By: _____

Name: Dr. Jayantee Kalita

Title: Professor

Date: 10 Feb 2023

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SGPGIMS,Lucknow

Annex1: Payment (and Equipment) Schedule

STUDY NUMBER: CLOU064C12301

STUDY NAME: A RANDOMIZED, DOUBLE-BLIND, DOUBLE-DUMMY, PARALLEL-GROUP STUDY, COMPARING THE EFFICACY AND SAFETY OF REMIBRUTINIB VERSUS TERIFLUNOMIDE IN PARTICIPANTS WITH RELAPSING MULTIPLE SCLEROSIS, FOLLOWED BY EXTENDED TREATMENT WITH OPEN-LABEL REMIBRUTINIB

Investigator's Name: Dr. Jayantee Kalita

Institute Name: Sanjay Gandhi Post Graduate Institute of Medical Sciences

Payee Name: Director, SGPGIMS Research Scheme Account

Pan Card Number: AAAJS3913N

GSTIN: 09AAAJS3913N2ZN

Committed Number of Study Subjects: 6

List of Equipment provided to Institution / Principal Investigator:

- eCOA Phone: To be retrieved post DBL
- ECG: To be retrieved post DBL
- Signant eCOA Tablet: To be retrieved post DBL
- Thermohygrometer: To be retrieved post DBL

1. Payment shall be made directly by Novartis

2. Payments to the Institution shall be subject to the following:

- "Evaluable" subjects shall be any and all subjects correctly entered into the Trial in accordance with the Protocol, i.e. those who satisfy all of the inclusion and exclusion criteria specified in the Protocol, commence the dosing regimen and complete the Trial.
- The final payment will not be due and payable until the entirely and duly completed Case Report Forms (CRFs) were sent to and have been accepted by Novartis and any potential queries have been resolved.
- Pharmacy dispensing costs are not included in the "per subject costs" and will be paid additionally upon receipt of a respective invoice along with supporting receipt.
- The amount of payment due to the Institution/Investigator will be calculated in respect of each patient visit according to the attached budget schedule.
- For patients who are not randomized into the study based on Screening results (Screen Failures) Institution/Investigator will not receive remuneration in the amount of a screening visit cost
- Any other third parties designated by the Institution/Investigator that would receive remuneration, will be managed by & paid by the Institution/Investigator.
- The work performed by the hospital laboratory in addition to budget schedule shall be paid based on actuals. It is the Investigators responsibility to liaise with the hospital laboratory and provide invoice along with supporting receipt on a quarterly basis.
- Sponsor shall reimburse patient's travel cost per protocol visit as per actuals for which institution/PI shall provide original invoice along with the supporting receipts.
- The Ethics committee charge will also be paid via Novartis as per the EC SOP, and this cost is not included in the budget schedule.
- Unscheduled visits covers subject visits that are not expressly set forth in the Study Schematic of the Protocol, but are otherwise required for the study. Medically necessary procedure, test performed during unscheduled visits would be paid as per actual bills. Payment for unscheduled visits will be payable to the institution within 60 days of receipt of original, itemized invoice by Novartis.
- All payments are based on actual patient visits.
- All values are in INR. All budget schedule payments are subject to TDS (subject to Government of India, Tax regulations) and GST as applicable. GST will be paid on providing valid tax invoice with relevant details mentioning GST registration number on it

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The Institution shall be solely responsible for the payment of any and all taxes or other charges that are or may be levied. Unless expressly approved by Novartis prior to incurring the cost or expense, the Institution shall be responsible for all costs and expenses incurred by it in conducting the Trial. This includes, among other things, the payment of all investigational staff, including the Principal Investigator [and fees for the pharmacy and laboratory tests].

Study Budget:

Assessment Schedule, Core Part

Visit		Investigator Fees	Protocol Procedures	EDSS Rater	Coordinator Fees	Institutional Overhead @ 25%	TOTAL (INR)	Total Per patient cost
Screening	Screening	5000	32000	1500	2500	10250	51250	**549375**
Treatment	D1	5000	20000	1500	2500	7250	36250	
	M1	5000	12000	-	2500	4875	24375	
	M3	5000	32000	1500	2500	10250	51250	
	M6	5000	32000	1500	2500	10250	51250	
	M9	5000	12000	1500	2500	5250	26250	
	M12	5000	18000	1500	2500	6750	33750	
	M15	5000	12000	1500	2500	5250	26250	
	M18	5000	12000	1500	2500	5250	26250	
	M21	5000	12000	1500	2500	5250	26250	
	M24	5000	32000	1500	2500	10250	51250	
	M27	5000	8000	1500	2500	4250	21250	
	M30 / EOS[4]	5000	32000	1500	2500	10250	51250	
	EOT	5000	32000	1500	2500	10250	51250	
Follow-up	Follow-up	5000	8000	1500	2500	4250	21250	

Assessment Schedule, Extension Part

Visit Name	Investigator Fees	Protocol Procedures	EDSS Rater	Coordinator Fees	Institutional Overhead @ 25%	TOTAL (INR)	Total Per patient cost
EP Day 1	5000	14000	1500	2500	5750	28750	**387500**
EP M1	5000	7000	1500	2500	4000	20000	
EP M6	5000	14000	1500	2500	5750	28750	
EP M12	5000	14000	1500	2500	5750	28750	
EP M18	5000	8000	1500	2500	4250	21250	
EP M24	5000	14000	1500	2500	5750	28750	
EP M30	5000	8000	1500	2500	4250	21250	
EP M36	5000	35000	1500	2500	11000	55000	
EP M42	5000	8000	1500	2500	4250	21250	
EP M48	5000	14000	1500	2500	5750	28750	
EP M54	5000	14000	1500	2500	5750	28750	
EP M60/EOS	5000	35000	1500	2500	11000	55000	
EP Follow-up	5000	8000	1500	2500	4250	21250	

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ANNEX 2: PRINCIPAL INVESTIGATOR – PERSONAL DATA DISCLOSURE FORM

1. You understand that Novartis may wish to process your personal data for administrative and commercial purposes for example in a database to be used for the organization of future clinical trials. You further understand and agree that your personal data may if necessary for these 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: 10 Feb 23

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Name: **Dr. Jayantee Kalita**

Principal Investigator

ANNEX 3: Applicable Anti-Corruption Legislation

The Institution, the Principal Investigator, the investigational staff and any other person contributing to the Trial (the ***Trial Parties***) shall at all times in the conduct of the Trial comply with the Bribery Act 2010 of the United Kingdom (***Bribery Act***), the Foreign Corrupt Practices 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.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

ANNEX 4: Privacy notice. To be shared by the Principal Investigator with Trial Staff

[Feb 23]

(Month/Year)

This privacy notice is addressed to:

- **Clinical investigators** (principal investigator, sub-investigator or co-investigator);
- **Other Site staff** such as nurses, pharmacists or technicians, whose Personal Data may be processed in the course of the clinical trial sponsored by Novartis.

You are receiving this Privacy Notice because Novartis Healthcare Pvt LTD (**"Novartis"**) will process information about you, which constitutes "Personal Data."

This privacy notice is provided to you to ensure transparency in relation to collection, use and disclosure of your Personal Data by Novartis for purposes related to the conduct of clinical trials sponsored by Novartis Healthcare Pvt LTD (**"Novartis Clinical Trials"**) which are being carried at your Clinical Trial Site [(the "**Site**"). For the purposes described in this Privacy Notice, **Novartis** is responsible for the processing of your Personal Data acting as a "Controller".

Collection of Personal Data

For the purposes described in this Privacy Notice, we may collect the following information about you including:

- name, identification number, address and other contact details,
- financial information (e.g. bank account number, financial interests in any of the Novartis group companies),
- qualifications, publications and information contained in the CV you provide to us where necessary,
- previous experience in clinical trials within or outside of Novartis and type of the GCP training received,
- technical data related to your use of Novartis IT systems.

Purposes and legal basis for processing your Personal Data

Processing purpose	Legal basis
1. to conduct Novartis Clinical Trials in accordance with good clinical practice and applicable laws;	Novartis' legitimate interest to conduct clinical trials to test potential treatments as well as compliance with legal and regulatory obligations;
2. to support applications for and to comply with the conditions of any marketing approval granted in respect of any medication studied under a Novartis Clinical Trial (**"Study Medication"**)	compliance with legal and regulatory obligations;
3. to support applications to vary the terms of any marketing approval granted in respect of a Study Medication;	Novartis' legitimate interest to conduct clinical trials to test potential treatments;
4. to carry out research related to the development of pharmaceutical products, diagnostics or medical aids and improve clinical trial practice;	Novartis' legitimate interest to conduct clinical trials to test potential treatments;
5. to comply with the US Financial Disclosure regulation, which is intended to ensure that financial interests and arrangements of clinical investigators that could affect the reliability of data submitted to the Federal Drug Administration of the U.S.A. ("FDA") are identified and disclosed to the FDA1;	Legitimate interest and compliance with legal and regulatory obligations;
6. to ensure traceability and follow-up of drug safety notification.	compliance with legal and regulatory obligations.

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Executive Registrar
SGPGIMS,Lucknow

1 **Clinical investigators:** principal investigator, sub-investigator or co-investigator who are directly involved in the treatment or evaluation of research subjects in NOVARTIS Clinical Trials affected by this law, must disclose information to

If applicable to Novartis Clinical Trial, your Personal Data (name and contact information) may be incorporated in subject recruitment advertisements (print media or on Internet). Any such advertisement would be approved by the Ethical Committee before it is made public.

Sharing of Personal Data

In the course of our activities and for the purposes listed in this Privacy Notice, your Personal Data can be accessed by, or transferred to the following categories of recipients, on a need to know basis to achieve such purposes:

- the sponsor of the Clinical Trial,
- our personnel (including personnel, departments or other companies of the Novartis group),
- our independent agents or brokers (if any),
- our suppliers and services providers that provide services and products to us,
- our partners in the context of consortia or industry initiatives,
- our IT systems providers, cloud service providers, database providers and consultants,
- our business partners who offer products or services jointly with us or with our subsidiaries or affiliates,
- any third party to whom we assign or novate any of our rights or obligations ,our advisors and external lawyers in the context of the sale or transfer of any part of our business or its assets,
- national and/or international regulatory bodies or Ethics Committees.

The above third parties are obliged to protect the confidentiality and security of your Personal Data, in compliance with applicable laws.

If we transfer your Personal Data to other jurisdictions, we will make sure to protect your Personal Data by (i) applying the level of protection required under the local data protection/privacy laws applicable in the country of destination, (ii) acting in accordance with our policies and standards and, (iii) for entities located in the European Economic Area (i.e. the EU Member States plus Iceland, Liechtenstein and Norway, the "EEA"), unless otherwise specified, by transferring your Personal Data on the basis of standard contractual clauses approved by the European Commission. You may request additional information in relation to international transfers of Personal Data and obtain a copy of the adequate safeguard put in place by exercising your rights as described below.

For intra-group transfers of Personal Data, the Novartis group has adopted Binding Corporate Rules, a system of principles, rules and tools, provided by European law, in an effort to ensure effective levels of data protection relating to transfers of Personal Data outside the EEA and Switzerland. Read more about the Novartis Binding Corporate Rules at novartis.com/privacy-policy

Duration of storage

We will keep your Personal Data as long as needed for legal and regulatory requirements. Please note that we are required to retain Clinical Trial Documentation for a minimum of 25 years.

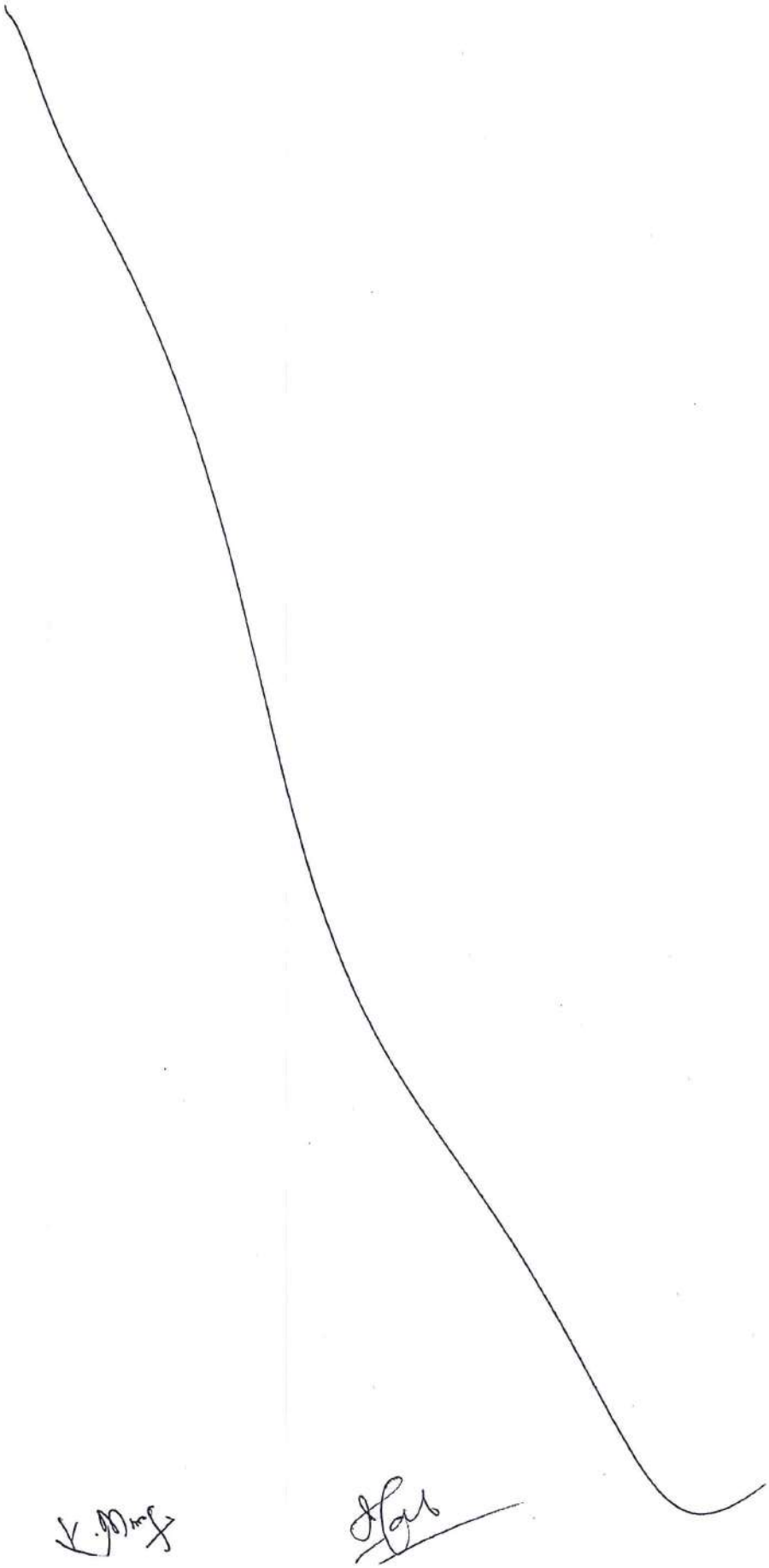
What are your rights and how can you exercise them?

Under conditions provided by the law, you have a right to request a copy of the personal information we hold about you. You may also object to its use or ask for it to be updated, restricted, deleted, or transferred to another organisation. If you wish to contact us regarding our use of your Personal Data or you wish to exercise your data privacy rights, you may send an email to < PI email ID >.

If you are not satisfied with how we process your Personal Data, please address your request to our Data Protection Officer at global.privacy_office@novartis.com, who will investigate your concern. In any case, you also have the right to file a complaint with a responsible supervisory authority, in addition to your rights above.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

ANNEX 5: NOVARTIS PROFESSIONAL PRACTICES POLICY



Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

INDIA NON JUDICIAL

Government of Uttar Pradesh

IN-UP01247166819988V

e-Stamp

Certificate No.	:	IN-UP01247166819988V
Certificate Issued Date	:	14-Dec-2023 04:40 PM
Account Reference	:	NEWIMPACC (SV)/ up14733204/ LUCKNOW SADAR/ UP-LKN
Unique Doc. Reference	:	SUBIN-UPUP14733204982705329731 89V
Purchased by	:	ANSHIKA SRIVASTAVA
Description of Document	:	Article 5 Agreement or Memorandum of an agreement
Property Description.	:	Not Applicable
Consideration Price (Rs.)	:	
First Party	:	ANSHIKA SRIVASTAVA
Second Party	:	Not Applicable
Stamp Duty Paid By	:	ANSHIKA SRIVASTAVA
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

CHANDRA PRAKASH DIXIT
SHCILACC CODE UP14733204
LUCKNOW

Please write or type below this line

MEMORANDUM OF AGREEMENT

This MEMORANDUM OF AGREEMENT is made on this Fourteen December day of Two thousand and Twenty Three 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 (SGPGIMS), Raebareli Road, Lucknow-226014, UP, India, a society under the Societies Registration Act – 1860, having its registered office in/at Sanjay Gandhi Postgraduate Institute of

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Statutory Alert:
1. The authenticity of this Stamp certificate should be verified at 'www.shcilestamp.com' or using e-Stamp Mobile App of Stock Holding. Any discrepancy in the details on this Certificate and as available on the website / Mobile App 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.

1860, having its registered office in/at **Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Raebareli Road, Lucknow-226014, UP, India,** hereinafter referred to as **SGPGIMS** (which expression shall where the context so admits include its successors and permitted assigns) of the OTHER PART; (154)

WHEREAS DBT being desirous of **Human genetics and cardiomyopathies** decided to support a project submitted by **Dr. Anshika Srivastava, Assistant Professor, Department of Medical Genetics, SGPGIMS, Lucknow, India** for the attainment of the objectives, hereinafter described in the Annexure I annexed hereto;

This Memorandum of Agreement (MoA) defines the role and responsibilities of the participating agencies, monitoring and other matters related to the **"Harnessing Genome sequencing and engineering (CRISPR/Cas9) technologies for identification of shared genetic and molecular etiology in pediatric and adult Cardiomyopathies."**

NOW THE PARTIES HERETO AGREE AS FOLLOWS:-

1.0 . ROLE OF DEPARTMENT OF BIOTECHNOLOGY, NEW DELHI

To provide funds to the extent of **Rs. 86,60,988.00 (Rupees Eighty Six Lakhs Sixty Thousand Nine Hundred and Eighty Eight Only)** over a period of **Three (03)** years from the date of sanction of the project **Sanction Letter No.- (BT/PR38372/GET/119/329/2020) dated 06.01.2022**, from 06.01.2022 to 05.01.2025 **(Dr. Anshika Srivastava, SGPGIMS, Lucknow** for undertaking activities as detailed in Annexure 1. Details of the funds to be provided are given in Annexure II.

2.0. ROLE OF Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Raebareli Road, Lucknow-226014, UP, India

2.1. To provide their contribution of (NIL) for (*duration in years)* years from date of sanction of the project as detailed in Annexure – II. *(Provide the cost in place of NIL 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.

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.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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

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3.0 DURATION OF PROJECT

3.1 Duration of project shall be **Three (03)** 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 **SGPGIMS, Lucknow** will be the joint property of **SGPGIMS, Lucknow** and DBT, Government of India. It shall be the responsibility of **Sanjay Gandhi Postgraduate Institute of Medical Sciences(SGPGIMS), Raebareli Road, Lucknow-226014, UP, India** 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.

4.3 All the assets including the equipment and produce acquired will be the property of DBT and shall not be utilized for purposes other than those for which the grant has been sanctioned. The rights of **SGPGIMS, Lucknow** under this MoA shall not be transferred to any other party without prior approval in writing of DBT.

4.4 It shall be the responsibility of the project investigator (s) and **SGPGIMS, Lucknow** to ensure that support of DBT is suitably acknowledged in the in scientific publication/ patents/ technology transfer documents etc. arising out of the PROJECT. It shall also be the responsibility of the project investigators and institute to ensure the inclusion of reference/ grant number and duration of the financial support while making the acknowledgement of the financial support received from DBT.

Anshika

Dr. Anshika Srivastava
Assistant Professor
Dept. of Medical Genetics
Sanjay Gandhi Post Graduate
Institute of Medical Sciences,
LUCKNOW-226014, INDIA

Bajpai

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

5. SECRECY

It is hereby agreed that the participating agencies shall keep information and data collected completely secret provided that the right to transfer the technology shall rest with the DBT.

6. MONITORING

6.1 The progress of implementation of the project and proper utilization of grant shall be reviewed by the DBT and by the Monitoring Committee set up by DBT.

6.2 The periodic progress of physical achievements and the utilization of funds, statement of expenditure shall be evaluated by the Monitoring Committee.

6.3 The Comptroller and Auditor General of India, at his discretion shall have the right of access to the books and accounts of **SGPGIMS, Lucknow** for the grants received from DBT for this project.

6.4 The DBT may terminate the grant at any stage if it is convinced that the grant has not been properly utilized or appropriate progress has not been made. In the event, DBT terminates the grant, **SGPGIMS, Lucknow** shall hand over all documents including technical details and equipment purchased related to the project.

7.0 DURATION OF MEMORANDUM OF AGREEMENT

This MoA will remain inforce for the duration of the project and until all claims are settled between DBT and **SGPGIMS, Lucknow.**

8.0 ARBITRATION

In the event of any question, dispute or difference whatsoever arising between the parties to this Agreement out of or relating to the construction, meaning, scope, operation or effect of this Agreement or the validity of the breach thereof shall be referred to an Arbitrator to be appointed by mutual consent of both the parties herein. If the parties cannot agree on the appointment of the Arbitrator within a period of one month from the notification by one party to the other of existence of such dispute, then the Arbitrator shall be nominated by the Secretary, Department of Legal Affairs, Ministry of Law & Justice, Government of India. The provisions of the Arbitration and Conciliation Act, 1996 will be applicable and the award made there under shall be final and binding upon the parties hereto, subject to legal remedies available under the law. Such differences shall be deemed to be a submission to arbitration under the Indian Arbitration and Conciliation Act, 1996, or of any modifications or reenactments thereof.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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9.0. GOVERNING LAW

This Contract shall be governed by the Law of India for the time being in force.

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:

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

(Designation)
For and on behalf of The President of India

Signatures of two witnesses (from DBT):

i.

ii.

Signed and stamped by: 10/1/24
Prof. R.K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA
(Director, SGPGIMS, Lucknow)

For and on behalf of SGPGIMS, Lucknow

Name, Signature and stamp of Two Witnesses (from ***Institute/ University/ Organization)***):

i. Deepti Saxena
Dr. Deepti Saxena
Associate Professor
Dept. of Medical Genetics
S G P G I M S.
Lucknow-226014

ii. Somya Srivastava
Dr. Somya Srivastava
Assistant Professor
Department of Medical Genetics
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226014 (U.P.) INDIA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Annexure – I of MoA

Detailed Project Activities

Details of the activities to be undertaken by Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Raebareli Road, Lucknow-226014, UP, India under the project entitled "Harnessing Genome sequencing and engineering (CRISPR/Cas9) technologies for identification of shared genetic and molecular etiology in pediatric and adult Cardiomyopathies".

Objective 1: Determine the pathogenic mechanism of chromatin modifier ASXL3 induced pediatric cardiomyopathy

hESCs ASXL3-mutation models and successful cardiac directed differentiation: I will create patient specific mutations (c.1448dupT; T484NfsX5 and c.1897_1898delCA; Q633VfsX13) in human embryonic stem cells (HUES9) using CRISPR/Cas9. As shown in our previous studies performed in patient fibroblasts that heterozygous mutations in *ASXL3* results in nonsense mediated decay and both the mutations are associated with congenital HCM as evident through our *Asxl3*$^{-/-}$ mice. hESCs will undergo cardiac-directed differentiation using sequential application of a highly efficient protocol relying on application of cytokines at specific time points hESCs.

Immunohistochemistry (IHC): A hypertrophic phenotype will be validated using cell size quantification with immunofluorescence imaging and with a qRT-PCR assay of NPPA. I will quantify the human cardiomyocytes diameter with WGA. Ki67 and PH3 staining will quantify proliferation and cells undergoing mitosis defects.

RNA-seq analysis: RNA will be isolated from three biologic replicates for each genotype (wildtype, heterozygous and homozygous). Random culture condition effects will be minimized by pooling samples from at least 3 different differentiation batches. Three biologic replicates will be obtained for each model to maximize the accuracy of RNA-Seq analysis at 30M paired end reads per sample. I will employ an existing RNA-Seq processing pipeline to map RNA-Seq reads (STAR) and quantify mRNA transcript abundance (RSEM). I will assess differential expression for each target gene using the software package EBSeq and control for false discovery rate (FDR) using established methods. Enrichment of differential expression signals at the pathway level (gene set enrichment analysis, or GSEA) will be performed using Fisher's exact test.

ATAC-seq: ATAC-seq will be performed on three biologic replicates for each genotype (wildtype, heterozygous and homozygous) in parallel with RNA-seq sample collection as above. Nuclei will be isolated and a transposase reaction performed using protocol outlined by Scott LJ et al. Analysis of ATAC-seq data will focus on quantification of availability of transcription factor binding sites that are known recognition sequences for hypertrophic signaling transcription factors and/or transcription factors that are differentially expressed based on the RNA-seq data. For the former, quantification of binding site availability is important since the transcription factor may be activated through phosphorylation (or other post-translational modification) but may not necessarily be upregulated at the mRNA level thus, the ATAC-seq methodology will be able to detect this level of activation that would be missed by solely RNA-seq analysis.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Objective 2. Determine the pathogenic mechanism of MYBPC3 induced pediatric cardiomyopathy:

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hESCs MYBPC-mutation models: I will create patient specific mutations using CRISPR/Cas9 and will perform the cardiac differentiation as outlined in objective 1.

Immunohistochemistry: IHC analysis will be performed as outlined in objective 1.

RNA-seq: Experiments will be performed and analyzed as outlined in objective 1.

***A*TAC-seq:** ATAC sequencing will be performed as outlined in objective 1.

Objective 3. Contrast signaling mechanisms of hypertrophy in hESC-CM models with sarcomere gene mutations vs mutation in the chromatin modifier ASXL3.

This objective directly compares two different genetic models of cardiac hypertrophy – one with a mutation in the contractile gene *MYBPC3* and one with a mutation in the chromatin modifier *ASXL3*. I hypothesize that there will be both shared and distinct hypertrophic pathways activated between the two models. Distinction of these pathways will have implications for therapeutic intervention for cardiac hypertrophy. The RNA and ATAC sequenced data from objective 1 and 2 will be intersected using custom R scripts. Common and distinct dysregulated genes and pathways will be analyze on Microsoft excel whereas regions of open chromatin and transcription factor binding will be visualized on https://epigenomegateway.wustl.edu website.

Objective 4. Develop a cohort of PHCM and adult-onset cardiomyopathies for expanding diseases mutation spectrum and validating the upstream and/or regulators identified through RNA and ATAC sequencing in objective 3.

Study Population The study population will be individuals of Indian origin who visit the hospitals for treatment and may encompass the north, northwest and north eastern and central parts of India. Pediatric and adult onset cardiomyopathy patients and their family members attending cardiology clinic of Sanjay Gandhi post-graduate institute of medical sciences (SGPGIMS) Lucknow, will be enrolled in this study after obtaining informed consent. Since pediatric cardiomyopathies have an annual incidence of 1.1-1.5 per 10,000 we will recruit PHCM from both cardiology and medical genetic clinic of SGPGIMS. Dr. Kausik will evaluate patients with pediatric cardiomyopathy at medical genetics clinic. In case of adult-onset HCM each patient will undergo heart catheterization for the angiographical exclusion of coronary artery disease in the same procedure. All the patients will undergo a physical examination, following by ECG, and trans-thoracic echocardiography and Doppler studies.

From all the patients complete information about medical history, complications associated with the disease will be noted. All the participants of the study will undergo a standardized interview using a questionnaire on family history, demographic profile, and lifestyle habits. Incase of PHCM, the guardian will fill out questionnaire. The questionnaire will include following details:

- Medical history of the participant, of family members, medication intake, and other
- Demographics, such as gender, age, place of birth, education
- Anthropometric data, such as weight, height, for calculation of BMI

Lt Col Varun Bajpai VSM
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SGPGIMS,Lucknow

- Associated risk factors as hypertension, diabetes mellitus, and smoking in case of adult-onset HCM
- Dietary and tobacco habits

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Echocardiography: Standard views for M-mode and two-dimensional studies will be obtained. For all cardiomyopathy patients end diastolic left ventricular wall thickness will be recorded at the level of the mitral valve and papillary muscle in the anterior, posterior, septal, and lateral walls using short-axis two-dimensional images. Anterior and posterior septal thickness at the apex will be assessed from apical short-axis view. The maximum left ventricular wall thickness will be defined as the maximal measurement recorded in any of the myocardial segments studied. Left ventricle inflow and outflow velocities will be determined using continuous and pulse wave Doppler echocardiography.

Sample Size: The proposed sample size is ~ 100 subjects i.e., 20 families with PHCM (trio-WES will be performed father, mother-proband) and 50 individuals with adult-onset cardiomyopathy.

Whole exome sequencing: DNA extraction will be performed using the QIAamp DNA Mini Kit (Qiagen, Germany). The quantity and purity of DNA will be checked by measuring optical density (OD) at 260 nm and 280 nm. The ratio of absorbance at 260 and 280 nm of DNA is around 1.7-1.9. The quality and purity will be also confirmed by 1% agarose gel electrophoresis in 1 X TBE buffer. Whole-exome sequencing (WES) will be performed to identify causative variations responsible for pediatric and adult-onset HCM. Genomic DNA (~5µg) will be used for library preparation followed by enrichment of the libraries using "Agilent SureSelectXT Target Enrichment System" (Agilent Inc). Enriched libraries will be equenced on Illumina Hiseq2000 platform. Identified variations/ mutations in different genes will be analyzed using different bioinformatics tools and pipelines.

Pathogenic variant prioritization: Every exome contains hundreds of variants, with few variants predicted to be pathogenic with known significance. We will use custom scripts in python and R and publically available GEMINI tool to prioritize the variants. During the variant prioritization if we identify variant of unknown significance (VUS) in novel PHCM and adult-onset HCM genes, it will be further annotated to determine if: (1) zygosity of variants are tolerated (EXAC) (3) predicted functional impairment correlates with phenotype (literature search, OMIM), (4) organ system involvement is conserved in model organisms (mouse & zebrafish databases, published literature), (5) similar pathology is observed for mutations in associated gene families or protein complexes (Phenominer, OMIM, literature), and (6) filter out variants associated with unrelated phenotypes (OMIM).

Genetic Validation: Sanger sequencing will be used to validate the variations identified and to check for segregation in other family members and controls.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Annexure – II of MoA

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Details of Funds

Dr. Anshika Srivastava, Assistant Professor, Department of Medical Genetics, Sanjay Gandhi Postgraduate Institute of Medical Sciences(SGPGIMS), Raebareli Road, Lucknow-226014, UP, India

Items	*I year*	*II year*	*III year*	Total
Non-recurring (Equipment etc.)	600000.00			600000.00
Manpower	486996.00	486996.00	486996.00	1460988.00
Consumables	2000000.00	2000000.00	2000000.00	6000000.00
Travel	50000.00	50000.00	50000.00	150000.00
Contingencies	50000.00	50000.00	50000.00	150000.00
Overhead	100000.00	100000.00	100000.00	300000.00
Others (If applicable)				
Total	**3286996.00**	**2686996.00**	**2686996.00**	**8660988.00**

Anshika

Dr. Anshika Srivastava
Assistant Professor
Dept. of Medical Genetics
Sanjay Gandhi Post Graduate
Institute of Medical Sciences,
LUCKNOW-226014, INDIA

Bajpai

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

TERMS & CONDITIONS OF THE GRANT

(To be signed and enclosed with MoA)

1. Approval of the Research proposal and the grant released would be for the specific project mentioned in paras I to V of this proposal and grant should be exclusively spent on the project for which it has been sanctioned within the stipulated time. The Institute is not permitted to seek or utilise funds from any other organisation (Government, Semi Government, Autonomous or Private) for this research project. Any unspent part of amount would be surrendered to the Govt. of India through an account payee demand draft drawn in favour of the "Drawing and Disbursing Officer, Department of Biotechnology, New Delhi", and carry forward of funds of the next financial year for utilization for the same project may be considered only with the specific approval of the Department of Biotechnology (DBT).

2. For permanent/semi-permanent assets acquired solely or mainly out of the grant, an audited record in the form of a register in the prescribed proforma (enclosed at **Appendix-'A'**) shall be maintained by the Institute. The term **"assets"** means (I) immovable property and (II) movable property of a capital nature, where the value exceeds Rs. 1000/- The grant will not be utilised for construction of any immovable property, Full facilities by way of accommodation, etc. for the project will be given by the Institute.

3. All the assets acquired from the grant will be the property of Govt. of India and should not without the prior sanction of the Deptt. of Biotechnology, be disposed of, or encumbered or utilised for purpose other than those for which the grant has been sanctioned.

4. At the conclusion of the project, the Govt. of India will be free to sell or otherwise dispose of assets which are the property of the Government. The Institute shall render to Govt. necessary facilities for arranging the sale / disposal of these assets. **The Government may, however, consider the request of host institutions to retain the assets created under a project for carrying out similar work for the promotion of science.**

5. The implementing Institute/PI will furnish progress report of work on the project every six months. The progress of the project will also be reviewed/monitored at least once a year by the concerned Task Force/Project Monitoring Committee, etc. In addition the DBT shall designate Scientists/Specialists to visit the Institute periodically for reviewing the progress of work and for suggesting such measures as to ensure early realisation of the objectives of the project. On completion of the project five copies of a consolidated report of the work done on the subject would be submitted to the Department of Biotechnology.

6. The Institute is required to send to DBT a list of assets referred to at Sl. No. 2 above at the end of each financial year as well as at the time of seeking further installments of the grant.

7. The Institute would furnish to the Deptt. of Biotechnology a Utilization Certificate (Copy enclosed at **Appendix - 'B'**) and an audited statement of expenditure (**Copy enclosed at Appendix - 'C'**) duly signed by the P.I., the Head of the Institute and the Head of the Finance wing, pertaining to the grant at the end of each financial year as well as a consolidated statement of expenditure at the end of the completion of the project.

8. A stamped receipt be sent to the Deptt. of Biotechnology on receipt of the Cheque/ Demand draft towards each release.

9. The Comptroller and Auditor-General of India at his discretion shall have the right of access to the books and accounts of the Institute for the grant received from the Government.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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10. The Institute would maintain separate audited accounts for the project. If it is found expedient to keep a part or whole of the grant in a bank account earning interest, the interest thus earned should be reported to the Deptt. of Biotechnology.

11. Sale proceeds, if any, as a result of the development of the project arising directly from funds granted by the Deptt. of Biotechnology shall be reported to the Govt. of India. The Govt. of India may at its discretion allow a portion of such receipt to be retained by the Institute for its utilisation for the project activities.

12. Investigators/Institutes wishing to publish papers based on the research work done under Deptt. of Biotechnology projects should acknowledge the financial support received from the Deptt. of Biotechnology.

13. Investigators/Institutes may utilize various resources such as the Bioinformatics resources, experimental materials, reagents, cell lines, animals, etc. from the National facilities/Institutes/Centres established by this Department as per the terms of transactions followed by them. More information may be obtained about such facility from DBT websites: http://www.dbtindia.org// www.dbtindia.nic.in, www.btisnet.ac.in.

14. Investigators / Institutes shall follow the detailed instructions on technology transfer and Intellectual Property Rights (IPR) as given at Annexure - V. The same has the approval of the Ministry of Finance, Govt. of India vide Deptt. of Expenditure, Plan Finance II – Division Letter No. 33 (5) /PF.II/99 dated 22nd February, 2000. Any deviation from these instructions may be brought to the notice of this Department.

15. Investigators / Institutes may file patents with the help of the Biotechnology Patents Facilitating Cell (BPFC) established at DBT on priority bases. The format for filing the patents may be seen at Annexure –VI.

16. The Govt. of India (Deptt. of Biotechnology) will have the right to call for drawings, specifications and other data necessary to enable the transfer of know-how to other parties and the Institute shall supply all the needed information at the request of the Department of Biotechnology which will ensure confidentiality. The information required for commercializing Biotechnologies may be furnished to this Deptt. as per the format enclosed at Annexure – VII. More information on commercialization can be found at the website www.ebc.nic.in.

17. The Institute may not entrust the implementation of the work for which the grant is being sanctioned to another institution and to divert the grant receipts as assistance to the latter institution. However, in such situations the express permission of DBT may be obtained. In case the grantee is not in a position to execute or complete the project, it may be required to refund forthwith to the Govt. of India (Department of Biotechnology) the entire amount of grant received by it.

18. The human resources that may be engaged for the project by the Institute are not to be treated as employees of the Govt. of India and the deployment of such human resource at the time of completion or termination of project, will not be the concern/responsibility of the Govt. of India. The Organisation may make reservations for Scheduled Castes, Schedule Tribes etc. in the human resource to be engaged for the project in accordance with the instruction issued by the Govt. of India from time to time.

19. The Deptt. of Biotechnology reserves the right to terminate the grant at any stage and also to recover the amounts already paid if it is convinced that the grant has not been properly utilized or the work on the project has been suspended for any unduly long period or appropriate progress is not being made.

20. The project will become operative with effect from the date of release of the first installment for the project.

Lt Col Vasun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

21. If the Investigator to whom a grant for a project has been sanctioned leaves the institution where the project is being implemented, he shall submit five copies of complete and detailed report of the work done by him on the project and the money spent till the date of his/her release and shall also arrange to refund the unspent balance , if any.

22. The Memorandum Agreement, to be sent to Department of Biotechnology should be on Non- Judicial stamp paper of Rs. 100/-.

23. The organisation should maintain subsidiary accounts of the Govt. of India grant and furnish it to the Audit Officer as and when the recurring and non-recurring expenditure exceeds the limits of Rs. 5.00 lakhs.

10/01/24

Signature of Executive Authority of Institute/ University With seal:(Director, SGPGIMS, Lucknow)

Prof. R. K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Date :

Signature and seal of Project Coordinator (If applicable)
Date:

Signature and seal of all Principal Investigator(s)/ Co- PI (s):
Date : 28.12.2023

Dr. Anshika Srivastava
Assistant Professor
Dept. of Medical Genetics
Sanjay Gandhi Post Graduate
Institute of Medical Sciences,
LUCKNOW-226014, INDIA

Signature and seal of all Co-Investigator (s)
Date :

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow



उत्तर प्रदेश UTTAR PRADESH

FY 346730

22 MAR 2021

MEMORANDUM OF AGREEMENT

This MEMORANDUM OF AGREEMENT is made on this **11 of January** of Two Thousand Twenty One and **Director, SGPGIMS Lucknow** BY AND BETWEEN President of India, acting through **Director**, 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 of Institute of Medical Science, Lucknow (SGPGI, hereafter), a society under the Societies Registration Act – 1860, having its registered office in/at **Lucknow**, hereinafter referred to as **SGPGIMS** (which expression shall where the context so admits include its successors and permitted assigns) of the OTHER PART;

WHEREAS DBT being desirous of **Basic Science Research** decided to support a project submitted by **Dr. Alok Kumar, Associate Professor, Department of**

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Molecular Medicine & Biotechnology and Dr. Shantanu Pande, Department of Cardiovascular and Thoracic Surgery, SGPGIMS, Lucknow for the attainment of the objectives, hereinafter described in the Annexure I annexed hereto;

This Memorandum of Agreement (MoA) defines the role and responsibilities of the participating agencies, monitoring and other matters related to the **"Determination and establishment of key molecular therapeutic approach for remodelling of pericardial heart valve of Tetralogy of Fallot"**

NOW THE PARTIES HERETO AGREE AS FOLLOWS:-

1.0 . ROLE OF DEPARTMENT OF BIOTECHNOLOGY, NEW DELHI

To provide funds to the extent of **Rs.66,50,240/- (Rupees Sixty Six Lakhs Fifty Thousand Two Hundred and Forty Only)** over a period of **Three** years from the date of sanction of the project, to **Dr. Alok Kumar, Associate Professor, Department of Molecular Medicine & Biotechnology and Dr. Shantanu Pande, Department of Cardiovascular and Thoracic Surgery, SGPGIMS, Lucknow** for undertaking activities as detailed in Annexure 1. Details of the funds to be provided are given in Annexure II.

2.0. ROLE OF SANJAY GANDHI POSTGRADUATE OF INSTITUTE OF MEDICAL SCIENCE, LUCKNOW (Institute)

2.1. To provide their contribution of **nil** for **3** 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.

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.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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 that 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 3 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 **SGPGIMS** will be the joint property of **SGPGIMS** and DBT, Government of India. It shall be the responsibility of **SGPGIMS** 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.

4.3 All the assets including the equipment and produce acquired will be the property of DBT and shall not be utilized for purposes other than those for which the grant has been sanctioned. The rights of **SGPGIMS** under this MoA shall not be transferred to any other party without prior approval in writing of DBT.

4.4 It shall be the responsibility of **SGPGIMS** to ensure that support of DBT is suitably acknowledged in the publications (papers, reports, etc.) arising out of the PROJECT.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

5. SECRECY

It is hereby agreed that the participating agencies shall keep information and data collected completely secret provided that the right to transfer the technology shall rest with the DBT.

6. MONITORING

6.1 The progress of implementation of the project and proper utilization of grant shall be reviewed by the DBT and by the Monitoring Committee set up by DBT.

6.2 The periodic progress of physical achievements and the utilization of funds, statement of expenditure shall be evaluated by the Monitoring Committee.

6.3 The Comptroller and Auditor General of India, at his discretion shall have the right of access to the books and accounts of **this research project at SGPGIMS** for the grants received from DBT for this project.

6.4 The DBT may terminate the grant at any stage if it is convinced that the grant has not been properly utilized or appropriate progress has not been made. In the event, DBT terminates the grant, **SGPGIMS** shall hand over all documents including technical details and equipment purchased related to the project.

7.0 DURATION OF MEMORANDUM OF AGREEMENT

This MoA will remain in force for the duration of the project and until all claims are settled between DBT and **SGPGIMS.**

8.0 ARBITRATION

In the event of any question, dispute or difference whatsoever arising between the parties to this Agreement out of or relating to the construction, meaning, scope, operation or effect of this Agreement or the validity of the breach thereof shall be referred to an Arbitrator to be appointed by mutual consent of both the parties herein. If the parties cannot agree on the appointment of the Arbitrator within a period of one month from the notification by one party to the other of existence of such dispute, then the Arbitrator shall be nominated by the Secretary, Department of Legal Affairs, Ministry of Law & Justice, Government of India. The provisions of the Arbitration and Conciliation Act, 1996 will be applicable and the award made there under shall be final

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

and binding upon the parties hereto, subject to legal remedies available under the law. Such differences shall be deemed to be a submission to arbitration under the Indian Arbitration and Conciliation Act, 1996, or of any modifications or reenactments thereof.

9.0. GOVERNING LAW

This Contract shall be governed by the Law of India for the time being in force.

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. Alok Kumar)

2.----------
(Dr. Shantanu Pande)

3.----------
(Dr. Surendra Kumar Agarwal)

4.----------
(Dr. Vikas Agarwal)

Signed by ---------- 22/11/22

(Designation) **DIRECTOR**

For and on behalf of **SGPGIM, LKo**

Prof. R. K. DHIMAN
Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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Check list for Sending MoA

1.	No portion of the MoA has been modified in any way	**Yes/No**
2.	The MoA has been **signed on stamp paper at an appropriate value of Rs. 100/-.**	**Yes/No**
3.	Blank spaces have been filled	**Yes/No**
4.	MoA is **signed and stamped by PI and competent authority** on every page.	**Yes/No**
5.	A copy of terms and condition **signed and stamped by PI and competent authority is attached as annexure**	**Yes/No**
6.	A copy of sanction order **signed and stamped by PI and competent authority** on every page is attached as an annexure	**Yes/No**

Signature and stamped of Principal Investigator
Date : 11.04.2022

Dr. Alok Kumar ..... Dr. Shantanu Pande.....

Signature and stamped of Co-Investigator
Date : 11.04.2022

Prof. Surendra Kumar Agarwal..... Prof. Vikas Agarwal.....

Signed and stamped of Director
Date : 11.04.2022

Prof. R. K. Dhiman..... 22/4/22

Prof. R. K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

TERMS & CONDITIONS OF THE GRANT

(To be signed and enclosed with concern filled proforma)

1. Approval of the Research proposal and the grant released would be for the specific project mentioned in paras I to V of this proposal and grant should be exclusively spent on the project for which it has been sanctioned within the stipulated time. The Institute is not permitted to seek or utilise funds from any other organisation (Government, Semi Government, Autonomous or Private) for this research project. Any unspent part of amount would be surrendered to the Govt. of India through an account payee demand draft drawn in favour of the "Drawing and Disbursing Officer, Department of Biotechnology, New Delhi", and carry forward of funds of the next financial year for utilization for the same project may be considered only with the specific approval of the Department of Biotechnology (DBT).

2. For permanent/semi-permanent assets acquired solely or mainly out of the grant, an audited record in the form of a register in the prescribed proforma (enclosed at **Appendix-'A'**) shall be maintained by the Institute. The term **"assets"** means (I) immovable property and (II) movable property of a capital nature, where the value exceeds Rs. 1000/- The grant will not be utilised for construction of any immovable property, Full facilities by way of accommodation, etc. for the project will be given by the Institute.

3. All the assets acquired from the grant will be the property of Govt. of India and should not without the prior sanction of the Deptt. of Biotechnology, be disposed of, or encumbered or utilised for purpose other than those for which the grant has been sanctioned.

4. At the conclusion of the project, the Govt. of India will be free to sell or otherwise dispose of assets which are the property of the Government. The Institute shall render to Govt. necessary facilities for arranging the sale / disposal of these assets. **The Government may, however, consider the request of host institutions to retain the assets created under a project for carrying out similar work for the promotion of science.**

5. The implementing Institute/PI will furnish progress report of work on the project every six months. The progress of the project will also be reviewed/monitored at least once a year by the concerned Task Force/Project Monitoring Committee, etc. In addition the DBT shall designate Scientists/Specialists to visit the Institute periodically for reviewing the progress of work and for suggesting such measures as to ensure early realisation of the objectives of the project. On completion of the project five copies of a consolidated report of the work done on the subject would be submitted to the Department of Biotechnology.

6. The Institute is required to send to DBT a list of assets referred to at Sl. No. 2 above at the end of each financial year as well as at the time of seeking further installments of the grant.

7. The Institute would furnish to the Deptt. of Biotechnology a Utilization Certificate (Copy enclosed at **Appendix - 'B'**) and an audited statement of expenditure (**Copy enclosed at Appendix - 'C'**) duly signed by the P.I., the Head of the Institute and the

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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Head of the Finance wing, pertaining to the grant at the end of each financial year as well as a consolidated statement of expenditure at the end of the completion of the project.

8. A stamped receipt be sent to the Deptt. of Biotechnology on receipt of the Cheque/ Demand draft towards each release.

9. The Comptroller and Auditor-General of India at his discretion shall have the right of access to the books and accounts of the Institute for the grant received from the Government.

10. The Institute would maintain separate audited accounts for the project. If it is found expedient to keep a part or whole of the grant in a bank account earning interest, the interest thus earned should be reported to the Deptt. of Biotechnology.

11. Sale proceeds, if any, as a result of the development of the project arising directly from funds granted by the Deptt. of Biotechnology shall be reported to the Govt. of India. The Govt. of India may at its discretion allow a portion of such receipt to be retained by the Institute for its utilisation for the project activities.

12. Investigators/Institutes wishing to publish papers based on the research work done under Deptt. of Biotechnology projects should acknowledge the financial support received from the Deptt. of Biotechnology.

13. Investigators/Institutes may utilize various resources such as the Bioinformatics resources, experimental materials, reagents, cell lines, animals, etc. from the National facilities/Institutes/Centres established by this Department as per the terms of transactions followed by them. More information may be obtained about such facility from DBT websites: http://www.dbtindia.org// www.dbtindia.nic.in, www.btisnet.ac.in.

14. Investigators / Institutes shall follow the detailed instructions on technology transfer and Intellectual Property Rights (IPR) as given at Annexure - V. The same has the approval of the Ministry of Finance, Govt. of India vide Deptt. of Expenditure, Plan Finance II – Division Letter No. 33 (5) /PF.II/99 dated 22nd February, 2000. Any deviation from these instructions may be brought to the notice of this Department.

15. Investigators / Institutes may file patents with the help of the Biotechnology Patents Facilitating Cell (BPFC) established at DBT on priority bases. The format for filing the patents may be seen at Annexure –VI.

16. The Govt. of India (Deptt. of Biotechnology) will have the right to call for drawings, specifications and other data necessary to enable the transfer of know-how to other parties and the Institute shall supply all the needed information at the request of the Department of Biotechnology which will ensure confidentiality. The information required for commercializing Biotechnologies may be furnished to this Deptt. as per the format enclosed at Annexure – VII. More information on commercialization can be found at the website www.ebc.nic.in.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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17. The Institute may not entrust the implementation of the work for which the grant is being sanctioned to another institution and to divert the grant receipts as assistance to the latter institution. However, in such situations the express permission of DBT may be obtained. In case the grantee is not in a position to execute or complete the project, it may be required to refund forthwith to the Govt. of India (Department of Biotechnology) the entire amount of grant received by it.

18. The human resources that may be engaged for the project by the Institute are not to be treated as employees of the Govt. of India and the deployment of such human resource at the time of completion or termination of project, will not be the concern/responsibility of the Govt. of India. The Organisation may make reservations for Scheduled Castes, Schedule Tribes etc. in the human resource to be engaged for the project in accordance with the instruction issued by the Govt. of India from time to time.

19. The Deptt. of Biotechnology reserves the right to terminate the grant at any stage and also to recover the amounts already paid if it is convinced that the grant has not been properly utilized or the work on the project has been suspended for any unduly long period or appropriate progress is not being made.

20. The project will become operative with effect from the date of release of the first installment for the project.

21. If the Investigator to whom a grant for a project has been sanctioned leaves the institution where the project is being implemented, he shall submit five copies of complete and detailed report of the work done by him on the project and the money spent till the date of his/her release and shall also arrange to refund the unspent balance , if any.

22. The organisation should maintain subsidiary accounts of the Govt. of India grant and furnish it to the Audit Officer as and when the recurring and non-recurring expenditure exceeds the limits of Rs. 5.00 lakhs.

22/11/22

Signature of Project Coordinator
(applicable only for multi-institutional projects)

Date :

Signature of Executive Authority of Institute/ University With seal

Prof. R. K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Date :

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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Witnesses:

Signature and stamped of Principal Investigator

Date : 09.04.2022

Dr. Alok Kumar ..... Dr. Shantanu Pande.....

Signature and stamped of Co-Investigator

Date : 09.04.2022

Prof. Surendra Kumar Agarwal..... Prof. Vikas Agarwal.....

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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No. BT/PR42952/MED/97/569/2021
E-Office No. RAD-21/56/2021-MED-DBT (Computer No. 15167)

GOVERNMENT OF INDIA
MINISTRY OF SCIENCE & TECHNOLOGY
DEPARTMENT OF BIOTECHNOLOGY

Block 2, 6-8th Floors
CGO Complex, Lodhi Road,
New Delhi- 110 003
Dated: 09.03.2022

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 **"Determination and establishment of key molecular therapeutic approach for remodelling of pericardial heart valve of Tetralogy of Fallot"** for a period of 3 Year 0 Month at a total cost of **Rs. 6650240/-** (Rupees Sixty Six Lakhs Fifty Thousand Two Hundred and Forty Only) on the terms and conditions detailed here under:-

2 The Project :

2.1 Title : Determination and establishment of key molecular therapeutic approach for remodelling of pericardial heart valve of Tetralogy of Fallot

2.2 Details of the Investigators:

Dr. Alok Kumar
Ramalingaswami re-entry fellow and Associate Professor
Molecular Medicine and Biotechnology
Sanjay Gandhi Postgraduate Institute of Medical Sciences,
Lucknow, Uttar Pradesh-226014

Dr. Shantanu Pande
Professor
Cardiovascular and Thoracic Surgery
Sanjay Gandhi Postgraduate Institute of Medical Sciences,
Lucknow, Uttar Pradesh-226014

CO-PI:

Prof. Surendra Kumar Agarwal
Professor
Department of CVTS,
Sanjay Gandhi Postgraduate Institute of Medical Sciences,
Lucknow, Uttar Pradesh-226014

Prof. Vikas Agarwal
Professor
Department of Clinical Immunology & Rheumatology
Sanjay Gandhi Postgraduate Institute of Medical Sciences,
Lucknow, Uttar Pradesh-226014

2.3 Objectives:

1. To determine that host immune responses involve in distortion of native pulmonary valve of Tetralogy of Fallot's Patients.
2. To determine that treatment of phosphodiesterase 5 inhibitor and 5-hydroxytryptamine receptor 2B inhibitor helps in maintaining the morphology of the neo pulmonary valve keeping it free of retraction and distortion

2.4 Time Schedule:

The duration of the project is 3 Year 0 Month from the date of this sanction order.

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Executive Registrar
SGPGIMS,Lucknow

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2.5 Project Cost:

The total cost of the project is Rs. **6650240/-**(Rupees Sixty Six Lakhs Fifty Thousand Two Hundred and Forty Only) as per details given below:

Budget Head	Year I	Year II	Year III	Total(Rs.)
Equipment	1900000.00	0.0	0.0	**1900000.00**
Manpower	431520.00	431520.00	487200.00	**1350240.00**
Consumables	1000000.00	500000.00	1000000.00	**2500000.00**
Contingency	50000.00	50000.00	50000.00	**150000.00**
Overhead	50000.00	50000.00	50000.00	**150000.00**
Travel	30000.00	30000.00	40000.00	**100000.00**
Outsourcing	0.0	500000.00	0.0	**500000.00**
Total (Rs.)	**3461520.00**	**1561520.00**	**1627200.00**	**6650240.00**

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 Quarterly Milestones and Deliverables:

The details of the Quarterly Milestones and Deliverables sanctioned for the implementation of the project at **Annexure-III**

3. Head of Account:

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

Demand No. 89	Department of Biotechnology
3425	Other Scientific Research 2021-2022
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 to Research and Development
3425.60.200.29.17.35	Grants for creation of capital assets

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

Demand No. 89	Department of Biotechnology
3425	Other Scientific Research 2021-2022
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 to Research and Development
3425.60.200.29.17.31	Grants -in-Aid General

4. Terms & Conditions:

(i) 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 percent thereon shall be recovered.
ii) Grantee Institution is a public funded organization.
iii) The equipment sanctioned under the project should be purchased within 18 months from the date of the release of the grant.
iv) The expenditure to be made as per the EAT module of the Government of India.

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Executive Registrar
SGPGIMS,Lucknow

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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 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-IV.**

4.3 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 earned should be remitted to the Consolidated fund of India through Bharat Kosh portal (www.bharatkosh.gov.in) as per GFR-2017-230(8) after finalization of the account for a given Financial Year.

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. PIs 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 30 Jan 2019. 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 (I) "The PIs/Implementing Agencies shall strictly adhere to the GoI instructions issued vide OM No.F.4.1.2021-PPD dated 30.6.2021 in the matter of issue of Global tender Enquiry with special reference to instructions contained under para 4 of the said OM for procurement of equipments, spares and consumables for research purposes and shall not issue Global Tenders Enquiries before seeking the approval of the competent authority".

(II) "After incurring the expenditure on import of such items and at the time of submission of UCs to the department next year, the PIs will also furnish the copy of the approval sought from the competent authority for issue of the GTE for such items of import. The release of next installment of grant will the subject to the fulfillment of the above condition."

11. This issues under the powers delegated to this Department as per IFD order No. G-17012/1/2020-IFD-DBT dated 15.02.2022 and with the concurrence of IFD. This has been noted in IFD at SAN No. **102/IFD/SAN/3085/2021-2022** dated **08.03.2022.**

12. This sanction order has been noted at serial no. 93 in the Register of Grants.

(Dr. Neha Bansal)
Scientist 'C'

डॉ. नेहा बंसल / Dr. NEHA BANSAL
वैज्ञानिक 'सी' / Scientist 'C'
बायोटेक्नोलॉजी विभाग / Department of Biotechnology
विज्ञान और प्रौद्योगिकी मंत्रालय
Ministry of Science & Technology
Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS, Lucknow

BT/PR42952/MED/97/56

To,
The Pay & Accounts Officer,
Department of Biotechnology,
New Delhi – 110 003.

Copy to:

1 The Principal Director of Audit (Scientific Departments), DACR Building, New Delhi- 110 002.
2 The Director, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow - 226014, Uttar Pradesh
3 Dr. Alok Kumar, Ramalingaswami re-entry fellow and Associate Professor, Molecular Medicine and Biotechnology, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow - 226014, Uttar Pradesh
4 Dr. Shantanu Pande, Professor, Cardiovascular and Thoracic Surgery, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow - 226014, Uttar Pradesh
5 Prof. Surendra Kumar Agarwal, Professor, Department of CVTS, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow - 226014, Uttar Pradesh
6 Prof. Vikas Agarwal, Professor, Department of Clinical Immunology & Rheumatology, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow - 226014, Uttar Pradesh
7 Cash Section, DBT (2 copies).
8 Sanction Folder.
9 File Copy.

(Dr. Neha Bansal)
Scientist 'C'

डॉ. नेहा बंसल / Dr. NEHA BANSAL
वैज्ञानिक 'सी' / Scientist 'C'
जैव प्रौद्योगिकी विभाग / Department of Biotechnology
विज्ञान और प्रौद्योगिकी मंत्रालय
Ministry of Science & Technology
भारत सरकार / Govt. of India
ब्लॉक-2, सी.जी.ओ. कॉम्प्लेक्स, लोधी रोड, नई दिल्ली-110003
Block-2, C.G.O. Complex, Lodhi Road, New Delhi-110003

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS, Lucknow

(16)

BT/PR42952/MED/97/569/2021

Annexure -I

Details of the Equipment sanctioned for the implementation of the project entitled **"Determination and establishment of key molecular therapeutic approach for remodelling of pericardial heart valve of Tetralogy of Fallot":**

Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow			
SNo.	**Name of Equipment**	**No.**	**Cost(Rs.)**
1.	RCCSMAX-HV Perfusion loop RotaryCell Culture System	1	1500000.00
2.	Small equipments: westernblot, shaker, vortex mixer, ph meter, 4°C freezer, variable single channel micropipette etc.	1	400000.00
		Total	**1900000.00**

Annexure –II

Details of the manpower sanctioned for the implementation of the project entitled **"Determination and establishment of key molecular therapeutic approach for remodelling of pericardial heart valve of Tetralogy of Fallot":**

Head	**No. of Position**	**Year I**	**Year II**	**Year III**	**Total** (Rs.)
JRF @ (Rs. 31,000/- pm + 16% HRA for 1st and 2nd year = Rs. 35960/- pm and SRF @ Rs. 35,000/- pm + 16% HRA for 3rd year = Rs. 40600/- pm	1	431520	431520	487200	**1350240**
Total (Rs.)		**431520**	**431520**	**487200**	**1350240**

Emoluments detail of research personal(s) mentioned in table(s) of Annexure-II shall be applicable only if candidate(s) met educational qualification and eligibility criteria as per DST OM No. SR/S9/Z-08/2018 dated 30.01.2019 for JRF/SRF/RA

(Dr. Neha Bansal)
Scientist 'C'

डॉ. नेहा बंसल / Dr. NEHA BANSAL
वैज्ञानिक 'सी' / Scientist 'C'
बायोटेक्नोलॉजी विभाग / Department of Biotechnology
विज्ञान और प्रौद्योगिकी मंत्रालय
Ministry of Science & Technology
भारत सरकार / Govt. of India
सी.जी.ओ. कॉम्प्लेक्स, लोधी रोड, नई दिल्ली–110003
C.G.O. Complex, Lodhi Road, New Delhi-110003

Lt Col Varun Baipai VSM
Executive Registrar
SGPGIMS,Lucknow

Quarterly Milestones and Deliverables

Annexure III

Title of the project: "Determination and establishment of key molecular therapeutic approach for remodelling of pericardial heart valve of Tetralogy of Fallot."

Quarterly Milestones

Quarter-wise	Action plan	Deliverables
Objective 1: To determine that host immune responses involve in distortion of Native pulmonary valve of Tetralogy of Fallot's Patients.		
	Aim 1: Host immune response characterization of a distorted pulmonary heart valve.	
Q1-Q8 (0-32 months)	Key activities: (1) Surgery will be performed to obtain distorted pulmonary heart valve from TOF patients; (2) Intra-operative harvesting of pericardium will be performed for valve designing and treatment	
Q3, Q4	(2) Immune cell activation profile will be examined by using nanostring analysis.	Gene signatures of individual immune cells will be identified to predict disease-specific biomarkers
Q3, Q4	(3) Host immune cell activation such as macrophages (CD45+/CD14+/CD64+, CCR2+/-), classical (CD14+CD16neg) and non-classical monocytes (CD14+CD16+/Ly-6Clow), neutrophils (Ly6G+), B-cell population (CD19+, CD27+, IgD+IgM+, IgD+IgM-, IgD-IgM+) and T-cell subsets (CD3+, CD8+, CD4+ IFN-γ+, CD4+IL-4+, CD4+IL-17+, and CD4+CD25+Treg) will be studied by using flow cytometry.	Host activated immune cells will be identified by using flow cytometry
Q3, Q4	(4) Activated immune cells will be sorted, and detailed proteomic and phosphor-proteomic analyses will be performed using LC-MS/MS.	Key protein signatures involved in isolated immune cell activation will be identified
Q3, Q4	(5) Further target validation will be performed using western blot analysis and ELISA kits as per the manufacturer's protocol.	Host immune response will be identified in distortion of pulmonary heart valve of Tetralogy of Fallot's Patients.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Objective 2: To determine that treatment of phosphodiesterase 5 inhibitor and 5-hydroxytryptamine receptor 2B inhibitor creates a competent pulmonary heart valve and reduces pulmonary heart valve pathophysiology.

Q1-Q8 (0-32 months)	**Key activities:** (1) Surgery will be performed to obtain distorted pulmonary heart valve from TOF patients (2) Intra-operative harvesting of pericardium will be performed for valve designing and treatment	
Q2, Q3	(2) Valve designing and treatment with phosphodiesterase 5 inhibitor and 5-Hydroxytryptamine receptor 2B inhibitor	
Q2, Q3, Q4 Q6, Q7	(3) Biocompatibility assessment will be performed through co-culture of human endothelial cells and treated pericardium heart valve. A. Cytotoxicity assay; B. Hemocompatibility assay; C. Biocompatibility assessment through in vitro 3D cell culture model of an interstitial treated pericardium heart valve by using perfusion bioreactor	Biocompatibility of the treated molecule of phosphodiesterase 5 inhibitor and 5-Hydroxytryptamine receptor 2B inhibitor will be examined in the heart valve
Q5, Q6	(4) Activated immune cells will be sorted from distorted heart valve, and treatment of phosphodiesterase 5 and 5-Hydroxytryptamine receptor 2B inhibitor will be performed	Modulation of immune cell activation by the treated molecule of phosphodiesterase 5 inhibitor and 5-Hydroxytryptamine receptor 2B inhibitor will be examined
Q5, Q6	(5) Host immune cell activation such as macrophages (CD45+/CD14+/CD64+, CCR2+/-), classical (CD14+CD16neg) and non-classical monocytes (CD14+CD16+/Ly-6Clow), neutrophils (Ly6G+), B-cell population (CD19+, CD27+, IgD+IgM+, IgD+IgM-, IgD-IgM+) and T-cell subsets (CD3+, CD8+, CD4+ IFN-γ+, CD4+IL-4+, CD4+IL-17+, and CD4+CD25+Treg) will be examined by using flow cytometry.	

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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Q1, Q2, Q3, Q4	(6) Activation of Human valve interstitial cells (VICs) by using TNFα , IFNγ, and treatment of phosphodiesterase 5 inhibitor & 5-hydroxytryptamine receptor 2B inhibitor will be performed	Utility of treated molecule of phosphodiesterase 5 inhibitor and 5-Hydroxytryptamine receptor 2B inhibitor in the modulation of fibrotic genes and involved in driving potential signaling (which can be beneficial for the heart valve modulation) will be examined by using VICs cell culture
Q1, Q2, Q3, Q4	Outcome measures: 1. Real-time quantitative PCR for pro-fibrotic [pCollagen Type I Alpha 1 Chain (Col1a1), Collagen Type I Alpha 2 Chain (Col1a2), Smooth Muscle Alpha (a)-2 actin (ACTA2), Connective Tissue Growth Factor (CTGF) and Fibronectin-1(FN1) genes] and anti-fibrotic genes [Matrix Metalloproteinase 2 (MMP2), Tissue inhibitor of metalloproteinases-1 (TIMP1) expression] will be performed.	
Q5, Q6, Q7, Q8	(7) Potential signaling of TGF-beta and Smad3 and their modulation after treatment will be evaluated by using the gene knockdown/siRNA approach	

Q-Quarter wise	Months
Q1	0-4
Q2	05-08
Q3	09-12
Q4	13-16
Q5	17-20
Q6	21-24

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

No. BT/PR42952/MED/97/569/2021
E-Office No. RAD-21/56/2021-MED-DBT (Computer No. 15167)
GOVERNMENT OF INDIA
MINISTRY OF SCIENCE & TECHNOLOGY
DEPARTMENT OF BIOTECHNOLOGY

Block 2, (6-8th Floors)
CGO Complex, Lodhi Road,
New Delhi- 110 003
Date: 09.03.2022

RELEASE ORDER

In continuation of this Department's sanction order of even number dated 09.03.2022 sanction of the President is hereby accorded, under Rule18 of the Delegation of Financial Powers Rule, 1978, for the release of **Rs. 1561520.00/-** (Rupees Fifteen Lakhs Sixty One Thousand Five Hundred and Twenty Only) being the first year release for the project entitled **"Determination and establishment of key molecular therapeutic approach for remodelling of pericardial heart valve of Tetralogy of Fallot"**, being implemented by:

Dr. Alok Kumar, Department of Molecular Medicine and Biotechnology, Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Lucknow - 226014, Uttar Pradesh.

The detailed break-up is as given below:

SN	Institute Name	Recurring						Total Release Amount (Rs)
		Manpower	Consumable	Travel	Contingency	Others	Overhead	
1	Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow	431520.00	1000000.00	30000.00	50000.00	0.00	50000.00	1561520.00

2. The amount of **Rs. 1561520.00/- (Rupees Fifteen Lakhs Sixty One Thousand Five Hundred and Twenty Only)** will be directly credited by the Pay & Accounts Officer, DBT in the account as detailed below:

The Director, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow - 226014, Uttar Pradesh

Bank Name :State Bank of India
Branch Name :SGPGIMS LUCKNOW
A/c No. :10095237491
IFSC Code :SBIN0007789
MICR Code :226002034

3. The expenditure involved is debitable to:

Demand No. 89	**Department of Biotechnology**
3425	Other Scientific Research 2021-2022
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 to Research and Development
3425.60.200.29.17.31	Grants -in-Aid General

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

4. The Director, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, Uttar Pradesh will submit audited utilization certificates and statements of expenditure in respect of the above-mentioned amount.
5. 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.
6. No International Travel will be undertaken from the sanctioned project grant unless specified otherwise.
7. 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 earned should be remitted to the Consolidated fund of India through Bharat Kosh portal (www.bharatkosh.gov.in) as per GFR-2017-230(8) after finalization of the account for a given Financial Year.
8. (i) 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 percent thereon shall be recovered.
   ii) Grantee Institution is a public funded organization.
   iii) The expenditure to be made as per the EAT module of the Government of India.
   The other terms and conditions governing the financial sanction will remain unaltered.
9. This issues under the powers delegated to this Department as per IFD order No. G-17012/1/2020-IFD-DBT dated 15.02.2022 and with the concurrence of IFD. This has been noted in IFD at SAN No. **102/IFD/SAN/3086/2021-2022** dated **08.03.2022.**
10. This sanction order has been noted at serial no. 94 in the Register of Grants.

(Dr. Neha Bansal)
Scientist 'C'
डॉ. नेहा बंसल / Dr. NEHA BANSAL
वैज्ञानिक 'सी' / Scientist 'C'
...टेक्नोलॉजी विभाग / Department of Biotechnology
...एवं प्रौद्योगिकी मंत्रालय
...stry of Science & Technology
...भारत सरकार / Govt. of India
...G.O. Complex, Lodhi ... -110003

To,

The Pay & Accounts Officer,
Department of Biotechnology,
New Delhi – 110 003.

Copy to:

1 The Principal Director of Audit (Scientific Departments), DACR Building, New Delhi- 110 002.
2 The Director, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow – 226014, Uttar Pradesh.
3 Dr. Alok Kumar, Department of Molecular Medicine and Biotechnology, Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Lucknow - 226014, Uttar Pradesh.
4 Dr. Shantanu Pande, Professor, Cardiovascular and Thoracic Surgery, Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Lucknow - 226014, Uttar Pradesh.
5 Cash Section, DBT (2 copies).
6 Sanction Folder.
7 File Copy.

(Dr. Neha Bansal)
Scientist 'C'
डॉ. नेहा बंसल / Dr. NEHA BANSAL
वैज्ञानिक 'सी' / Scientist 'C'
बायोटेक्नोलॉजी विभाग / Department of Biotechnology
विज्ञान और प्रौद्योगिकी मंत्रालय
Ministry of Science & Technology
भारत सरकार / Govt. of India
सी.जी.ओ. कॉम्प्लेक्स, लोधी रोड, नई दिल्ली–110003
C.G.O. Complex, Lodhi Road, New Delhi-110003

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(13)

BT/PR42952/MED/97/569/2021

No. BT/PR42952/MED/97/569/2021
E-Office No. RAD-21/56/2021-MED-DBT (Computer No. 15167)
GOVERNMENT OF INDIA
MINISTRY OF SCIENCE & TECHNOLOGY
DEPARTMENT OF BIOTECHNOLOGY

Block 2, (6-8th Floors)
CGO Complex, Lodhi Road,
New Delhi- 110 003
Date:09.03.2022

RELEASE ORDER

In continuation of this Department's sanction order of even number dated 09.03.2022 sanction of the President is hereby accorded, under Rule18 of the Delegation of Financial Powers Rule, 1978, for the release of **Rs. 1900000.00/-** (Rupees Nineteen Lakhs Only) being the first year release for the project entitled **"Determination and establishment of key molecular therapeutic approach for remodelling of pericardial heart valve of Tetralogy of Fallot",** being implemented by:

Dr. Alok Kumar, Department of Molecular Medicine and Biotechnology, Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Lucknow - 226014, Uttar Pradesh.

The detailed break-up is as given below:

SN	Institute Name	Non Recurring		Total Release Amount (Rs)
		Equipment	Other	
1	Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow	1900000.00	0.00	**1900000.00**

2. The amount of **Rs. 1900000.00/- (Rupees Nineteen Lakhs Only)** will be directly credited by the Pay & Accounts Officer, DBT in the account as detailed below:

The Director, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow - 226014, Uttar Pradesh

Bank Name :State Bank of India
Branch Name :SGPGIMS LUCKNOW
A/c No. :10095237491
IFSC Code :SBIN0007789
MICR Code :226002034

3. The expenditure involved is debitable to:

Demand No. 89	**Department of Biotechnology**
3425	Other Scientific Research 2021-2022
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 to Research and Development
3425.60.200.29.17.35	Grants for creation of capital assets

4. The Director, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, Uttar Pradesh will submit audited utilization certificates and statements of expenditure in respect of the above-mentioned amount.

Lt Col Arun Bajpai (Retd)
Executive Registrar
SGPGIMS,Lucknow

Generated through eProMIS

5. 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.

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

7. 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 earned should be remitted to the Consolidated fund of India through Bharat Kosh portal (www.bharatkosh.gov.in) as per GFR-2017-230(8) after finalization of the account for a given Financial Year.

8. (i) 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-percent thereon shall be recovered.
ii) Grantee Institution is a public funded organization.
iii) The equipment sanctioned under the project should be purchased within 18 months from the date of the release of the grant.
iv) The expenditure to be made as per the EAT module of the Government of India.
The other terms and conditions governing the financial sanction will remain unaltered.

9. This issues under the powers delegated to this Department as per IFD order No. G-17012/1/2020-IFD-DBT dated 15.02.2022 and with the concurrence of IFD. This has been noted in IFD at SAN No. **102/IFD/SAN/3087/2021-2022** dated **08.03.2022.**

10. This sanction order has been noted at serial no. 95 in the Register of Grants.

(Dr. Neha Bansal)
Scientist 'C'
डॉ. नेहा बंसल / Dr. NEHA BANSAL
वैज्ञानिक 'सी' / Scientist 'C'
बायोटेक्नोलॉजी विभाग / Department of Biotechnology
विज्ञान और प्रौद्योगिकी मंत्रालय
Ministry of Science & Technology
भारत सरकार / Govt. of India
सी.जी.ओ. कॉम्पलैक्स, लोधी रोड, नई दिल्ली-110003
C.G.O. Complex, Lodhi Road, New Delhi-110003

To,

The Pay & Accounts Officer,
Department of Biotechnology,
New Delhi – 110 003.

Copy to:

1 The Principal Director of Audit (Scientific Departments), DACR Building, New Delhi- 110 002.
2 The Director, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow - 226014, Uttar Pradesh.
3 Dr. Alok Kumar, Department of Molecular Medicine and Biotechnology, Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Lucknow - 226014, Uttar Pradesh.
4 Dr. Shantanu Pande, Professor, Cardiovascular and Thoracic Surgery, Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Lucknow - 226014, Uttar Pradesh.
5 Cash Section, DBT (2 copies).
6 Sanction Folder.
7 File Copy.

(Dr. Neha Bansal)
Scientist 'C'
डॉ. नेहा बंसल / Dr. NEHA BANSAL
वैज्ञानिक 'सी' / Scientist 'C'
बायोटेक्नोलॉजी विभाग / Department of Biotechnology
विज्ञान और प्रौद्योगिकी मंत्रालय
Ministry of Science & Technology
भारत सरकार / Govt. of India
सी.जी.ओ. कॉम्पलैक्स, लोधी रोड, नई दिल्ली-110003
C.G.O. Complex, Lodhi Road, New Delhi-110003

Bajpai

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

INDIA NON JUDICIAL

Government of Uttar Pradesh

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सत्यमेव जयते

Certificate No.	:	**IN-UP48166778929699T**
Certificate Issued Date	:	31-Aug-2021 11:26 AM
Account Reference	:	NEWIMPACC (SV)/ up14267604/ LUCKNOW SADAR/ UP-LKN
Unique Doc. Reference	:	SUBIN-UPUP14267604851029974615 51T
Purchased by	:	SGPGIMS LUCKNOW
Description of Document	:	Article 5 Agreement or Memorandum of an agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	
First Party	:	SGPGIMS LUCKNOW
Second Party	:	DBT NEW DELHI
Stamp Duty Paid By	:	SGPGIMS LUCKNOW
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

MEMORANDUM OF AGREEMENT

This MEMORANDUM OF AGREEMENT is made on this _____ day of Two thousand and Nineteen BY AND BETWEEN President of India, acting through 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

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Statutory Alert:

1. The authenticity of this Stamp certificate should be verified at 'www.shcilestamp.com' or using e-Stamp Mobile App of Stock Holding. Any discrepancy in the details on this Certificate and as available on the website / Mobile App renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.

Sanjay Gandhi postgraduate Institute of Medical Sciences, Raiberali Road, Lucknow. UP Act No 30 of 1983(2906(2)/XVII---I-1(Ka)-29-82) dated Oct 13. 1983 having its registered office at *Lucknow* hereinafter referred to as '**SGPGIMS**' (which expression shall where the context so admits include its successors and permitted assigns) of the OTHER PART;

WHEREAS DBT being desirous of **(Centres of Excellence (COE) on Translational Research on Bio-inspired Nanomaterials and Drugs from endophytes)**, decided to support a project submitted by ***Dr Sanjay Gambhir*** *(Project Co-Investigator)* ***and Dr Manish Dixit*** *(Project Co-Investigator)* for the attainment of the objectives, hereinafter described in the Annexure I annexed hereto:

This Memorandum of Agreement (MoA) defines the role and responsibilities of the participating agencies, monitoring and other matters related to the **"Centres of Excellence (COE) on Translational Research on Bio-inspired Nanomaterials and Drugs from endophytes** ***(sanction Order No.*** **102/IFD/SAN/295/2018-19)"**.

NOW THE PARTIES HERE TO AGREE AS FOLLOWS:

1.0 ROLE OF DEPARTMENT OF BIOTECHNOLOGY, NEW DELHI

To provide funds to the extent of 43,75,000.00 ***(Forty Three Lakh seventy five Thousand rupees only)*** over a period of ***five years*** from the date of sanction of the project, to ***SGPGIMS*** for undertaking activities as detailed in Annexure-I. Details of the funds to be provided are given in Annexure-II.

2.0 ROLE OF Sanjay Gandhi postgraduate Institute of Medical Sciences, Raiberali Road, Lucknow.

2.1 To provide their contribution of ***NIL*** for 05 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.

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.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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 that the contact 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 ***Five (05)*** years from the date the Project has been sanctioned by DBT-New Delhi.

4.0 RIGHTS OF OWNERSHIP/TECHNOLOGY TRANSFER AND UTILIZATION

4.1 The know-how generated from the project by ***Dr Sanjay Gambhir*** *(Project Co-Investigator)* ***and Dr Manish Dixit*** *(Project Co-Investigator)* will be the joint property of ***SGPGIMS-Lucknow*** and DBT, Government of India. It shall be the responsibility of ***Dr Sanjay Gambhir*** *(Project Co-Investigator) and* ***Dr Manish Dixit*** *(Project Co-Investigator)*, **SGPGIMS-Lucknow** 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.

4.3 All the assets including the equipment and produce acquired will be the property of DBT and shall not be utilized for purposes other than those for which the grant has been sanctioned. The rights of **SGPGIMS-Lucknow** under this MoA shall not be transferred to any other party without prior approval in writing of DBT.

4.4 It shall be the responsibility of SGPGIMS-Lucknow to ensure that support of DBT is suitably acknowledged in the publications (papers, reports, etc.) arising out of the Project.

5. SECRECY

It is hereby agreed that the participating agencies shall keep information and data collected completely secret provided that the right to transfer the technology shall rest with the DBT.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

MONITORING

6.1 The progress of implementation of the project and proper utilization of grant shall be reviewed by the DBT and by the Monitoring Committee set up by DBT.

6.2 The periodic progress of physical achievements and the utilization of funds, statement of expenditure shall be evaluated by the Monitoring Committee.

6.3 The Comptroller and Auditor General of India, at his discretion shall have the right of access to the books and accounts of ***SGPGIMS-Lucknow*** for the grants received from DBT for this project.

6.4 The DBT may terminate the grant at any stage if it is convinced that the grant has not been properly utilized or appropriate progress has not been made. In the event, DBT terminates the grant, ***Dr Sanjay Gambhir*** *(Project Co-Investigator)* ***and Dr Manish Dixit*** *(Project Co-Investigator)* shall hand over all documents including technical details and equipment purchased related to the project.

7.0 DURATION OF MEMORANDUM OF AGREEMENT

This MoA will remain in-force for the duration of the project and until all claims are settled between DBT and ***SGPGIMS-Lucknow.***

8.0 ARBITRATION

In the event of any question, dispute or difference whatsoever arising between the parties to this Agreement out of or relating to the construction, meaning, scope, operation or effect of this Agreement or the validity of the breach thereof shall be referred to an Arbitrator to be appointed by mutual consent of both the parties herein. If the parties cannot agree on the appointment of the Arbitrator within a period of one month from the notification by one party to the other of existence of such dispute, then the Arbitrator shall be nominated by the Secretary, Department of Legal Affairs, Ministry of Law & Justice, Government of India. The provisions of the Arbitration and Conciliation Act, 1996 will be applicable and the award made there under shall be final and binding upon the parties hereto, subject to legal remedies available under the law. Such differences shall be deemed to be a submission to arbitration under the Indian Arbitration and Conciliation Act, 1996, or of any modifications or reenactments thereof.

9.0 GOVERNING LAW

This Contract shall be governed by the Law of India for the time being in force.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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 Sanjay Gambhir 06/09/2021

2. Dr Manish Dixit

Signed by _____ 14/9/21

(Designation) _____

For and on behalf of SGPGIMS-Lucknow

Prof. R. K. DHUMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Annexure - I

Detailed Project Activities

Details of the activities to be undertaken by *SGPGIMS-Lucknow* under the project entitled "**Centres of Excellence (COE) on Translational Research on Bio-inspired Nanomaterials and Drugs from endophytes**"

Objectives:

Radiolabelling of nanoparticles/nano-drug formulates and animal studies to see their bio-distribution and clearance time from blood.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Details of Funds

Items	*I year*	*II year*	*III year*	IV year	V year	Total
Non-recurring	0	0	0	0	0	0
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	**875000.0**	**875000.0**	**875000.0**	**875000.0**	**875000.0**	**4375000.0**

Dr Sanjay Gambhir
(Project Co-Investigator)
Department of Nuclear Medicine,
Rai-Berali Road, **SGPGIMS-Lucknow**

Dr Manish Dixit
(Project Co-Investigator)
Department of Nuclear Medicine,
Rai-Berali Road, **SGPGIMS-Lucknow**

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Annexure - III

TERMS & CONDITIONS OF THE GRANT

(To be signed and enclosed with concern filled proforma)

1. Approval of the Research proposal and the grant released would be for the specific project mentioned in paras I to V of this proposal and grant should be exclusively spent on the project for which it has been sanctioned within the stipulated time. The Institute is not permitted to seek or utilize funds from any other organization (Government, Semi Government, Autonomous or Private) for this research project. Any unspent part of amount would be surrendered to the Govt. of India through an account payee demand draft drawn in favour of the "Drawing and Disbursing Officer, Department of Biotechnology, New Delhi", and carry forward of funds of the next financial year for utilization for the same project may be considered only with the specific approval of the Department of Biotechnology (DBT).

2. For permanent/semi-permanent assets acquired solely or mainly out of the grant, an audited record in the form of a register in the prescribed proforma (enclosed at Appendix-'A') shall be maintained by the Institute. The term "assets" means (I) immovable property and (II) movable property of a capital nature, where the value exceeds Rs. 1000/- The grant will not be utilized for construction of any immovable property. Full facilities by way of accommodation, etc. for the project will be given by the Institute.

3. All the assets acquired from the grant will be the property of Govt. of India and should not without the prior sanction of the Department of Biotechnology, be disposed of, or encumbered or utilized for purpose other than those for which the grant has been sanctioned.

4. At the conclusion of the project, the Govt. of India will be free to sell or otherwise dispose of assets which are the property of the Government. The Institute shall render to Govt. necessary facilities for arranging the sale/disposal of these assets. The Government may, however, consider the request of host institutions to retain the assets created under a project for carrying out similar work for the promotion of science.

5. The implementing Institute/PI will furnish progress report of work on the project every six months. The progress of the project will also be reviewed / monitored at least once a year by the concerned Task Force/Project Monitoring Committee, etc. In addition the DBT shall designate Scientists/Specialists to visit the Institute periodically for reviewing the progress of work and for suggesting such measures as to ensure early realization of the objectives of the project. On completion of the project five copies of a consolidated report of the work done on the subject would be submitted to the Department of Biotechnology.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

6. The Institute is required to send to DBT a list of assets referred to at Sl. No. 2 above at the end of each financial year as well as at the time of seeking further installments of the grant.

7. The Institute would furnish to the Department of Biotechnology a Utilization Certificate and an audited statement of expenditure (necessary formats can be obtained from the dealing officer of DBT) duly signed by the P.I., the Head of the Institute and the Head of the Finance wing, pertaining to the grant at the end of each financial year as well as a consolidated statement of expenditure at the end of the completion of the project.

8. A stamped receipt be sent to the Department of Biotechnology on receipt of the Cheque/Demand draft towards each release.

9. The Comptroller and Auditor-General of India at his discretion shall have the right of access to the books and accounts of the Institute for the grant received from the Government.

10. The Institute would maintain separate audited accounts for the project. If it is found expedient to keep a part or whole of the grant in a bank account earning interest, the interest thus earned should be reported to the Department of Biotechnology.

11. Sale proceeds, if any, as a result of the development of the project arising directly from funds granted by the Department of Biotechnology shall be reported to the Govt. of India. The Govt. of India may at its discretion allow a portion of such receipt to be retained by the Institute for its utilization for the project activities.

12. Investigators/Institutes wishing to publish papers based on the research work done under Department of Biotechnology projects should acknowledge the financial support received from the Department of Biotechnology.

13. Investigators/Institutes may utilize various resources such as the Bioinformatics resources, experimental materials, reagents, cell lines, animals, etc. from the National facilities/Institutes/Centres established by this Department as per the terms of transactions followed by them. More information may be obtained about such facility from DBT websites: http://dbtindia.nic.in, http://www.btisnet.ac.in.

14. Investigators/Institutes shall follow the detailed instructions on technology transfer and Intellectual Property Rights (IPR) as given at Annexure - V. The same has the approval of the Ministry of Finance, Govt. of India vide Department of Expenditure, Plan Finance II – Division Letter No. 33 (5) /PF.II/99 dated 22nd February, 2000. Any deviation from these instructions may be brought to the notice of this Department.

15. Investigators/Institutes may file patents with the help of the Biotechnology Patents Facilitating Cell (BPFC) established at DBT on priority bases. The format for filing the patents may be seen at Annexure – VI.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

16. The Govt. of India (Department of Biotechnology) will have the right to call for drawings, specifications and other data necessary to enable the transfer of know-how to other parties and the Institute shall supply all the needed information at the request of the Department of Biotechnology which will ensure confidentiality. The information required for commercializing Biotechnologies may be furnished to this Department as per the format enclosed at Annexure VII. More information on commercialization can be found at the website http://www.ebc.nic.in.

17. The Institute may not entrust the implementation of the work for which the grant is being sanctioned to another institution and to divert the grant receipts as assistance to the latter institution. However, in such situations the express permission of DBT may be obtained. In case the grantee is not in a position to execute or complete the project, it may be required to refund forthwith to the Govt. of India (Department of Biotechnology) the entire amount of grant received by it.

18. The human resources that may be engaged for the project by the Institute are not to be treated as employees of the Govt. of India and the deployment of such human resource at the time of completion or termination of project will not be the concern/responsibility of the Govt. of India. The Organization may make reservations for Scheduled Castes, Schedule Tribes etc. in the human resource to be engaged for the project in accordance with the instruction issued by the Govt. of India from time to time.

19. The Department of Biotechnology reserves the right to terminate the grant at any stage and also to recover the amounts already paid if it is convinced that the grant has not been properly utilized or the work on Project has been suspended for any unduly long period or appropriate progress is not being made.

20. The project will become operative with effect from the date of release of the first installment for the project.

21. If the Investigator to whom a grant for a project has been sanctioned leaves the institution where the project is being implemented, he shall submit five copies of complete and detailed

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

report of the work done by him on the project and the money spent till the date of his/her release and shall also arrange to refund the unspent balance, if any.

22. The organization should maintain subsidiary accounts of the Govt. of India grant and furnish it to the Audit Officer as and when the recurring and non-recurring expenditure exceeds the limits of Rs. 5.00 lakhs.

Manish Dixit

Signature of Co-Investigator

Date: 06/9/21

Signature of Co-Investigator

06/09/2021

Date:

14/9/21

Signature of Executive Authority of Institute/ University with seal

Prof R K DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Date:

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Uttar Pradesh

e-Stamp

Certificate No.	:	IN-UP67093582423558U
Certificate Issued Date	:	16-Apr-2022 01:58 PM
Account Reference	:	NEWIMPACC (SV)/ up14238304/ MOHANLALGANJ/ UP-LKN
Unique Doc. Reference	:	SUBIN-UPUP14238304254061207373 86U
Purchased by	:	DR AMITA MOIRANGTHEM
Description of Document	:	Article 5 Agreement or Memorandum of an agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	
First Party	:	DR AMITA MOIRANGTHEM
Second Party	:	Not Applicable
Stamp Duty Paid By	:	DR AMITA MOIRANGTHEM
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

MEMORANDUM OF AGREEMENT

This MEMORANDUM OF AGREEMENT is made on this 30th March day of Two thousand and twenty two BY AND BETWEEN President of India, acting through _____, 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

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Sworn & Verified Before Me

16/04/2022
AKHILESH KUMAR
ADVOCATE & NOTARY

The authenticity of this Stamp certificate should be verified at 'www.shcilestamp.com' or using e-Stamp Mobile App of Stock Holding

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, a society under the Societies Registration Act – 1860, having its registered office in/at Raebareli Road, Lucknow, Pin 226014, Uttar Pradesh, hereinafter referred to as SGPGIMS (which expression shall where the context so admits include its successors and permitted assigns) of the OTHER PART;

WHEREAS DBT being desirous of Clinical research Project decided to support a project submitted by Dr Amita Moirangthem, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow for the attainment of the objectives, hereinafter described in the Annexure I annexed hereto;

This Memorandum of Agreement (MoA) defines the role and responsibilities of the participating agencies, monitoring and other matters related to the Mission Project on Pediatric Rare Genetic Disorders.

NOW THE PARTIES HERETO AGREE AS FOLLOWS:-

1.0 . ROLE OF DEPARTMENT OF BIOTECHNOLOGY, NEW DELHI

To provide funds to the extent of _____over a period of five years from the date of sanction of the project, to Dr Amita Moirangthem, SGPGIMS for undertaking activities as detailed in Annexure 1. Details of the funds to be provided are given in Annexure II.

2.0. ROLE OF SGPGIMS..... (Institute/NGO)

2.1. To provide their contribution of ____(NIL)____ for five years from date of sanction of the project as detailed in Annexure – II. *(provide the cost in place of NIL 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.

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.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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 that 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 five 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 SGPGIMS will be the joint property of SGPGIMS and DBT, Government of India. It shall be the responsibility of SGPGIMS 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.

4.3 All the assets including the equipment and produce acquired will be the property of DBT and shall not be utilized for purposes other than those for which the grant has been sanctioned. The rights of SGPGIMS under this MoA shall not be transferred to any other party without prior approval in writing of DBT.

It shall be the responsibility of the project investigator (s) and SGPGIMS to ensure that support of DBT is suitably acknowledged in the in scientific publication/ patents/ technology transfer documents etc. arising out of the PROJECT. It shall also be the responsibility of the project investigators and institute to ensure the inclusion of reference/ grant number and duration of the financial support while making the acknowledgement of the financial support received from DBT.

NOTARY Mahesh Kumar Advt. & Notary Govt. of U.P. India

5. SECRECY

It is hereby agreed that the participating agencies shall keep information and data collected completely secret provided that the right to transfer the technology shall rest with the DBT.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

6. MONITORING

6.1 The progress of implementation of the project and proper utilization of grant shall be reviewed by the DBT and by the Monitoring Committee set up by DBT.

6.2 The periodic progress of physical achievements and the utilization of funds, statement of expenditure shall be evaluated by the Monitoring Committee.

6.3 The Comptroller and Auditor General of India, at his discretion shall have the right of access to the books and accounts of SGPGIMS for the grants received from DBT for this project.

6.4 The DBT may terminate the grant at any stage if it is convinced that the grant has not been properly utilized or appropriate progress has not been made. In the event, DBT terminates the grant, SGPGIMS shall hand over all documents including technical details and equipment purchased related to the project.

7.0 DURATION OF MEMORANDUM OF AGREEMENT

This MoA will remain inforce for the duration of the project and until all claims are settled between DBT and SGPGIMS.

8.0 ARBITRATION

In the event of any question, dispute or difference whatsoever arising between the parties to this Agreement out of or relating to the construction, meaning, scope, operation or effect of this Agreement or the validity of the breach thereof shall be referred to an Arbitrator to be appointed by mutual consent of both the parties herein. If the parties cannot agree on the appointment of the Arbitrator within a period of one month from the notification by one party to the other of existence of such dispute, then the Arbitrator shall be nominated by the Secretary, Department of Legal Affairs, Ministry of Law & Justice, Government of India. The provisions of the Arbitration and Conciliation Act, 1996 will be applicable and the award made there under shall be final and binding upon the parties hereto, subject to legal remedies available under the law. Such differences shall be deemed to be a submission to arbitration under the Indian Arbitration and Conciliation Act, 1996, or of any modifications or reenactments thereof.

9.0. GOVERNING LAW

This Contract shall be governed by the Law of India for the time being in force.

NOTARY
Adv. & Notary
U.P. INDIA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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:

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

-

(Designation)

For and on behalf of The President of India

Signatures of two witnesses (from DBT):

i.

ii.

Signed and stamped by: 27/9/22

(Director Please also mentioned name and designation of Executive Authority of Institute/ University/ Organization)----------

Acting Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences
Lucknow-226014, INDIA

NOTARY Nilesh Kumar Adv. & Notary GOVT. OF U.P. INDIA

For and on behalf of-- ***Sanjay Gandhi Postgraduate Institute of Medial Sciences, Lucknow***

--- ***(Please mentioned here name of Institute/ University/ Organization)***-------

Name, Signature and stamp of Two Witnesses (from ***Institute/ University/ Organization)***):

i.

ii.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Annexure – I of MoA

Detailed Project Activities

Details of the activities to be undertaken by *SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, RAEBARELI ROAD, LUCKNOW, UTTAR PRADESH* **under the project entitled** *" MISSION PROGRAM ON PEDIATRIC RARE GENETIC DISORDERS (PROJECT TITLE)"*

Objectives:

1. Recruitment of patients with pediatric rare genetic disorders
2. Awareness programmes- workshops/training programs, webinars, community genetics awareness-open day programmes, lectures in schools/colleges

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Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Annexure – II of MoA

Details of Funds

DR AMITA MOIRANGTHEM, DEPARTMENT OF MEDICAL GENETICCS, SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, RAEBARELI ROAD, LUCKNOW-226014, UTTAR PRADESH.

Items	*I year*	*II year*	*III year*	*IV year*	*V year*	Total
Non-recurring (Equipment etc.)	NIL	NIL	NIL	NIL	NIL	NIL
Manpower	1016160.00	1016160.00	1016160.00	1016160.00	1016160.00	**5080800.00**
Consumables	900000.00	900000.00	900000.00	900000.00	900000.00	900000.00
Travel	50000.00	50000.00	50000.00	50000.00	50000.00	**250000.00**
Contingencies	50000.00	50000.00	50000.00	50000.00	50000.00	**250000.00**
Overhead	100000.00	100000.00	100000.00	100000.00	100000.00	100000.00
Others (If applicable)	NIL	NIL	NIL	NIL	NIL	NIL
Total	**2116160.00**	**2116160.00**	**2116160.00**	**2116160.00**	**2116160.00**	**10580800.00**

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

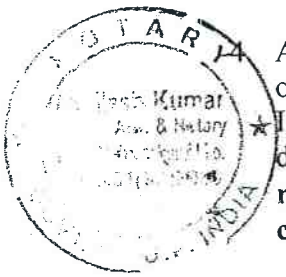
TERMS & CONDITIONS OF THE GRANT

(To be signed and enclosed with MoA)

1. Approval of the Research proposal and the grant released would be for the specific project mentioned in paras I to V of this proposal and grant should be exclusively spent on the project for which it has been sanctioned within the stipulated time. The Institute is not permitted to seek or utilize funds from any other organisation (Government, Semi Government, Autonomous or Private) for this research project. Any unspent part of amount would be surrendered to the Govt. of India through an account payee demand draft drawn in favour of the "Drawing and Disbursing Officer, Department of Biotechnology, New Delhi", and carry forward of funds of the next financial year for utilization for the same project may be considered only with the specific approval of the Department of Biotechnology (DBT).

2. For permanent/semi-permanent assets acquired solely or mainly out of the grant, an audited record in the form of a register in the prescribed proforma (enclosed at **Appendix-'A'**) shall be maintained by the Institute. The term **"assets"** means (I) immovable property and (II) movable property of a capital nature, where the value exceeds Rs. 1000/- The grant will not be utilised for construction of any immovable property, Full facilities by way of accommodation, etc. for the project will be given by the Institute.

3. All the assets acquired from the grant will be the property of Govt. of India and should not without the prior sanction of the Deptt. of Biotechnology, be disposed of, or encumbered or utilised for purpose other than those for which the grant has been sanctioned.



At the conclusion of the project, the Govt. of India will be free to sell or otherwise dispose of assets which are the property of the Government. The Institute shall render to Govt. necessary facilities for arranging the sale / disposal of these assets. **The Government may, however, consider the request of host institutions to retain the assets created under a project for carrying out similar work for the promotion of science.**

5. The implementing Institute/PI will furnish progress report of work on the project every six months. The progress of the project will also be reviewed/monitored at least once a year by the concerned Task Force/Project Monitoring Committee, etc. In addition the DBT shall designate Scientists/Specialists to visit the Institute periodically for reviewing the progress of work and for suggesting such measures as to ensure early realisation of the objectives of the project. On completion of the project five copies of a consolidated report of the work done on the subject would be submitted to the Department of Biotechnology.

6. The Institute is required to send to DBT a list of assets referred to at Sl. No. 2 above at the end of each financial year as well as at the time of seeking further installments of the grant.

7. The Institute would furnish to the Deptt. of Biotechnology a Utilization Certificate (Copy enclosed at **Appendix - 'B'**) and an audited statement of expenditure (**Copy enclosed at Appendix - 'C'**) duly signed by the P.I., the Head of the Institute and the Head of the Finance wing, pertaining to the grant at the end of each financial year as well as a consolidated statement of expenditure at the end of the completion of the project.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

8. A stamped receipt be sent to the Deptt. of Biotechnology on receipt of the Cheque/ Demand draft towards each release.

9. The Comptroller and Auditor-General of India at his discretion shall have the right of access to the books and accounts of the Institute for the grant received from the Government.

10. The Institute would maintain separate audited accounts for the project. If it is found expedient to keep a part or whole of the grant in a bank account earning interest, the interest thus earned should be reported to the Deptt. of Biotechnology.

11. Sale proceeds, if any, as a result of the development of the project arising directly from funds granted by the Deptt. of Biotechnology shall be reported to the Govt. of India. The Govt. of India may at its discretion allow a portion of such receipt to be retained by the Institute for its utilisation for the project activities.

12. Investigators/Institutes wishing to publish papers based on the research work done under Deptt. of Biotechnology projects should acknowledge the financial support received from the Deptt. of Biotechnology.

13. Investigators/Institutes may utilize various resources such as the Bioinformatics resources, experimental materials, reagents, cell lines, animals, etc. from the National facilities/Institutes/Centres established by this Department as per the terms of transactions followed by them. More information may be obtained about such facility from DBT websites: http://www.dbtindia.org// www.dbtindia.nic.in, www.btisnet.ac.in.

14. Investigators / Institutes shall follow the detailed instructions on technology transfer and Intellectual Property Rights (IPR) as given at Annexure - V. The same has the approval of the Ministry of Finance, Govt. of India vide Deptt. of Expenditure, Plan Finance II – Division Letter No. 33 (5) /PF.II/99 dated 22nd February, 2000. Any deviation from these instructions may be brought to the notice of this Department.

15. Investigators / Institutes may file patents with the help of the Biotechnology Patents Facilitating Cell (BPFC) established at DBT on priority bases. The format for filing the patents may be seen at Annexure –VI.

16. The Govt. of India (Deptt. of Biotechnology) will have the right to call for drawings, specifications and other data necessary to enable the transfer of know-how to other parties and the Institute shall supply all the needed information at the request of the Department of Biotechnology which will ensure confidentiality. The information required for commercializing Biotechnologies may be furnished to this Deptt. as per the format enclosed at Annexure – VII. More information on commercialization can be found at the website www.ebc.nic.in.

17. The Institute may not entrust the implementation of the work for which the grant is being sanctioned to another institution and to divert the grant receipts as assistance to the latter institution. However, in such situations the express permission of DBT may be obtained. In case the grantee is not in a position to execute or complete the project, it may be required to refund forthwith to the Govt. of India (Department of Biotechnology) the entire amount of grant received by it.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

18. The human resources that may be engaged for the project by the Institute are not to be treated as employees of the Govt. of India and the deployment of such human resource at the time of completion or termination of project, will not be the concern/responsibility of the Govt. of India. The Organisation may make reservations for Scheduled Castes, Schedule Tribes etc. in the human resource to be engaged for the project in accordance with the instruction issued by the Govt. of India from time to time.

19. The Deptt. of Biotechnology reserves the right to terminate the grant at any stage and also to recover the amounts already paid if it is convinced that the grant has not been properly utilized or the work on the project has been suspended for any unduly long period or appropriate progress is not being made.

20. The project will become operative with effect from the date of release of the first installment for the project.

21. If the Investigator to whom a grant for a project has been sanctioned leaves the institution where the project is being implemented, he shall submit five copies of complete and detailed report of the work done by him on the project and the money spent till the date of his/her release and shall also arrange to refund the unspent balance , if any.

22. The Memorandum Agreement, to be sent to Department of Biotechnology should be on Non- Judicial stamp paper of Rs. 100/-.

23. The organisation should maintain subsidiary accounts of the Govt. of India grant and furnish it to the Audit Officer as and when the recurring and non-recurring expenditure exceeds the limits of Rs. 5.00 lakhs.

NOTARY
Akhilesh Kumar
Advt. & Notary
STATE OF U.P. INDIA

27.4.2022
Acting Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
Lucknow - 226014, INDIA

Signature of Executive Authority of Institute/ University With seal:

Date :

Signature and seal of Project Coordinator (If applicable)
Date:

Signature and seal of all Principal Investigator(s)/ Co- PI (s):
Date :

16/04/2022
AKHILESH KUMAR
ADVOCATE & NOTARY
Tahsil Mohanlalganj, Lucknow

16/4/2022
Dr. Moirangthem Amita
Assistant Professor
Department of Medical Genetics
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226014 (U.P.)

19/4/22

Signature and seal of all Co-Investigator (s)
Date :

I identified the deponent/executant/surety who has Signed/put T.I. before me.

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1.1.2 **Trial Staff and Facilities.** Institution and/or Investigator will provide an adequate number of qualified Trial Staff, and adequate facilities and will require the Trial Staff and facilities to conduct the Trial properly and safely and in accordance with the Protocol and Applicable Law (as defined below under Section 1.1.4). "Trial Staff" means any employees of Institution or Investigator, and/or contractors engaged by Institution or Investigator, who are involved in performing the Trial, including, without limitation, any sub-investigator(s), study coordinator(s), and any other contractors, agents and employees of Institution or Investigator who assist Institution and Investigator with the Trial. Institution and Investigator shall inform Sponsor and CRO promptly in writing about all changes impacting the Trial Staff and/or facilities.

1.1.3 **Performance and Delegation.** Any and all research and procedures pertaining to the Trial will be performed only by the Investigator or Trial Staff assigned thereto by Institution and/or Investigator and Investigator will personally supervise the work of all assigned Trial Staff, and neither Institution nor Investigator may delegate this duty. Notwithstanding the foregoing, Institution may delegate other duties of Investigator and/or duties of Institution's assigned Trial Staff under this Agreement to third-parties provided that (i) Investigator will personally supervise the work of the third-party; (ii) the third-party will only assign and/or delegate Trial related activities to its own employees; *(iii)* the third-party will be deemed Institution's agent, and Institution will remain fully responsible for the performance of such third-parties under this Agreement; *(iv)* Institution and the third-party have entered into a written agreement (the "Side Agreement") that *(a)* binds such third-party to terms and conditions that are at least as stringent as those contained in this Agreement, including, but not limited to, those regarding Trial conduct, confidentiality, intellectual property, use of information, record retention, and monitoring, and *(b)* does not conflict with any of Sponsor's or CRO's rights and obligations under this Agreement; and *(v)*, (if applicable under Applicable Law, as defined below) Sponsor will be deemed a third-party beneficiary of the Side Agreement and will be entitled to enforce any applicable terms thereunder as related to this Agreement and/or the Trial. Institution will provide a copy of any Side Agreement to Sponsor and/or CRO.

1.1.4 **Compliance**. Institution and Investigator will (and warrant that the Trial Staff will) conduct the Trial in a diligent, efficient, and skillful manner, consistent with sound scientific procedures and in strict accordance with

(i) this Agreement,
(ii) the Protocol including any amendments / modifications (the "Protocol"),
(iii) the Investigator Site File ("ISF"),
(iv) any specific Trial instructions, other than the Protocol, issued by Sponsor;
(v) any applicable international, national, federal, state, provincial, commonwealth, or local government law, statute, rule, requirement, code, regulation, ordinance, guideline or official publication that applies, directly or indirectly, to any party or to the conduct of clinical trials, this Trial, or this Agreement, as amended from time to time, in particular, without being limited to, New Drugs and Clinical

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Trials Rules, 2019 including the gazette notification as issued from time to time, National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017, Indian GCP guidelines released by CDSCO, the International Conference on Harmonisation Harmonised Tripartite Guideline for Good Clinical Practice ("ICH GCP"), the principles laid down in the Declaration of the Helsinki, most current version (as long as local laws do not require to follow other versions), and, where applicable, the rules governing good manufacturing practice and good laboratory practice, and rules governing the collection and storage of human tissue samples and the performance of DNA testing as well as related governmental and regulatory authorities' regulations, any conditions imposed by a competent Institutional Review Board/ Ethics Committee ("IRB/EC"), as well as all applicable drug, data protection/privacy, anti-competitive, anti-corruption, anti-bribery and anti-kickback law and all industry regulations on the cooperation of the pharmaceutical industry with the medical profession, including but not limited to, the IFPMA Code of Marketing Practices, the EFPIA Code of practice on the promotion of medicines, the PhRMA Code on Interactions with Health Care Professionals and the German FSA Code of Conduct, the Singapore Association of Pharmaceutical Industries Guiding Principles on Ethical Conduct on Promotion (SAPI Code of Marketing Practices), OPPI Code of Pharmaceutical Practices India, if applicable (e.g. for investigator meetings) (in the following collectively "Applicable Law").

1.2 Qualification of Investigator and other Trial Staff.

1.2.1 **Qualification.** Institution will ensure that the Investigator and Trial Staff are, at all times during the term of this Agreement, qualified by education, training and experience with appropriate expertise to conduct the Trial in accordance with this Agreement and the Protocol. If the Investigator is, at any time, no longer qualified or unable to perform any of the activities of the Trial, Institution, Sponsor and CRO may mutually agree to a substitute Investigator. Institution will notify Sponsor and CRO in writing, immediately upon learning that the Investigator is or will be unable to perform any of the activities of the Trial. Institution will use its best efforts to identify and obtain a substitute Investigator acceptable to Sponsor within thirty (30) days following such notice to Sponsor and CRO. If an acceptable Investigator cannot be obtained within thirty (30) days, CRO with written authorization from Sponsor may, at its discretion, immediately terminate this Agreement in accordance with Section 14.3 below. Prior to assuming the role of Investigator, the substitute Investigator must agree in writing to be bound by all obligations, terms and conditions of this Agreement.

1.2.2 **Curriculum Vitae.** Institution and/or Investigator will provide an up to date curriculum vitae for Investigator, any sub-investigators as well as other relevant documentation requested by competent IRB/ECs, regulatory authorities, CRO or Sponsor needed for the conduct of the Trial.

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1.3 Notifications and Submissions

1.3.1 **Notification/Submission to Authorities and IRB/EC.** In accordance with Applicable Law, before initiating and during the conduct of the Trial, Institution and Investigator will ensure that *(i)* all necessary submissions, notifications and/or application(s) have been made, *(ii)* all necessary documentation and information is available, and *(iii)* all required reviews and approvals (or favourable opinions) by applicable regulatory authorities and competent IRB/EC have been obtained.

1.3.2 **Agreement.** Institution and Investigator agree that this Agreement may be forwarded to competent regulatory authorities as well as competent IRB/ECs, where requested by such.

1.4 Recruitment and Enrollment of Trial Participants.

1.4.1 **General.** Investigator will enroll subjects as participants in the Trial ("Trial Participants") in accordance with the terms and conditions of the Protocol and this Agreement. Investigator will enroll Trial Participants in strict compliance with the exclusion and inclusion criteria set forth in the Protocol without deviation or exception.

1.4.2 **Recruitment Phase.** The planned recruitment phase of this multi-center Trial at a global level will be from Dec 2020 to Dec 2021. Institution shall use reasonable endeavors to recruit or cause the Investigator to use reasonable endeavors to recruit approximately up to 13 randomized Trial Participants within this phase. The recruitment and inclusion of Trial Participants by the Investigator above and beyond this number, or any adjustment of this number, shall be subject to prior written approval of Sponsor.

1.4.3 **Competitive Recruitment.** Institution and Investigator acknowledge and agree that the Trial will involve the participation of multiple sites and recruitment will be competitive and closed when the desired overall number of evaluable Trial Participants has been obtained.

1.5 Informed Consent, Data Protection / Privacy.

1.5.1 **Trial Participant Consent.** Institution and Investigator shall ensure to have

(i) all requirements for obtaining informed consent and data protection/privacy related documents are satisfied,

(ii) he/she has obtained from each Trial Participant prior to enrolling such subject in the Trial a valid, dated, signed informed consent (the "IC") covering *(a)* Trial Participant's participation in the Trial, and *(b)* collection, storage and processing of Trial Participant's personal data in relation with the Trial (and a separate consent for future research/biobanking, where applicable), in accordance with the IC form provided by Sponsor and approved by the competent IRB/EC, and

(iii) the respective data collection form on file before the Trial Participant begins to participate in the Trial.

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1.5.2 **Data Protection Laws.** During the term of this Agreement, BI and Institution/Investigator may collect, share, process or use certain personal data (as the term is defined in the Data Protection Laws). "Data Protection Laws" means *(i)* any law, statute, declaration, decree, directive, legislative enactment, order, ordinance, regulation, rule or other binding restriction (as amended, consolidated or re-enacted from time to time) which relates to the protection of individuals with regards to the processing of personal data to which a Party is subject, in particular, Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data (the "General Data Protection Regulation – GDPR"); and *(ii)* any code of practice or guidance published by a relevant regulatory body from time to time. Institution and Investigator will only process personal data as permitted under applicable Data Protection Laws.
Under this Agreement, Sponsor and Institution/Investigator are Joint-Controllers, Covance is the Processor of personal data.

1.5.3 **Notification and Cooperation**. Investigator and/or Institution shall notify the Sponsor about the identity of the Data Protection Officer / Data Privacy Officer appointed at Investigator/Institution. Institution and Investigator shall notify Sponsor immediately in writing (but in no event later than three (3) days from the date) of any *(i)* loss or misuse (by any means) of personal data of Trial Participants or of the Sponsor's personnel; *(ii)* inadvertent, unauthorized, and/or unlawful processing, collection, storage, disclosure, access, alteration, corruption, transfer, or sale or rental, destruction, or use of personal data of Trial Participants or of the Sponsor's Personnel; or *(iii)* any other act or omission that compromises the security, confidentiality, or integrity of personal data of Trial Participants or of the Sponsor's Personnel to enable the Sponsor to consider what action is required in order to resolve the issue in accordance with applicable Data Protection Laws. If requested by Sponsor in order to enable Sponsor to comply with applicable Data Protection Laws, Institution and Investigator will, and will cause its Trial Staff to assist and cooperate with Sponsor to address any data protection/privacy issue relating to the Trial.

1.5.4 **Contact Point.** Under the IC Institution will be appointed as the point of contact for any data protection related requests concerning Institution or Sponsor in connection with the Trial and any use of personal data according to the IC. Institution shall be responsible to handle such requests (including sharing such requests with Sponsor, where required) and communicate with Trial Participants; Sponsor will provide reasonable assistance where required to ensure compliance with Trial Participants' rights under applicable Data Protection Laws.

1.6 **Adverse Event Reporting.** Investigator will collect, document and report information on all adverse events, serious and non-serious, as defined in the Protocol ("Adverse Events"), that occur for each Trial Participant from the point the Trial Participant signs the informed consent until completion of the Trial, including any post treatment period specified in the Protocol, in accordance with the instructions provided in the Investigator Site File ("ISF"), Applicable Law and any condition imposed by the IRB/EC, or any (sub)investigators, or the competent regulatory or governmental authority. This includes provision of available follow-up case data and detailed medical information.

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1.7 Use of Investigational Product and Other Materials

1.7.1 **Definition Trial Drug.** Sponsor provide the Investigational Product to be used in the Trial in accordance with the Protocol. The Investigational Product collectively referred to herein as "Trial Drug".

1.7.2 **Use of Trial Drug.** Institution and Investigator will ensure that any Trial Drug is administered only to Trial Participants in strict accordance with the Protocol and only under the supervision of Investigator. At no time will any Trial Drug be employed for any purpose other than as described in the Protocol.

1.7.3 **Storage, Accounting, Return and Destruction.** Institution and Investigator will be responsible for *(i)* storing the Trial Drug in a secure, limited access area under appropriate climate conditions specified in the Protocol and *(ii)* accounting for all Trial Drug whether or not such Trial Drug is used which will be documented in the Trial Drug accountability log. Upon completion or termination of the Trial, Institution and Investigator will account for all quantities used of the Trial Drug and shall return, retain or destroy, at Sponsor's option, all unused Trial Drug in accordance with instructions to be provided by Sponsor and/or CRO at Sponsor's sole expense.

2. OBLIGATIONS OF SPONSOR

2.1 **Supply of Trial Drug.** Sponsor will supply that may be done through third party providers the Investigational Product, if applicable, for use in the Trial at no cost to Institution or Investigator. Sponsor may also supply or arrange for the provision of any other Trial Drug to be used in the Trial at no cost to Institution or Investigator, either through provision of such Trial Drug by Sponsor or reimbursement to Institution by a third party payor.

2.2 **Information of Investigator**. Sponsor and/or CRO will provide Investigator with the current Investigator Brochure containing information about the chemical, pharmaceutical, toxicological, pharmacological and clinical data concerning the Trial Drug.

2.3 **Notification/Submission to Authorities and IRB/EC.** In accordance with Applicable Law, before initiating and during the conduct of the Trial, Sponsor will ensure that *(i)* all necessary submissions, notifications and/or application(s) have been made, *(ii)* all necessary documentation and information is available, and *(iii)* all required reviews and approvals (or favourable opinions) by applicable regulatory authorities and competent IRB/EC have been obtained.

2.4 Compensation

2.4.1 **Budget**. As compensation for all Trial services performed under this Agreement, Sponsor or Sponsor's designee, acting on behalf of Sponsor, will compensate Institution at fair market value according to the itemized "Clinical Trial Budget and Payment Schedule" attached as Appendix 1. Such amounts are fully inclusive for all services provided by Institution and Investigator in connection with the Trial and include all applicable direct

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and indirect costs, overhead, fees, and other assessments due to Institution, Investigator and other persons or entities providing any services or goods in connection with the Trial, but does not include standard of care costs. Except as specifically agreed to by Sponsor and/or CRO in writing, neither Institution, nor Investigator, nor any other person or entity will be entitled to any payments in connection with the Trial or activities conducted pursuant to this Agreement in addition to the amounts set forth in the Clinical Trial Budget. Any Party to this Agreement shall bear its own costs arising in connection with the preparation, negotiation, execution and performance of this Agreement, including but not limited to, all legal fees, auditor's fees and other professional fees.

2.4.2 **Invoices**. All payments due according to Appendix 1 shall be made to Institution within forty five (45) days of receipt of an invoice by Institution detailing goods and services tax (GST) separately to a bank designated by Institution. For the purpose of this agreement, the term 'GST' shall include the Central Goods and Services Tax ('CGST'), the State Goods and Services Tax ('SGST'), Integrated Goods and Services Tax ('IGST'), Union Territory Goods and Service Tax ('UTGST') and any other taxes levied under the GST related legislations in India as may be applicable. The term 'GST legislation/s' should be accordingly interpreted.

2.4.3 Invoices shall be made in accordance with the specifications set forth in the Clinical Trial Budget, which shall be modified in the event of a change in the applicable legal requirements. The Institution and Investigator shall be responsible for identifying the Place of supply of services supplied to Sponsor/CRO in accordance with the provisions of GST law.

(a) CRO hold right to hold further payments till the completion of following events;

1. Invoice details are reflected in GSTR-2 of CRO and payment of GST is made by Institution or Investigator; or

2. If not reflected in GSTR-2, amendments made by CRO in its GSTR-2 are accepted by Institution and Investigator and payment of GST is made; or

3. In case GST is actually paid by the Institution and Investigator, then the same can be deducted from subsequent payments if credit is not available

2.4.4 All invoices, debit notes, credit notes and receipts against advances, etc. issued to Covance India Pharmaceutical Services Pvt. Ltd. should be in accordance with the format prescribed under the GST Invoice Rules with the correct GST registration numbers to ensure that entire input tax credit is available.

2.4.5 **Overpayment, Final Accounting and Payment.**

(i) If during the course of the Trial Sponsor and/or CRO compensates Institution any funds in excess of the amount due under the Clinical Trial Budget,

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Institution will return such excess funds to Sponsor within sixty (60) days of written notification by Sponsor and/or CRO to Institution or Institution's discovery of such overpayment, whichever first occurs.

(ii) Final payment hereunder will be expressly conditioned upon receipt by Sponsor and/or CRO of any and all required data or other information from Institution and Investigator in a timely manner and as required by this Agreement and the Protocol, in a form satisfactory to Sponsor and CRO. The final payment will be processed by CRO after Sponsor's close-out visit to Institution, when all (original paper and electronic) case report forms (the "CRFs/eCRFs") have been completed and logged for all Trial Participants enrolled at Institution, all queries to Institution have been resolved, and Institution's data, including the Trial data accountability log, has been reviewed and accepted by the Sponsor or CRO clinical monitor. The final payment will include any remaining approved interim Trial Participant visit fees and/or any remaining approved invoiceable items noted on the Clinical Trial Budget.

(iii) Within ninety (90) days following the earlier of the date of termination of this Agreement or completion of the Trial by Institution and Investigator, Sponsor or CRO will submit to Institution a final report and documentation of all costs incurred and all funds received by Institution pursuant to this Agreement. Subject to the limits set forth in the Clinical Trial Budget and, (a) if the payments previously made by Sponsor/CRO to Institution exceed Institution's costs and allowable commitments incurred, such report will include a request for refund to Sponsor/CRO by the Institution, which refund will be made within sixty (60) days following the date of such report, or (b) if the payments previously made by Sponsor/CRO to Institution are less than Institution's costs and allowable commitments incurred, Sponsor/CRO will issue payment to Institution within sixty (60) days following the date of such report in the amount by which its costs and allowable commitments incurred exceed the payments previously made by CRO to Institution.

(iv) Except as otherwise provided in this Agreement, the failure of Institution to make demand for payment within the earlier of twelve (12) months of termination of this Agreement, or completion of the Trial by Institution and Investigator will be considered a waiver by Institution of its right to receive payment.

2.4.6 **Taxes.**

(i) **General.** All payments under or in connection with this Agreement shall be inclusive of any Taxes and each party shall be responsible for and shall bear, pay or set-off its own Taxes assessed by a tax or other authority except as otherwise set forth in this Agreement. "Taxes" mean all present and future taxes, import deposits assessments, and other governmental charges and any related penalties and interest not attributable to the fault or delay of a party.

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"Taxes" shall mean all forms or preliminary or finally imposed taxation, domestic and foreign taxes, fees, levies, duties and other assessments or charges of whatever kind (including but not limited to sales, use, excise, stamp, transfer, property, value added, goods and service, withholding and franchise taxes) together with any interest, penalties or addition payable in connection with such taxes, fees, levies, duties and other assessments or charges.

(ii) If Applicable Law requires withholding (of licensee) of any taxes imposed upon (by licensor) on account of any royalties and other payments, paid under this Agreement, such taxes shall be retained (by licensee) as required by law from such remittable royalty and other payment and shall be paid (by licensee) to the proper tax authorities on account of (licensor). Official receipts of payment of any retained local withholding tax shall be secured and sent to (licensor) as evidence of such payment. The parties shall cooperate and exercise their best efforts to ensure that any withholding taxes imposed are reduced as far as possible under the provisions of any relevant double tax treaty.

(iii) **GST or similar Taxes.** All payments due to the terms of this agreement are expressed to be exclusive of indirect taxes (e.g. goods and service tax). GST/indirect taxes shall be added to the payments due to the terms if legally applicable.

(iv) The GST amounts of invoices received by Institution and Investigator are not billable to Sponsor as far as Institution and Investigator have an input GST deduction, i.e., Institution and Investigator are able to receive a refund by the competent authority. If GST is not refundable because of legal restrictions, which are not caused by Institution or Investigator, the GST amounts are billable to Sponsor/CRO. Prior to the invoicing of the aforementioned billable amounts written approval of Sponsor and/or CRO is mandatory. Legal restrictions which are caused by Institution or Investigator and lead to a non-billable amount to BI shall be the following, but not limited to, (i) failure of Institution or Investigator of adhering to applicable statutes of limitations, or (ii) inaccurate documents in order to receive the input GST deduction.

I. In cases, where Institution and Investigator is GST unregistered, Institution and Investigator should declare the same at the time of Clinical trial agreement sign off and should not charge any tax on service to CRO. Where the Institution/ site fails to inform CRO that they are GST unregistered, the Institution and Investigator shall be liable to reimburse for loss of any input tax credit, interest or penalty levied by the tax authorities on such supplies of services.

II. In respect of notified supplies of services received by CRO/Sponsor, where Sponsor may be required to deduct tax at source (under GST law) on certain payments made to the Investigator and Institution, Sponsor/CRO shall deposit such amount with appropriate government within 10 days after the end of the month in which such deduction is made. Sponsor/CRO shall also furnish a certificate in Form GSTR 7A to the Institution and Investigator against such deduction. The

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Institution and Investigator shall be responsible for providing the correct details of address, GSTIN, HSN code and other details as may be required to be mentioned by Sponsor/CRO in the certificate to be issued in Form GSTR 7A. In case of any incorrect / incomplete details provided by the Institution and Investigator which results in denial of credit (of TDS deducted) by the authorities to the Institution and Investigator along with levy of interest or penalty on the Institution and Investigator for incorrect availement or utilization of credit, Sponsor/CRO shall not be responsible to reimburse the same to the Institution and Investigator

III. If the Institution and Investigator is a composition dealer, Institution and Investigator should declare the same at the time of Clinical trial agreement sign off. Where composite scheme is availed without informing Sponsor/CRO, Institution and Investigator is liable to reduce the price to the extent of tax applicable on similar services.

(v) The Investigator/Institution shall support Sponsor/CRO on various aspects to comply with the transitional provisions under GST and assist Sponsor/CRO in identifying tax benefits or refunds as the case may be, that may accrue on stocks, credits, taxes, etc. on the GST implementation appointed date and pass-on the same to Sponsor/CRO.

(vi) The Investigator/ Institution shall pass on to Sponsor/CRO all the benefits of either reduction in tax rates, exemptions, concessions, rebate, set off, credits, etc. or introduction of new tax rates, exemptions, concessions, rebate, set off, credits etc. pertaining to all taxes, duties, imposts, fees and levies in respect of the supplies of services or performance of obligations including reduction in procurement price, including reduction of tax rates as a result of statutory changes or judicial rulings and reduction in price where the Investigator/ Institution is benefited due to reduction in taxes.

3. TRIAL DOCUMENTS

3.1 **Collection and Storage**. Institution and Investigator will accurately maintain, organize, keep current, complete and preserve all essential documents relating to the Trial which allow verification of the conduct of the Trial and the quality of the data generated (Investigator Site File), including, but not limited to, *(i)* written or electronic records, copies of paper original and electronic CRFs, accounts, notes, reports, materials and data collected or performed as part of the Trial under this Agreement, including clinical data and patient medical care records and progress reports for each Trial Participant (including, without limitation, treatment entries, x-rays, biopsy reports, ultrasound photographs and other diagnostic images); *(ii)* and any other records, data or reports related to or generated as part of the Trial (e.g., Protocol, informed consent form, source data, documents facilitating identification of Trial Participants); required by Applicable Law, in full compliance with the Protocol.

3.2 **Document Storage and Protection.** Institution and Investigator shall *(i)* maintain and store such documents in a secure manner appropriate to the applicable data type and in accordance with Applicable Law, and *(ii)* protect the documents from unauthorized use, access, duplication, disclosure, loss and damage. Institution and Investigator will make all documents available for review, copying, audit, and inspection in accordance with Article 4 hereof.

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3.3 **Retention and Destruction.** Institution and Investigator will archive the Investigator Site File containing all essential documents which allow the verification of the conduct of the Trial and the quality of the data generated in their original format for fifteen (15) years After the expiration of the retention period required above, Institution and Investigator shall provide written notice to the Sponsor or its designated party and destroy all essential documents.

3.4 **Access to Documents.** Institution and Investigator must not transfer or make in any other way accessible to Sponsor and/or CRO any essential documents containing personal data of Trial Participants, unless such data has been pseudonomized (de-identified) or if such disclosure is required under Applicable Law or requested by the competent authorities. Sponsor may assign certain of its employees, CRO employees or external vendors (clinical research associates, the "CRAs") to review and control accuracy and completeness of the essential documents in order to comply with Applicable Law at Institution or Investigator; however, such CRAs are restricted from disclosing any personal data of Trial Participants to the Sponsor stored at Institution or Investigator.

3.5 **Information Delivery to Sponsor and/or CRO**. Institution and/or Investigator will provide to Sponsor and/or CRO completed CRFs/eCRFs, as applicable, for each Trial Participant and other such reports when and as required by the Protocol and Applicable Law. Institution and Investigator warrant that all eCRFs or CRFs submitted to Sponsor/CRO are true, complete, correct and accurately reflect the results of the Trial. Within sixty (60) days following the completion of the Trial by Institution and Investigator or the earlier termination of this Agreement, Institution and Investigator will provide to Sponsor/CRO any and all data required pursuant to the terms of this Agreement and the Protocol.

3.6 **Incomplete Data.** In the event that essential documents and any other original records and data related to or generated as part of the Trial are either incomplete or out-of-date, Sponsor/CRO may retain trained health care professionals to assist in satisfactory completion of such documents. The cost of such professional assistance (which will be reasonable in the circumstances) will be charged to Institution and may be offset against compensation owed to Institution hereunder.

4. MONITORING, AUDITS AND INSPECTIONS

4.1 **Access**. Sponsor, CRO and/or their agents and, when applicable, IRB/EC and regulatory authorities, including foreign regulatory authorities, may, at any time during normal business hours, (i) inspect any facilities used for the conduct of the Trial, (ii) monitor and/or audit the conduct of the Trial, (iii) inspect, audit and/or copy any and all Trial documents, source data/documents, medical records, work product, and required licenses, certificates and accreditations, or (iv) interview any person involved in the Trial. Additionally, during the term of this Agreement and for a period of twenty-four (24) months after completion of the Trial, Sponsor and/or its designee shall be entitled to inspect Institution's financial accounts directly related to the Trial. Institution and Investigator will, and will cause its Trial Staff to, cooperate with any of the foregoing activities and will provide timely access to requested documentation and facilities.

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4.2 Electronic Records System. Without limiting the foregoing, if Institution stores and retains its records in an electronic records system, Institution will promptly upon request allow access to Trial documents and other required documents and information through such electronic records system. In the event it is not possible, after exercise of commercially reasonable efforts, to allow access to Trial documents in Institution's electronic records system without jeopardizing data protection or privacy rights of other patients of Institution, Institution will print and provide to the requestor certified hardcopies of all relevant documents and information. Institution will maintain, create, modify, archive, retrieve and transmit, and make available for inspection by regulatory authorities, all electronic records in compliance with any Applicable Law, including, but not limited to, Title 21 U.S. Code of Federal Regulations, Part 11 "Electronic Records; Electronic Signatures."

4.3 Regulatory Authority Inspections.

4.3.1 **Notification.** Institution and/or Investigator will notify Sponsor and CRO immediately by telephone, facsimile or email if, in connection with the Trial or in connection with any matter that may affect Institution's or Investigator's performance of the Trial, a governmental or regulatory authority requests permission to or does inspect Institution's and/or Investigator's facilities or research records.

4.3.2 Copies. In accordance with Applicable Law, Institution and/or Investigator will provide in writing to Sponsor and/or CRO copies of all materials, reports, correspondence, statements, forms and records which Institution and/or Investigator receives, obtains or generates pursuant to any such inspection in connection with the Trial, or in connection with any matter that may affect Institution's or Investigator's performance of the Trial.

4.3.3 **Sponsor Attendance.** Institution and Investigator shall permit Sponsor and/or its designees to attend any such inspection unless prohibited by Applicable Law or the competent governmental or regulatory authority. If any proposed correspondence from Institution and/or Investigator to a governmental or regulatory authority relates directly or indirectly to Institution's and/or Investigator's activities under this Agreement, Sponsor and/or its designee(s) will have the right to review such correspondence and request reasonable revisions thereto.

5. CONFIDENTIALITY

5.1 Non-Disclosure and Non-Use Obligation. Institution and Investigator shall keep any and all data, know-how, substances and all other information (including, but not limited to, documents, descriptions, data, (e)CRFs, photographs, videos and instructions), and material (including, but not limited to, the Investigational Product and comparator products), provided to or made available, no matter how it is disclosed (e.g. in writing or electronically), to Institution or Investigator by Sponsor, CRO or their Affiliates, or their agents, and/or generated under this Agreement and/or relating to the Trial (collectively referred to as "Sponsor Confidential Information") confidential and shall not (i) disclose the Sponsor Confidential Information to any third party without the prior written approval of Sponsor, or (ii) use the Sponsor Confidential Information for any purpose other than for the conduct of the Trial and its obligations under this Agreement. Sponsor Intellectual Property (as

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defined in 6.2.1) and Results (as defined in 6.3) shall be considered Sponsor Confidential Information; provided that Results shall not be considered Sponsor Confidential Information for the sole purpose of publication in accordance with the terms set forth in Article 7. For the purpose of this Agreement, "Affiliate" or "Affiliates" shall mean any person or entity controlled by, controlling, or under common control with either Sponsor or Institution. For this purpose, "control" means direct or indirect beneficial ownership of at least fifty percent (50%) interest in the voting stock (or the equivalent) of such person or entity or having the right to direct, appoint or remove a majority or more of the members of its board of directors (or their equivalent), or having the power to control the general management of such person or entity, by contract, law or otherwise.

5.2 **Dissemination to Others.** Institution and Investigator will restrict the dissemination of Sponsor Confidential Information to those persons participating in the Trial on behalf of Institution and/or Investigator who have a need to know and will ensure that each such person is contractually bound by confidentiality and non-use obligations at least as onerous as those set forth in this Agreement before being engaged or involved in the Trial.

5.3 **Non-Written Information.** If Sponsor Confidential Information is disclosed by Sponsor or its Affiliates to Institution and/or Investigator other than in written or electronic form, then Institution and/or Investigator 's obligations of confidentiality and non-use shall only apply if the respective Sponsor Confidential Information is indicated upon disclosure as being confidential and is then summarised electronically or in writing and provided to Institution and/or Investigator within thirty (30) days after initial disclosure, except for any such Sponsor Confidential Information that, based on the nature of the information, a reasonable person would understand is the confidential information of Sponsor.

5.4 **Return of Sponsor Confidential Information.** Institution and Investigator agree and bind themselves, either immediately upon request of Sponsor or upon expiry or termination of this Agreement, to return all Sponsor Confidential Information to Sponsor, except for those documents generated by Institution or Investigator necessary to comply with applicable record retention requirements or procedures, but only to the extent required by Applicable Law, and all such retained documents will continue to be subject to the confidentiality provisions of this Agreement.

5.5 **Exemption.** These confidentiality and non-use obligations do not apply to: (i) information already in the possession of Institution and/or Investigator prior to its disclosure by Sponsor or its Affiliates as evidenced by written records, (ii) information which comes into the public domain by publication or otherwise through no breach by Institution and/or Investigator or others involved in the Trial, (iii) information which has been disclosed to Institution and/or Investigator from another source free from any obligation of confidentiality and which was not directly or indirectly obtained from Sponsor or its Affiliates, or (iv) information required to be disclosed under Applicable Law or for making applications or submissions to or otherwise dealing with an IRB/EC or competent regulatory authority in connection with the Trial provided, however, that such information shall be disclosed only to the extent reasonably necessary (v) information required to be disclosed under the order of a court of competent jurisdiction, provided that Institution and/or promptly notifies Sponsor of such obligation beforehand and the information to be disclosed and fully cooperates with Sponsor, if so requested, in maintaining the confidentiality of such information by applying for a protective order or any similar legal instrument.



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5.6 **Encryption Technology.** Institution and Investigator undertake to protect Sponsor Confidential Information (including but not limited to patent-relevant, scientific or technical information) against unauthorized access by third parties. If Sponsor Confidential Information is communicated via internet mail, use of internet mail encryption technology is compulsory (for direct communication between the Parties, Sponsor provides for a suitable technology at http://guides.boehringer-ingelheim.com free of charge).

5.7 **Breach Notification.** Institution and/or Investigator will notify Sponsor immediately of any loss, compromise, or unauthorized use or disclosure of any part or all of Sponsor Confidential Information.

6. INTELLECTUAL PROPERTY

6.1 Background IP

6.1.1 **Ownership.** Each Party and or its Affiliates shall be and shall remain the owner of any data, documents, know-how, information, material, substances, including but not limited to the Investigational Product, and any other intellectual property, which are provided to the other party for use in the Trial (the "Background Intellectual Property") and this Agreement shall not affect the ownership of any Background Intellectual Property.

6.1.2 **Licence Grant.** Each party grants the other party a royalty free, non-exclusive license to use its or its Affiliates' Background Intellectual Property only for the purpose of carrying out the Trial. Neither Party may grant any sublicense to use the other Party's Background Intellectual Property, except that Sponsor may allow its Affiliates or any third party working for or on behalf of Sponsor or its Affiliates to use the Institution and/or Investigator's Background Intellectual Property for the purpose of carrying out the Trial. Additionally, Institution and Investigator shall and hereby grant Sponsor and its Affiliates a worldwide, perpetual, irrevocable, sub-licensable, fully paid-up, non-exclusive license to use its Background Intellectual Property as may be necessary for Sponsor and/or its Affiliates to fully exploit Sponsor's and/or its Affiliates rights in and to any Sponsor Intellectual Property and the Results as defined below.

6.2 Foreground IP

6.2.1 **Definition "Sponsor Intellectual Property".** As used herein, "Sponsor Intellectual Property" shall mean all rights, title and interest in and to the intellectual property and materials that are the subject of the Trial or the Protocol, including, without limitation: (i) all intellectual property rights in the Investigational Product, (ii) all data, technical information, inventions, discoveries, developments, improvements, enhancements, software, know-how, methods, techniques, formulae, data, processes and other proprietary ideas (whether or not patentable or registrable under any patent, copyright or

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similar laws) and materials related to the Investigational Product or its uses, the Trial or the Protocol, (iii) all intellectual property otherwise derived, conceived, discovered, developed or reduced to practice as a direct or indirect result of the Institution or Investigator's performance of any services under or pursuant to this Agreement or during the course of or in connection with the Trial and relating to or incorporating the Investigational Product or its use, including but not limited to any such intellectual property generated upon any review or other use of Trial data, and (iv) any intellectual property incorporating or derived from Sponsor Confidential Information, whether generated or developed by Institution, Investigator or Sponsor or their respective agents, employees or contractors, either solely or jointly with others.

6.2.2 **Ownership.**

(i) Sponsor Intellectual Property is the sole and exclusive property of Sponsor. Institution and Investigator shall assign and hereby assign to Sponsor all of their right, title and interest in Sponsor Intellectual Property. Institution will ensure that the Investigator and all Trial Staff or other persons carrying out Institution's obligation under or pursuant to this Agreement have already assigned to the Institution, by their employment obligations or otherwise, or shall assign to the Institution all right, title and interest that they may have in Sponsor Intellectual Property in order to give full effect of the foregoing assignment of rights to Sponsor.

(ii) All intellectual property derived, conceived, discovered, developed or reduced to practice solely by Institution and as a direct or indirect result of the Institution or Investigator's performance of any services under or pursuant to this Agreement or during the course of or in connection with the Trial, but that is not within the scope of Sponsor Intellectual Property as defined in Section 6.2.1, is the sole and exclusive property of Institution ("**Institution Intellectual Property**"). Institution hereby grants to Sponsor a worldwide, perpetual, irrevocable, sub-licensable, fully paid-up and royalty free, non-exclusive license to use such Institution Intellectual Property as may be necessary or useful for Sponsor and/or its Affiliates to fully exploit Sponsor's and/or its Affiliates rights in and to Investigational Product, any Sponsor Intellectual Property and Results.

(iii) All intellectual property derived, conceived, discovered, developed or reduced to practice jointly by Institution and Sponsor under or pursuant to this Agreement or during the course of or in connection with the Trial, but that is not within the scope of Sponsor Intellectual Property as defined in Section 6.2.1, is the joint property of Institution and Sponsor ("**Joint Intellectual Property**"). Sponsor is hereby granted an option to negotiate an exclusive, worldwide, compensation-bearing license under Institution's rights to any Institution Intellectual Property or Joint Intellectual Property, which option shall extend for one-hundred and eighty (180) days following of the relevant intellectual property. Upon Sponsor's exercise of the option the Parties shall promptly negotiate a license agreement in good faith.

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6.8 **No Conflict.** Institution and Investigator warrant by the execution of this Agreement, that neither they nor any Trial Staff involved in the Trial have entered, and that none of them will enter, into any contractual agreement or relationship which would in any way conflict with or compromise Sponsor's proprietary interest in, or rights to, any Sponsor Intellectual Property, Institution Intellectual Property, Joint Intellectual Property or Results existing at the time of the execution of this Agreement or arising out of or related to its performance thereunder.

7. PUBLICATION, PUBLICITY AND TRANSPARENCY

7.1 **Publication.**

7.1.1 **Publication by Sponsor**. Sponsor shall have unrestricted publication rights for the Results and may give the data to third parties for publication.

7.1.2 Publication by Institution or Investigator. Sponsor acknowledges that Institution and Investigator have the right to publish the results that Institution and Investigator contribute and generate as a result of the Trial for non-commercial purposes with due regard to the protection of Sponsor Confidential Information and consistent with the below paragraph regarding joint multi-center publications. If Institution and/or Investigator publish the results of the Trial, Sponsor is hereby granted a perpetual, royalty-free license to make, display and distribute copies of such publications under any copyright rights or privileges of Investigator or Institution.

7.1.3 **Good Publication Practice.** For all publications relating to the Trial or including any Trial data, Sponsor, Institution and Investigator agree to comply with the Good Publication Practice Guidelines (found at: http://www.ismpp.org) and all ethical standards concerning publications and authorship, including the "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals" as established by the International Committee of Medical Journal Editors ("ICMJE") (found at http://www.icmje.org).

7.1.4 Submission of Publications. Prior to submission for any written, electronic, oral or audio-visual publication, Institution and/or Investigator shall first submit to Sponsor a copy of any proposed abstract, poster, presentation slides, manuscript or any other material at least sixty (60) days in advance of such proposed date of submission for publication for review by Sponsor. Unless Sponsor informs Institution and/or Investigator in writing during the sixty (60) day period, that the proposed publication must be (i) delayed in order to protect a potentially patentable invention or (ii) changed to avoid the potential disclosure of Sponsor Confidential Information, Institution and/or Investigator shall be free to proceed with the proposed publication. Institution and/or Investigator shall remove from any proposed publication material all Sponsor Confidential Information identified by Sponsor in writing to Institution and/or Investigator during the sixty (60) day period. In no event will any Sponsor Confidential Information be included in any published material without the prior written approval of

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Sponsor. For the sole purpose of publications approved by Sponsor under this Article 7, all data and results generated by Institution and/or Investigator during the performance of the Trial shall not be considered Sponsor Confidential Information. If within the sixty (60) day review period Sponsor notifies Institution that it desires to file a patent application covering a potentially patentable invention disclosed in the publication Institution and Investigator shall withhold such submission for publication for an additional period agreed upon in good faith by the Parties, however no longer than eighteen (18) months after the filing of the patent application covering the respective invention.

7.1.5 Multi-Center Publication. Institution and Investigator acknowledge that if the Trial is part of a multi-center trial, Sponsor anticipates a joint multi-center primary full publication. Therefore, Institution and Investigator agree not to publish, present or otherwise disclose any results of or information pertaining to Institution's and Investigator's activities conducted under this Agreement before such multi-center publication has been published. Without limiting the foregoing, if there is no joint multi-center publication within eighteen (18) months after completion of the Trial at all sites, Institution and Investigator shall have the right to publish and present the results of Institution's and Investigator's activities conducted under this Agreement, including Results generated and contributed by them, subject to review and comment as set forth in the preceding paragraph.

7.1.6 Authorship. Authorship of any publications relating to the Trial should be determined by mutual agreement. Sponsor has the right to name co-authors.

7.2 Publicity.

7.2.1 **Use of Trial Information.** Neither Institution nor Investigator will use any information regarding the Trial, including, but not limited to, the existence of the Trial or other publicly available information in any publicity, advertising or subject recruitment materials without Sponsor's prior written consent.

7.2.2 Use of Name, Logo and Trademarks. No Party hereto shall use the other party's/parties' or its Affiliates' name(s), logo(s), trademark(s), physical likeness, employee name, owner symbol, or other image in any press release, advertising or other form of publicity without prior written consent of the other party/parties, except as otherwise required by Applicable Law. Sponsor may use the name of Institution's and/or Investigator's name and other identifying information in Trial publications and communications, including clinical trial websites and Trial newsletters, applications or forms, or other materials submitted to any regulatory authority and/or other disclosures required by Applicable Law such as disclosures in clinical trial registries. (for e.g. Indian clinical trial registry; http://www.ctri.nic.in/

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7.3 Transparency.

7.3.1 Registry and Reporting. Sponsor will adhere to the ICMJE requirements on clinical trial registration and represents that the Trial will be registered according to ICMJE applicable requirements and all applicable laws regarding clinical trial registration prior to the recruitment of the first Trial Participant and will report the results of the Trial publicly when and to the extent legally required.

7.3.2 Data and Document Sharing. Institution and Investigator acknowledge that, Sponsor may, in accordance with the joint 'Principles for Responsible Clinical Trial Data Sharing' by EFPIA and PhRMA (found at: www.efpia.eu or www.phrma.org), share the clinical study report, related clinical documents, and patient-level clinical study data with third party requestors (more information to be found at http://trials.boehringer-ingelheim.com/transparency_policy.html).

8. PROVISION OF EQUIPMENT AND REMOTE DATA CAPTURE

8.1 Use of Computer and Remote Data Capture. If computer systems are used for Remote Data Capture ("RDC") by Institution and/or Investigator for the Trial (own computer or notebook computer supplied by Sponsor), Institution and Investigator will ensure that all requirements for RDC are in place and comply with the RDC terms and conditions set forth in Appendix 2 "Remote Data Capture (RDC) – Terms and Conditions" and the RDC User Guide provided by Sponsor or CRO.

8.2 Use of other Equipment. If Sponsor or its designees provide(s) Institution and/or Investigator with any other equipment ("Equipment") for use in connection with performance of services in the Trial, Institution and/or Investigator will document the Equipment in the "Equipment Loaned Log" which is part of the ISF. The terms and conditions for provision of Equipment are set forth in Appendix 3 of this Agreement.

9. TRIAL PARTICIPANT INJURY, INSURANCE INDEMNIFICATION AND LIABILITY

9.1 **Trial Participant Injury.** Institution and or Investigator shall promptly notify Sponsor and/or CRO in writing of any claim of illness or injury actually or allegedly due to their participation in the Trial and allow Sponsor to handle such claim (including settlement negotiations), and shall cooperate fully with Sponsor and CRO in its handling of the claim. Institution will provide to Sponsor and/or CRO sufficient documentation to review and process any Trial Participant injury reimbursements, provided, however, that any and all patient identifiers will be removed from any documentation submitted to Sponsor and/or CRO.

9.2 **Liability Insurance.** Institution and Investigator will each secure and maintain in full force and effect throughout the performance of the Trial, at their own expense, insurance or self-insurance that provides appropriate coverage for claims for damages arising out of acts or omissions of Institution, Institution's employees and/or agents, and/or Investigator, Investigator's employees

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and/or agents in the Trial and in their performance of this Agreement. Institution and Investigator shall promptly provide evidence of its insurance upon request by Sponsor/CRO.

9.3 Clinical Trial Insurance. Sponsor, where required by Applicable Law, has affected sufficient insurance to compensate damages suffered by Trial Participants as a direct result of their participation in the Trial. To that extent, such clinical trial insurance may also cover the relevant liability of Institution or Investigator. However, the Parties understand that the clinical trial insurance is not intended as nor is a substitute for full and complete malpractice and other forms of liability insurance.

9.4 Indemnification

9.4.1 Covance and Sponsor shall not be responsible for, and Investigator shall indemnify, defend and hold Covance and Sponsor harmless from any loss or third party claim resulting from Investigator's or Research Staff's negligence, willful misconduct, or their breach of this Agreement.

9.4.2 **Institution Indemnification**. Institution will indemnify, defend and hold harmless Sponsor, Covance and their Affiliates, their directors, their officers, managers, agents and employees and their respective successors (collectively "Sponsor Indemnitees" and/or "CRO Indemnitees") from any Losses incurred by or imposed upon a Sponsor/CRO Indemnitee as a result of any third party claim made or suit brought against the Sponsor and/or CRO Indemnitee to the extent the same is arising directly from any injuries or damages that are a result of *(i)* the negligence or willful misconduct of any Institution Indemnitee; *(ii)* research activities conducted by any Institution Indemnitee contrary to or outside the scope of the Protocol, this Agreement or; or *(iii)* actions by any Institution Indemnitee in violation of Applicable Law, this Agreement or any written instruction relating to the conduct of the Trial.

9.4.3 **Conditions of Indemnity**. Either party (herein referred to as the "Indemnified Party") wishing to be indemnified by the other will: *(i)* promptly and in no event longer than ten (10) days after receipt of notice of any claims and/or legal proceedings, notify the other party thereof in writing and enclose a copy of all papers served, and *(ii)* allow the other party to retain exclusive control of the defense against such legal proceedings and claims without limitation the right to select defense counsel and to settle such legal proceedings and claims at its sole discretion, provided that the other party will not make any settlement which admits fault on the part of the Indemnified Party or could reasonably be expected to have a negative effect on the reputation of the Indemnified Party without the prior written consent of the Indemnified Party, which will not be unreasonably withheld. Institution and Investigator undertake to fully cooperate with Sponsor and/or Covance to determine the actions in the cases referred to above, and take no action that could harm the interests of Sponsor in Covance.

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11. DEBARMENT

11.1 **Representation and Warranty.** Institution and Investigator each represent and warrant that Institution, Investigator and their respective employees, contractors, and agents, including sub-investigators, have not been restricted, debarred, suspended, disqualified or banned from conducting clinical trials or are under investigation by any regulatory authority for debarment, or otherwise subject to any restrictions or sanctions by the U.S. FDA or any other governmental or regulatory authority or professional body with respect to the performance of scientific or clinical investigations.

11.2 **Notification.** Institution and/or Investigator shall notify Sponsor immediately in writing if Institution, Investigator or any of their respective employees, contractors or agents, including sub-investigators, is so restricted, debarred, suspended, disqualified or banned or becomes subject to an investigation for debarment, or becomes otherwise subject to any restrictions or sanctions.

11.3 **Termination.** Debarment, suspension or proposed debarment of Institution, Investigator or their employees by any any governmental or regulatory authority will constitute grounds for automatic termination of this Agreement by Sponsor, in Sponsor's sole discretion, in accordance with Article 13 below.

12. ANTI-BRIBERY AND ANTI-CORRUPTION

12.1 **Prohibition.** Institution and Investigator each represents and warrants that it, its owners, directors, officers, employees, sub-contractors and agents will act in full compliance with any applicable anti-corruption laws and regulations, industry and professional codes of practice (MCI code of Ethics, OPPI code) and will not offer, promise, pay or arrange for payment or giving of any benefit or advantage to any individual or entity, including but not limited to Public Officials, as defined below, in exchange for an improper advantage in any form either directly or indirectly. In particular, Institution and Investigator may not offer, promise or pay a bribe in order to fulfil, obtain or retain *(i)* regulatory requirements, *(ii)* any kind of business including any commercial transaction to which Sponsor and/or CRO is a party, or *(iii)* any other improper advantage in connection with the business of Sponsor and/or CRO. Institution and Investigator are prohibited to request, accept a promise of or receive any payment, benefit or advantage from any individual or entity for oneself or for a third party in return for giving another person or entity unfair preferences in the procurement of goods or commercial or other services. In case of any doubt regarding the question whether or not a particular transaction may be regarded as a bribe, Institution and Investigator must seek prior advice and approval of the Sponsor and/or CRO.

12.2 **Public Official.** For the purpose of this Agreement, "Public Official" means any officer or employee of a local or foreign government or any department, agency, or instrumentality thereof, or of a public international organization as well as any person acting in an official capacity for or on behalf of any such government, department, agency, or instrumentality, or for or on behalf of any such public international organization as well healthcare professionals, working in healthcare institutions, in which the central, regional or local government owns an interest or has control or which are paid partly or as a whole by the government. Regardless of whether or not such transfer might constitute a bribe, Institution and Investigator may not transfer anything of value to a Public Official without

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the prior approval of the Sponsor and/or CRO. Institution and Investigator may not transfer anything of value to agents for the purpose of offering, promising, paying, receiving, soliciting, or arranging for the payment of, or reimbursing anyone for payment of, a bribe or a transaction of anything of value to a Public Official.

12.3 **Reporting to Sponsor and CRO.** Institution and Investigator shall report any suspicion of past, actual or potential violations of this Section to the Sponsor and the CRO. If Institution is in doubt whether a certain act violates its obligations under this Section, Institution shall contact the Sponsor and CRO and shall delay the decision before taking the action.

12.4 **Consequences of Violation.** Any violation of this Section constitutes a material breach of this Agreement. In addition to any other sanction provided by Applicable Law and/or this Agreement, CRO, with written authorization by Sponsor, may terminate this Agreement after giving an opportunity to the institution/Investigator to explain their position in that regard for cause and with immediate effect, if Institution violates its obligations under this Section. I nstitution and Investigator shall indemnify and hold Sponsor and CRO harmless for any loss or damage resulting of a breach by the Institution and Investigator, its directors, officers, employees, sub-contractors and agents of this Section or of any Applicable Law.

12.5 **Certificate**. Upon Sponsor's request from time to time, Institution and Investigator agree to certify compliance with the foregoing in a form suitable for Sponsor.

13. EXPORT CONTROL

13.1 **Sponsor/CRO provides items.** Institution and Investigator understand and agree that the items incl. goods, software, technology (specific technical information necessary for the development, production, or use of a product) and technical services provided by the Sponsor or by CRO, acting on behalf of the Sponsor or by their third party vendors under this Agreement may be subject to international, **India** and US Export Control laws and regulations (hereinafter "Laws") restricting exports, re-exports, transfers or disclosures, regardless of the mode of provision (hereinafter "Transactions"). Institution and Investigator shall comply with all such Laws. Institution and Investigator shall not, without first obtaining permission to do so from the appropriate authorities, perform any further Transactions of items provided by the Sponsor and/or CRO under this Agreement *(i)* if the item is controlled under the Laws; *(ii)* to any country, person or other party that is ineligible to receive such item, i.e. sanctioned by any embargo or sanctioned party list (hereinafter: "Sanctioned Party") under the Laws; or *(iii)* to a person or other party if Institution and Investigator know or have reason to assume that such person or party intends to provide the item to any such country, person or party, or intends to use or allow others to use the item for activities related to military or otherwise restricted use.

13.2 **Sponsor receives items.** Institution and Investigator understand and agree that the items incl. goods, software, technology (specific technical information necessary for the development, production, or use of a product) and technical services (hereinafter "Item") provided to Sponsor/CRO under this Agreement may be subject to Laws restricting Transactions. Institution and Investigator shall comply with all such Laws. Institution and Investigator shall determine whether an item is

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controlled under the Laws and identify the specific export control status of the item. If the item is subject to any restrictions or license requirements under the Laws, Institution and Investigator shall notify Sponsor/CRO about these restrictions prior to providing the item to Sponsor, incl. information on where the controlled item is listed (e.g., U.S. Commerce Control List). Institution and Investigator shall cooperate with Sponsor by providing upon request information and other assistance necessary for the classification (e.g., on the US Export Control List), export documentation, license determination, export licensing etc. of items provided to Sponsor under this Agreement.

14. TERM, TERMINATION AND EFFECTS OF TERMINATION

14.1 **Term.** This Agreement will become effective on as of the last date of signature (the "Effective Date") and shall continue until completion of the Trial (i.e. until the close-out visit date at the site has been performed), unless earlier terminated as provided herein below.

14.2 **Termination by CRO.** CRO, with written authorization from Sponsor, may terminate this Agreement or terminate or suspend enrollment or randomization of Trial Participants for any reason and upon at least thirty (30) days prior written notice to Institution and/or Investigator. The date of termination will be the date specified in such notice.

14.3 Immediate Termination initiated by Sponsor or CRO. CRO may terminate this Agreement or Sponsor may terminate or suspend enrollment or randomization of Trial Participants immediately upon written notice to Institution and/or Investigator if within the first three (3) months after Trial initiation Institution or Investigator *(i)* fails to enroll any patient or recruits such a low number of patients that it can be assumed that the agreed number of Trial Participants will not be reached during the global recruitment phase as specified in the Protocol and this Agreement, *(ii)* Sponsor becomes aware of any efficacy or safety information that could significantly affect or alter continuation of the Trial, *(iii)* Sponsor terminates its conduct of the entire Trial in Sponsor's sole discretion; or *(iv)* there is a violation or a suspected violation by Institution or Investigator of any Applicable Law, the Protocol or this Agreement, as determined within Sponsor's reasonable discretion. The date of termination will be the date specified in such notice, (v) if Sponsor terminates its services agreement with Covance for the conduct of the Trial.

14.4 **Termination by Institution.** Institution may terminate this Agreement effective upon written notice to Sponsor and CRO if Sponsor and/or CRO materially breaches any of the terms or conditions of this Agreement, and fails to cure such breach within thirty (30) days after receiving written notice thereof from Institution specifying the breach alleged by Institution. Further, if Institution has indication of serious physical harm being suffered by any of the Trial Participants at its site, it may immediately suspend enrollment of Trial Participants at its site. In such event, Institution will immediately notify Sponsor of any such indication and its determination to suspend enrollment of Trial Participants at its site but will continue to perform follow-up procedures as set forth hereunder.

14.5 **Effects of Suspension or Termination of Enrollment.** If enrollment or randomization of Trial Participants has begun and enrollment or randomization of additional Trial Participants is

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terminated or suspended, Institution and Investigator will either terminate or suspend enrollment, as appropriate, and will continue to conduct the Trial in accordance with the Protocol and this Agreement for all Trial Participants then enrolled, except if the safety of such Trial Participants could be endangered thereby or if the Institution and Investigator are otherwise instructed by Sponsor that may be communicated via CRO.

14.6 Effects of Termination. The effect of any such termination will be as follows

14.6.1. Continued Monitoring and Data Maintenance. Upon receipt of notice of termination by Sponsor, Institution and Investigator will terminate enrollment or randomization and will terminate treatment of all Trial Participants pursuant to the Protocol, except if the safety of such Trial Participants could be endangered or if the Institution and Investigator are otherwise instructed by Sponsor, that may be communicated via CRO. Following such termination, Institution and Investigator will continue to monitor Trial Participants and maintain clinical data as set forth in the Protocol and in accordance with ICH GCP.

14.6.2 Provision of Data and Medical Records. Institution and Investigator will *(i)* provide to Sponsor any and all data required pursuant to the terms of this Agreement and/or the Protocol, and *(ii)* provide Sponsor representatives access, both prior to and following final payment, to data and medical records for review and completion of necessary documentation and appropriate transfer or discontinuation of Trial Participants' participation in the Trial.

14.6.3. Reimbursement of Costs. Upon early termination for any reason, Institution and Investigator will use their best efforts to promptly limit or terminate any outstanding commitments and to conclude the work. Except as specifically set forth herein in regards to termination by Sponsor pursuant to Sections 11.3 and 14.3(iv), all costs incurred by Institution prior to such termination and authorized under the Protocol and Clinical Trial Budget will be reimbursable, including, without limitation, all non-reimbursable costs and non-cancelable commitments incurred in accordance with the Clinical Trial Budget prior to the receipt of the termination notice.

Notwithstanding the foregoing, if this Agreement is terminated by Sponsor pursuant to Section 14.3.(iv) as a result of a violation by Institution or Investigator of any applicable laws or regulations or ICH GCP Guidelines and such violation negatively affects the integrity of the Trial data and/or results generated by Institution, Institution will reimburse Sponsor any and all amounts paid (other non-cancelable expenses) by Sponsor and/or CRO to Institution under this Agreement within thirty (30) days following written request by Sponsor and/or CRO.

15. CONCLUDING PROVISIONS

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15.1 **No Violation.** Institution and Investigator represent and warrant that the execution, delivery, and performance of this Agreement by such party do not *(i)* require the consent, waiver, approval, license, or authorization of any person or public authority which has not heretofore been obtained; *(ii)* violate any provision of law applicable to such party; *(iii)* conflict with or result in a default under any agreement or instrument; or *(iv)* violate any judicial or administrative decree, regulation, or any other restriction of any kind or character to which such party is a party or by which such party is bound.

15.2 **Conflict of Interest.** Institution and Investigator represent and warrant that neither Institution nor Investigator and/or any Trial Staff have any conflict of interest that would affect conduct of the Trial and that neither Institution nor Investigator have received any extra benefits from Sponsor or any of its Affiliates for participation in the Trial, including offers to family members. Institution and Investigator will promptly notify Sponsor in writing if any conflict of interest arises during the term of this Agreement.

15.3 **Assignment.** Neither Institution nor Investigator shall be entitled to assign, to sub-contract or otherwise transfer its rights and obligations under this Agreement in whole or in part to any third party without the prior written consent of Sponsor and CRO. Any such consent shall relieve neither Institution nor Investigator of its obligations hereunder. It is understood by the Parties that any right or obligation of Sponsor and/or CRO under this Agreement may be assigned to any of their Affiliates or a third party upon written notice to Institution, and that any right or obligation of Sponsor and/or CRO under this Agreement may be performed by any of its Affiliates or a third party. Any legal successor of Sponsor and/or CRO shall be deemed an Affiliate of Sponsor and/or CRO, as applicable, for the purpose of this Agreement.

15.4 **Entire Agreement.** This Agreement sets forth the entire agreement between the Parties and supersedes all previous agreements, written or oral, regarding the subject matter hereof. This Agreement may be amended only by an instrument in writing duly executed on behalf of the Parties.

15.5 **Conflict.** In case of inconsistencies between this Agreement and any Appendix hereof, the terms of this Agreement shall prevail unless agreed to explicitly that the Appendix should prevail. In the event there is a discrepancy between this Agreement and the Protocol, the Protocol will govern with respect to medical and scientific issues and the Trial conduct, and this Agreement will govern with respect to all other issues.

15.6 **Force Majeure.** If the performance by either Party of any of its obligations under this Agreement is delayed or prevented by circumstances beyond its reasonable control, that Party will not be in breach of this Agreement because of that delay in performance. However, such Party shall promptly give to the other Party written notice claiming force majeure and shall use its best efforts to eliminate the effect of such force majeure, insofar as is possible and with all reasonable dispatch. If the period of delay or failure should extend for more than three (3) months then the non-defaulting Party shall have the right to terminate this Agreement forthwith upon written notice at any time after expiration of said three (3) months period.

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SGPGIMS,Lucknow

15.7 **Waiver.** Any waiver shall be made in writing for it to be effective and unless expressly stated shall not be a continuing waiver nor shall it prevent the waiving Party from enforcing any term or condition of this Agreement not so waived.

15.8 **Severability.** The invalidity of any provision of this Agreement or any loophole in this Agreement shall not affect the validity of any other provision hereof. The Parties undertake to replace the invalid provision or close the loophole in the Agreement with another provision which reflects legally the originally intended commercial objectives of the Parties as closely as possible.

15.9 **Independent Contractors.** In the performance of this Agreement each party shall be an independent contractor, and therefore, no Party shall be entitled to any benefits applicable to any employees of the other Party. In particular, this agreement gives the Investigator no right of employment to the Sponsor or CRO. No Party is authorized to act as an agent for the other Party for any purpose, and no Party shall enter into any contract, warranty or representation as to any matter on behalf of the other Party.

15.10 **Survival.** The terms and conditions of the Sections titled Compliance; Safety Reporting; Overpayment, Final Accounting and Payment; Reporting of Payments; Trial Documents; Effects of Termination; Data Protection / Privacy; Confidentiality; Sponsor Intellectual Property; Publication, Publicity and Transparency; Monitoring, Audits, and Inspections; Indemnification; Insurance; and Financial Disclosure will survive termination or completion of this Agreement.

15.11 **Notice.** Any notice under this Agreement will be mailed (by certified or registered mail, postage prepaid, return receipt requested) or delivered by a reputable overnight courier service. Notices will be directed to the name and address set forth below: Either party may change its notice address by sending written notification to the other party clearly indicating the change.

If to Institution:

Name: Sanjay Gandhi Post Graduate Institute of Medical Sciences
Address: Rae Bareli Road, Lucknow, UP – 226014, India
Attention: Prof. R.K. Dhiman (Director of SGPGIMS)

If to Investigator:

Name: Dr. Sudeep Kumar,
Address: Sanjay Gandhi Post Graduate Institute of Medical Sciences, Rae Bareli Road, Lucknow, UP – 226014, India
Office: +91 522 2495198
Fax: +91 522 2668017
Email: sudeepkum@yahoo.com

If to Sponsor:

Boehringer Ingelheim India Private Limited

COVANCE INDIA PHARMACEUTICAL PRIVATE LIMITED

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

IN WITNESS WHEREOF, the Parties have executed this Agreement in 3 originals by their duly authorized representatives.

Covance India Pharmaceutical Services Pvt. Ltd.

DocuSigned by:
By: Dr. Shekhar Dawkhar
1843503F9B8F4B2...
Name: Dr. Shekhar S Dawkhar
Title: Senior Director
Date: 6/21/2022

INSTITUTION

By:
Name: Prof. R.K. Dhiman
Title: Director
Date: 11/7/22

Prof. R.K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

INVESTIGATOR:

By:

Name: Dr. Sudeep Kumar

Date: 27 June 2022

COVANCE INDIA PHARMACEUTICAL SERVICES PRIVATE LIMITED

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Should any remote visits be done on site - the visit cost provided in the visit schedule will be reimbursed

Table 2: Payment Per Visit: Optional Visits

Visit Description	**Payment INR**
Screening done remotely (instead of on-site)	18,266.00
Visit 4 done remotely (instead of on-site)	9,930.00
Unscheduled visit	10,450.00
Randomised Treatment Period: 6 monthly visits; Visit 5 onwards	10,450.00

For each Evaluable Patient, payment will be made according to actual visits performed and the evaluable data produced and entered correctly in the eCRF.

It is understood and agreed that no payment will be made by Covance for any visits performed after screening in relation to any Trial Participant who does not conform to the Protocol's inclusion and exclusion criteria or in relation to whom serious deviations from the Protocol have been made.

2. Conditional Procedures

Table 3: Conditional Procedures

Description	**Detail** (Maximum per Trial Participant)	**Cost Per Procedure** INR	**Total Cost per Trial Participant** (INR)
Re-consent (due to protocol amendment)	All will be reimbursed	1,224.00	1,224.00
SAE	All will be reimbursed	2,792.00	2,792.00
Shipment of IMP, if Trial Participant cannot attend an on-site visit	actual cost upon invoice will be reimbursed	NA	NA
Urine pregnancy test	2	1,020.00	2,040.00
Dispense Trial medication visits at follow-up: If the trial is prolonged additional medication kits can be assigned	1	1,038.00	1,038.00

(a) Patient Travel Costs

Patient travel expenses and associated other reasonable out of pocket expenses (e.g. parking) will be paid to a maximum of 500 INR per visit per Trial Participant upon Covance's receipt of an invoice detailing **actual** amounts from Institution, which shall be supported by appropriate documentation. Higher expenses exceeding 500 INR per visit can only be reimbursed prior written approval from Covance is obtained.

Reimbursement payments under this section 2 (a) are payable quarterly upon receipt of an invoice detailing actual amounts reimbursed by Institution to each patient in the preceding quarter. All payments are subject to verification.

COVANCE INDIA PHARMACEUTICAL PRIVATE LIMITED

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS, Lucknow



पश्चिमबङ्गा पश्चिम बंगाल WEST BENGAL AG 794091

CLINICAL STUDY AGREEMENT

This Clinical Study Agreement ("Agreement") is made as of _____ (the "Effective Date") by and among

1. **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Raebareli Road, Lucknow-226014**, hereafter referred to as **Institution**.

   And

2. **Dr.Ujjala Ghoshal**, Professor and HOD, Department of Microbiology, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Raebareli Road, Lucknow- 226014, India , hereafter referred to as **Principal Investigator (PI)**

   And

3. **Medclin Research Pvt. Ltd.** Having its registered office at Acropolis, unit 10/5, 10th floor 1858/1, Rajdanga Main Road, Kol-107, hereafter referred to as **Clinical Research Organization (CRO)**

Ughoshal

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

WHEREAS,

Sponsor (Alkem Laboratories, Alkem House, Senapati Bapat Marg,Lower Parel, Mumbai – 400013) based on the representation and warranties given by the CRO, desires to engage CRO on non-exclusive basis to initiate study of "In vitro susceptibility of Ceftriaxone or Ceftriaxone combination with Sulbactam & Tazobactam in community acquired and nosocomial infections against gram-negative and gram -positive bacteria." (Hereinafter referred to as the "Study")

a. The CRO has approached the Institution and Principal Investigator to perform the study in accordance with the corresponding Protocol, and all applicable rules and regulations. The Institution and PI agree to conduct the study in accordance with the same.

b. The Institution is equipped to undertake the Study and the Institution, CRO and Principal Investigator have agreed to perform the Study according to the terms and conditions hereinafter set forth.

1. REPRESENTATIONS AND WARRANTEES:

a. Each party represents and warrants to and covenants with the other that:

i. It has been duly incorporated or created and is validly subsisting and in good standing under the applicable laws of its incorporation mentioned elsewhere in this agreement; wherever applicable,

ii. It has the corporate power and authority to enter into and perform its obligations under this Agreement, whenever applicable,

iii. This Agreement has been duly authorized, executed and delivered by it and constitutes a valid and binding obligation enforceable against it in accordance with its terms;

iv. Neither the execution and delivery of this Agreement by either party, nor the performance by such party of its obligations here under nor compliance by such party with the provisions hereof will violate, adversely effect, contravene or breach or create a default or accelerate any obligation under any indenture, mortgage, lease, agreement, instrument, Memorandum or Articles of Association or charter or by-law provision, statute, regulation, judgment, ordinance, decree, writ, injunction or law applicable to such party;

b. Institution represents that

i. It is entitled to procure the services of Principal investigator and shall ensure the performance of the obligations of the Principal Investigator set out in this agreement.

ii. The Institution shall notify Medclin if the Principal Investigator ceases to be employed by or associated with the Institution and shall use its best endeavors to find a replacement acceptable to both The Sponsor and CRO. In order to ensure high standard of clinical trials, if no mutually acceptable replacement can be found, The CRO may terminate this agreement pursuant to clause 19(c).

c. Principal Investigator represents:

i. A competent person to sign this agreement on behalf of his sub-investigators and research staff. The terms "Investigator" or "Investigators" as used in this Agreement refers, as applicable, to the Principal Investigator and his sub investigators and research staff and the Institution.

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SGPGIMS,Lucknow

vii. 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, and agrees to immediately inform The Sponsor/CRO if such cases arise.

viii. The Institution shall ensure that the Principal Investigator and any Additional Personnel conduct the Clinical Trial in accordance with the Protocol and all other terms of this Agreement; Any and all Sponsor's/CRO's requirements, directions or instructions, including but not limited to the SOPs; Those policies, standards, procedures, conventions and techniques that are of a high, recognized and acceptable professional standard in the scientific community, such as GCP; All applicable laws and regulations.

b. Principal Investigator:

i. Will ensure that only individuals, who are appropriately trained and qualified, assist in the conduct of the Study as sub investigators or research staff. The duties and responsibilities delegated will be only to the extent permitted by the relevant laws and regulations governing the conduct of clinical investigations in India.

ii. Will ensure that all personnel, who assist in the conduct of the Study, are informed of and agree to abide by all terms of this Agreement applicable to the activities they perform. Principal Investigator is accountable for the compliance of Investigators to the terms of this Agreement.

iii. Principal Investigator shall not reassign the conduct of the Study to a different Principal Investigator without prior written authorization from Sponsor and CRO.

iv. Will comply with the policies and procedures of the organization / institute with which Principal Investigator is affiliated, including any applicable financial policies. Principal Investigator will notify CRO 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.

v. Shall be responsible for obtaining and maintaining all approvals from the relevant local research ethics committee/other Authorities for the conduct of the Clinical Trial keeping The CRO fully apprised of the progress of ethics committee submissions. The written evidence of review shall be provided prior to initiation. All other communications, upon request be made available to Medclin. Investigator will notify The CRO and the responsible Institutional Review Board as soon as possible. The Protocol may be modified only by a written amendment ("Protocol Amendment"), signed by Sponsor and the Principal Investigator. If applicable, the Parties acknowledge that Protocol Amendments are also subject to approval by the responsible Independent or Institutional Ethics Committee ("IEC") and/or Regulatory Authority ("RA").

vi. The PI and Institution will provide for (i) access to the research subject's medical records by Sponsor/CRO and other appropriate regulatory agencies and (ii) the facilities where the Study is being conducted (iii) Raw data (iv) the use of Study data by Sponsor/CRO for any purpose that it deems appropriate provided that the research subject's personal identifying information has been removed. In the event of a conflict between terms of the Protocol and this Agreement, the terms of this Agreement shall govern (v) any other relevant information necessary for Sponsor, other regulatory authority to confirm that the Study is being conducted in conformance with the Protocol and in compliance with all applicable laws and regulations.

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iv. Any income tax, withholding tax or similar taxes deductible from the payment will be deducted by CRO.

4. NO ADDITIONAL RESEARCH: The Institution & Principal Investigator ensures that no additional research may be conducted on Study subjects during the conduct of the Study unless it is approved and documented as a sub-study protocol or an Amendment to the original Protocol.

5. ETHICS COMMITTEE ("EC"): Before the Study is initiated, Investigator will ensure that both the Studies and the informed consent forms are approved by an Ethics Committee that complies with all applicable laws and regulations. Investigator will further ensure that the Study is subject to continuing oversight by the EC throughout its conduct

6. STUDY APPROVAL: If, through no fault of Investigator, the Study is disapproved by EC, this Agreement will immediately terminate with no penalty to the Investigator, as provided in Section 18(a).

7. DATA PROTECTION: The Investigator will comply with all relevant laws relating to the protection and use of personal data and data privacy in its conduct and reporting of the Study. The Investigator shall take all technical and organizational measures to prevent unauthorized or unlawful processing or accidental loss or destruction of, or damage to, or disclosure of data. The Sponsor / CRO will take appropriate measures to protect the confidentiality and security of all data that it receives from Investigator in connection with the Study. Personal data relating to the Investigator shall be processed and used for the purposes of administration of this agreement and in connection with the Study and will be held on one or more databases for the purposes of determining the Investigator's involvement in future research and in order to comply with any other requirements. Such data may be disclosed or transferred to other members of sponsor team, to representatives and contractors working on behalf of The Sponsor.

8. CONFIDENTIAL INFORMATION: During the course of the Study, Investigator may receive or generate information that is confidential to The Sponsor. Any information marked by The Sponsor as confidential and provided to the investigator before the execution of this agreement will also be treated as confidential information

9. OBLIGATIONS OF CONFIDENTIALITY: Unless the Sponsor provides prior written consent, Investigator may not use Confidential Information for any purpose other than that authorized in this Agreement, nor may Investigator disclose Confidential Information to any third party except as authorized in this Agreement or as required by law.

a. Required disclosure of Confidential Information to the EC or to regulatory representatives is specifically authorized.

b. Publication of the results of the Study based on Study Data collected or generated by Investigator is specifically authorized, subject to the provisions of Section 16, Publications, of this Agreement.

9.1 Disclosure Required by Law: If disclosure of Confidential Information to any party other than the EC is required by law, that disclosure does not constitute a breach of this Agreement so long as Investigator:

a) Notifies the sponsor in writing in 15 working days advance of the disclosure so as to allow The Sponsor to take legal action to protect its Confidential Information,

b) Discloses only that Confidential Information required to comply with the legal requirement, and

c) Continues to maintain the confidentiality of this Confidential Information with respect to all other parties.

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study unless the Sponsor authorizes, in writing, earlier destruction. Investigator agrees to notify the Sponsor and CRO before destroying any Study data after the required retention period. Investigator further agrees to permit The Sponsor to ensure that the records are retained for a longer period, if necessary, at the Sponsor expense, under an arrangement that protects the confidentiality of the records (e.g., secure off-site storage).

12. MONITORING AND AUDITS:

12.1 Monitoring and Audits: The Sponsor / CRO shall be entitled at its absolute discretion (and in such form as the Sponsor / CRO sees fit) to monitor and audit the conduct of the Study. Upon reasonable notice, Investigator will permit The Sponsor's / CRO's representatives' access to the premises, facilities, procedures and records relating to the Study, investigators, and research staff as required to accomplish this. The Investigator agrees to co-operate and provide all reasonable assistance with any monitoring and/or auditing activity. No such monitoring and/or auditing by Sponsor / CRO will relieve the Investigator of any of its obligations hereunder.

a) **Cooperation.** Investigator will cooperate with the Sponsor / CRO in the conduct of audits and will ensure that Study Records are maintained in a way that facilitates such activities.

b) **Resolution of Discrepancies**. Investigator will promptly resolve any discrepancies that are identified within the study data.

c) **Study Conduct Evaluations**. The Sponsor / CRO may document and evaluate the performance of Investigator in the conduct of the Study. The Sponsor / CRO or its representative will use these evaluations solely for internal purposes

13. INVENTIONS:

13.1 Notification. If the conduct of Study results in any invention or discovery whether patentable or not ("Invention"), Investigator will promptly inform the Sponsor and CRO.

13.2 Assignment. Investigator will assign all interest in any such Invention to the Sponsor, or its representative free of any obligation or consideration beyond that provided for in this Agreement.

13.3 Assistance. Investigator will provide reasonable assistance to the Sponsor or its representative in filing and prosecuting any patent applications relating to Invention, at the Sponsor's expense.

14. PUBLICATIONS: The findings of this study may be published in a scientific journal or presented at a scientific meeting with prior permission from Sponsor and CRO. The Sponsor reserves the right to review all manuscripts prior to submission for publication or any paper before it is presented. In accordance with standard editorial and ethical practice, the Sponsor will generally support publication of multicentric trials only in their entirety and not as individual center data. Authorship will be determined by mutual agreement between The Sponsor in conjunction with the CRO and the Principal investigator(s).

15. DEBARMENT AND EXCLUSION: Investigators certify that s/he is not debarred and that s/he is not and will not use in any capacity the services of any person debarred under such law with respect to services to be performed under this Agreement. During the term of this Agreement and after its termination, Investigator will notify the Sponsor/CRO promptly if either of these certifications needs to be amended in light of new information.

16. USE OF NAME: 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, the Sponsor reserves the right to identify The PI and Investigator in association with a listing of the Protocol

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h) **Return of Materials**. Unless The Sponsor / CRO instructs otherwise in writing, Investigator will promptly return all materials supplied by The Sponsor / CRO for Study conduct, other study related material and any The Sponsor / CRO - supplied Equipment.

i) **Survival of Obligations**. Obligations relating to Funding, Confidential Information, Study data, Inventions, Publications, Indemnification, and Debarment and Exclusion 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.

19. FORCE MAJEURE: Neither party shall be liable to the other party or shall be in default of its obligations hereunder if such default is the result of war, hostilities, revolution, civil commotion, strike, epidemic, accident, fire, wind, and flood or because of any act of God or other cause beyond the reasonable control of the Party affected. The Party affected by such circumstance shall promptly notify the other party in writing when such circumstance causes a delay or failure in performance ('a Delay') and when they cease to do so. Any such non-performance shall be excused for the period of such delay, provided Investigator / Institution / CRO has used best efforts to mitigate the disruption in services and the resulting costs of such delays to Sponsor / CRO. Sponsor / CRO shall have the right to terminate an agreement affected by the Delay if Delay affect the performance and such delay lasts for more than ninety (90) days.

20. NOTICE: Notices under this Agreement shall be duly given or forwarded by facsimile, by Certified Mail-Return Receipt Requested or by express courier service providing evidence of receipt to the parties at the addresses below or to such other addresses as the parties may from time to time indicate in writing.

If to Institution:
Name: Prof. R.K.Dhiman (Director, SGPGIMS, Lucknow)
Phone: 05222494001/2/3
OR
If to Principal Investigator:
Name: Dr. Ujjala Ghoshal
Phone: 7706997492

OR
If to CRO:
Dr Monjori Mitra (Research Director, Medclin Research Pvt. Ltd);
Phone: +91 9831075734

21. ENTIRE AGREEMENT: This Agreement and any Exhibits and Attachments represent the entire understanding between the parties relating to the conduct of this Study. This Agreement supersedes all previous agreements (If any) between the parties (oral and written) relating to this Study, except for any obligations that, by their terms, survive termination.
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 will be retained for a period as per required Regulations after the completion/termination of the study whichever is later. 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. Subjects' files should be retained 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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Executive Registrar
SGPGIMS,Lucknow

Executed by the parties
INSTITUTION, PRINCIPAL INVESTIGATOR and the CONTRACT RESEARCH ORGANIZATION.

The Institution: **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow**	**The Principal Investigator**	**CRO** **Medclin Research Pvt. Ltd., Kolkata**
Signature: Prof. R.K. DHIMAN Director Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226 014, INDIA	Signature: Ughoshal	Signature: Monjori Mitra
Name: Prof. R.K. Dhiman	Name: Dr. Ujjala Ghoshal	Name: Dr. Monjori Mitra
Designation: Director	Designation: Principal Investigator	Designation: Research Director
Date:	Date: 8/9/2022	Date: 13/07/2022
Stamp:	Stamp: Dr. Ujjala Ghoshal Professor & Head Dept. of Microbiology SGPGIMS., Lucknow-14	Stamp: MEDCLIN RESEARCH PVT. LTD.

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Executive Registrar
SGPGIMS,Lucknow

सत्यमेव जयते

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Government of Karnataka

Rs. 100

e-Stamp

Certificate No.	:	IN-KA97508375867238T
Certificate Issued Date	:	07-Apr-2021 12:45 PM
Account Reference	:	NONACC (FI)/ kaksfcl08/ HALASURU/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKAKSFCL08665517732766607
Purchased by	:	BIOQUEST SOLUTIONS PVT LTD
Description of Document	:	Article 12 Bond
Description	:	AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	DR RAJIV PARAKH
Second Party	:	BIOQUEST SOLUTIONS PVT LTD
Stamp Duty Paid By	:	BIOQUEST SOLUTIONS PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

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CLINICAL REGISTRY AGREEMENT

Please write or type below this line

THIS AGREEMENT IS MADE ON THE 07 Apr 2021 AT Bangalore.

BY AND BETWEEN

Dr. Rajiv Parakh, Chairman having his office at **Division of Peripheral Vascular & Endovascular Sciences, Medanta- The Medicity, Sec-38, Gurgaon, Haryana - 122001, India** (hereinafter referred to as "NATIONAL INVESTIGATOR", which term shall also include his heirs, representatives, successors, permitted assigns) of the One Part;

National Investigator

BioQuest Solutions Bangalore

Principal Investigator

Head of Institution

Dr. RAJIV PARAKH, M S, FRCS
Chairman, Division of Peripheral Vascular & Endovascular Surgery
Medanta - The Medicity
Sec-38, Gurugram Haryana, India

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

1

Statutory Alert:

1. The authenticity of this Stamp certificate should be verified at 'www.shcilestamp.com' or using e-Stamp Mobile App of Stock Holding. Any discrepancy in the details on this Certificate and as available on the website / Mobile App 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.

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AND

BIOQUEST SOLUTIONS PRIVATE LIMITED, a company registered under the Companies Act, 1956, having its registered office at #24, wellington street, Richmond town, Bangalore - 560 025 *(hereinafter referred to as* **"BIOQUEST"**, which term shall also include its successors or permitted assigns) of the **Second Part**

AND

Dr. Raghunandan Prasad, Associate Professor, Department of Radiodiagnosis, Sanjay Gandhi Postgraduate Institute of Medical Sciences, New PMSSY Rd, Raibareli Rd, Lucknow, Uttar Pradesh 226014, India. (hereinafter referred to as the **'Principal Investigator'** which expression shall wherever the context so requires mean and include his legal heirs, administrators, executors, representatives, successors and permitted assigns) of the Third Part

AND

Sanjay Gandhi Postgraduate Institute of Medical Sciences, New PMSSY Rd, Raibareli Rd, Lucknow, Uttar Pradesh 226014, India. (hereinafter referred to as **'Participating Institution'** which expression shall wherever the context so requires mean and include its doctors, their respective legal heirs, administrators, executors, representatives, successors and permitted assigns) of the Third Part

National Investigator, BioQuest, Participating Institution and Principal Investigator are referred to individually as a "**Party**" and collectively as the "**Parties**".

WHEREAS:

1. The National Investigator has engaged BioQuest for conducting observational registry titled "A Prospective, Multicentric, Non-Interventional, Real-World, Data Collection Registry to Evaluate the Effectiveness, Safety and Durability of SUPERA Stent for the Treatment of De Novo or Restenotic Superficial Femoral Artery or Complex Femoropopliteal Artery Lesions in Indian patients" through its separate agreement dated 13th Feb 2020 between National Investigator and BioQuest.

2. The Participating Institution and Principal Investigator have the qualified personnel and the facilities equipped according to Good Clinical Practices (GCP) to undertake the registry (defined herein below);

3. **NOW THEREFORE**, it is agreed as follows between the Parties hereto:

1 **DEFINITIONS** In this agreement, unless the context otherwise requires, the following words shall have the meanings ascribed to them in this Clause.

1.1 "**Agreement**" means this Agreement, including its appendix, if any and all amendments and modifications thereto made in accordance with the provisions hereof or which are incorporated herein expressly by reference.

1.2 "**Force Majeure**" means labour disturbances, riots, war, unexpected weather conditions for the time and location of the Services, or any other cause beyond the reasonable control of the affected Party which by exercise of reasonable diligence could not have been prevented or provided against, except financial distress.

1.3 Site/Registry Site means the participating institutions that take part in the registry.

1.4 In this Agreement, unless the context otherwise requires, the singular includes the plural and vice versa, references to persons includes corporations, words importing the

National Investigator | BioQuest Solutions | Principal Investigator | Head of Institution

BioQuest Solutions Pvt. Ltd. Bangalore

Dr. RAJIV PARAKH, M.S., FRCS
Chairman, Division of Peripheral Vascular & Endovascular Surgery
Medanta - The Medicity

Dr. Raghunandan Prasad

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

masculine gender include the feminine and neuter gender and vice versa and a month means a calendar month.

1.5 Headings to clauses, sub-clauses and schedules are for convenience only and shall not be used in the construction or interpretation of this Agreement.

1.6 National Investigator means the Sponsor Investigator who is receiving the grant for conducting the registry. In this registry, it is **Dr. Rajiv Parakh**

2 **REGISTRY, SCOPE, ROLES AND RESPONSBILITIES OF PARTIES:**

The registry shall be conducted, under the direction of the Principal Investigator, in the treatment of patients in accordance with this Agreement and the protocol identified as Protocol No. iSUPREME/01/2019, titled "A Prospective, Multicentric, Non-Interventional, Real-World, Data Collection Registry to Evaluate the Effectiveness, Safety and Durability of SUPERA Stent for the Treatment of De Novo or Restenotic Superficial Femoral Artery or Complex Femoropopliteal Artery Lesions in Indian patients". The Registry will be monitored on behalf of the National Investigator by BioQuest. The roles and responsibilities of National Investigator, BioQuest and Principal Investigator are described below.

2.1 **Responsibilities of National Investigator**

- Approval of Essential documents (Protocol, CRF and ICF)
- To provide support in case of any comments from Ethical committee
- Review and approve all registry related documents (clinical registry report and article for publication)

2.2 **Responsibilities of BIOQUEST**

- To liaise with participating investigators and brief about the proposed registry
- To collect and prepare Ethics committee documents/ dossiers.
- Co-ordination with National Investigator and participating investigators for clarifying any registry related queries from Ethics committee
- To register registry in CTRI
- Making necessary amendments to Essential documents (protocol, CRF and ICF), if any
- Train designated registry site staff for this registry on eCRF portal and share usernames and passwords for accessing the portal
- Handling registry site queries
- Continually monitor registry progress and update all investigators periodically
- To perform registry site monitoring (source document verification)
- TO liaise with Independent lab
- To close all registry sites and archive documents at site and centrally
- To perform data review and analysis
- To prepare Clinical registry report
- To develop manuscript and submit it to Publication
- To process payments to Ethics committee and Investigator as and when registry milestones are achieved

2.3 **Principal Investigator:**

- Review of Essential documents (protocol, CRF and ICF)
- Providing Ethics committee (EC) SOP for preparation of Dossier
- Submission of dossier to EC
- Be present in EC meeting if required
- Identify and consent patients for registry participation
- Data collection and entry into eCRF portal

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- Clarify and help resolve all data related queries
- Maintain registry files at the registry site
- Support BioQuest and National investigator in all registry related activities
- Report all AEs/SAEs as per registry protocol to BioQuest and National investigator

3 **Activity**

3.1 **Adherence:** Participating Institution, Principal Investigator and their personnel shall render service under this Agreement in accordance with the protocol approved by the Institutional Review Board and according to Good Clinical Practice Standards. Participating Institution, Principal Investigator and their personnel shall comply with: (i) all applicable local, state and federal laws, regulations, and guidelines; (ii) good clinical practices; (iii) the applicable requirements of the concerned Regulatory Authorities ("Applicable Regulatory Authorities"); and the Institutional Review Board (or ethics board, as applicable) (for the purposes of this Agreement, the "IRB")

4 **Registry Details**

4.1 **Registry Initiation.** The Principal Investigator shall initiate the Registry at the earliest after receiving the applicable regulatory / IEC / IRB approvals.

4.2 **Enrolment.** Principal investigator shall enroll the patients as described in the registry protocol.

4.3 **Registry Documents.** electronic case record forms (eCRF) to be used for this registry will be duly filled by the registry team within 3 working days after the registry patient's visit. The Principal Investigator shall ensure the accuracy, completeness, legibility and timeliness of the data reported to the National Investigator in the eCRFs and in all required reports. Safety data (Serious Adverse Event Report Forms) will be faxed/scanned/emailed to National Investigator and BioQuest within 24 hours of (i) the Subjects visit and (ii) receipt of the test results at, or from which, such event was reported, noted or recognized.

4.4 **Registry Completion.** The Participating Institution shall complete the enrollment of all the patients within the specified timeline given or informed by the National Investigator/ BioQuest. The Participating Institution shall input all final CRF data and complete the final eCRFs not later than five days after the last patient's last visit.

5 **Payment**

5.1 **Budget and Payment.** BioQuest shall pay the Participating Investigator in accordance with the Milestone set out in Annexure A - Budget and Payment Schedule hereto. On completion of each milestone the Participating Investigator shall raise an invoice on BioQuest which shall be cleared within 30 days of receipt of the same.

5.2 **Payment of Costs outside Budget and Payment Schedule.** Payment for any costs not specifically described in the Budget and Payment Schedule must be approved in advance in writing by the National Investigator and/or BioQuest.

5.3 **Reimbursement.** BioQuest shall make payment in relation to the IEC/IRB approvals for conducting the Registry. BioQuest on receipt of any Invoice from the Principal Investigator shall also forward the same to the National Investigator. All such approval costs and related expenses or invoices shall be communicated in writing by BioQuest to the National Investigator and the same shall be reimbursed by invoice, and in no event later than 30 days from the receipt of such intimation or invoice.

National Investigator	BioQuest Solutions	Principal Investigator	Head of Institution

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Executive Registrar
SGPGIMS,Lucknow

6 Principal Investigator & Institution's Obligations.

6.1 IRB/ Ethics Committee Approval. Principal Investigator shall obtain IRB approval for the registry protocol and associated submission documents. Principal Investigator shall send BioQuest, a copy of the written IRB approval when obtained, and any other relevant documents. Further, Principal Investigator shall promptly provide to BioQuest, a copy of any follow-up reports or submissions provided to the IRB. The Principal Investigator or the Participating Institution shall inform BioQuest before beginning the data collection activity if the Principal Investigator or the Participating Institution or the IRB determines that the activity is a significant risk activity. If the IRB withdraws approval at any time, the principal investigator shall within twenty-four (24) hours notify BioQuest and provide a written explanation of the circumstances leading to the withdrawal. In the event the IRB requires changes in the protocol, Principal Investigator shall immediately notify BioQuest, and provide a written explanation of the reasons for the changes. Any modifications to the protocol must be approved in advance by the National Investigator and BioQuest. Participating Institution and Principal Investigator shall not modify the protocol without the prior written approval of the National Investigator and BioQuest. Modifications to the protocol shall not be implemented by the Principal Investigator until receipt of any necessary IRB approvals.

6.2 Reports. Upon request of National Investigator and BioQuest, Principal Investigator shall cooperate with National Investigator and BioQuest in the preparation or review of any reports and to facilitate reporting to the regulatory body/bodies. In addition, Principal Investigator shall submit the progress reports and / or final report upon closure of the registry to IRB as per the standards of the IRB. The same report shall be submitted to National Investigator and BioQuest for the records purpose.

6.3 Meetings. Principal Investigator shall attend activity-related meetings, training sessions (including self-study training sessions), or conference calls (collectively the "Meetings") when requested by National Investigator and BioQuest.

6.4 Warranties and Covenants.
Participating Institution and Principal Investigator/s each warrant and covenant, on behalf of itself and its personnel, that: (a) it has not been found by the Applicable Regulatory Authorities and state regulatory or governmental officials, to have violated any statutes, rules, or regulations concerning the conduct of clinical investigations; (b) it has not received an Applicable Regulatory Authorities warning or other regulatory letter; (c) it has not been terminated from any investigation or research project for reasons other than completion of the research project, and it and the IRB have not been disqualified by the Applicable Regulatory Authorities; and (d) it is not currently and has not been the subject of a proceeding by any Board of Medical Examiners or similar agency. Participating Institution and Principal Investigator each agree that if the foregoing warranties or covenants set forth in this Section should change, Participating Institution or Principal Investigator, shall notify National Investigator and BioQuest in writing within 7 (seven) business days of such change. If Principal Investigator or any individual, corporation, partnership or association providing services to the Participating Institution which directly or indirectly relate to the Participating Institution's activities pursuant to this Agreement becomes disqualified or receives notice of action or threat of action with respect to disqualification, in such an event the National Investigator and BioQuest shall have the right to terminate this Agreement with immediately effect.

7 Replacement of Principal Investigator

7.1 Replacement. If the Principal Investigator is unable to continue to serve as the Principal Investigator of the activity, or otherwise unable to fulfill his/her duties under this Agreement, he/she can notify by providing 15 days prior written notice to the IRB and National Investigator and BioQuest, the Principal Investigator shall also promptly

National Investigator | BioQuest Solutions | Principal Investigator | Head of Institution

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propose to appoint another appropriately qualified successor to assume the duties of Principal Investigator under this Agreement. National Investigator and BioQuest shall determine, whether the proposed replacement is acceptable. The appointment of a successor shall not relieve the preceding Principal Investigator of his duties under this Agreement. The new Principal Investigator shall provide a letter to the IRB, National Investigator and BioQuest accepting the appointment. By accepting such appointment, the new Principal Investigator shall assume the duties, representations and warranties of the Principal Investigator under this Agreement. If National Investigator BioQuest and Participating Institution are unable to promptly agree on an acceptable successor, this Agreement may be terminated at either National Investigator and/or BioQuest's discretion.

7.2 **Records.** Principal Investigator and Participating Institution shall promptly contact National Investigator and BioQuest in writing if the Principal Investigator leaves or will be leaving the Participating Institution, so that National Investigator and BioQuest can determine, whether the activity and the records relating thereto can be transferred to another party affiliated with Participating Institution or the departing Principal Investigator.

8 **Records and Access**

8.1 **Records».** Principal Investigator/s and Participating Institution shall maintain the following records relating to the activity: (i) all correspondence with the IRB, National Investigator, BioQuest, the Applicable Regulatory Authorities, or another investigator involved in the activity, including required reports; (ii) the protocol with documents showing the dates of and reasons for each deviation from the protocol; and (iii) other records that the Applicable Regulatory Authorities require to be maintained regarding the activity. Principal Investigator shall maintain such records during the activity and for a period of three (3) years after the termination or completion of the activity, whichever is later.

8.2 **Access.** Principal Investigator and Participating Institution each agree to permit National Investigator and BioQuest, its designated representatives, or appropriate representatives of regulatory agencies, at reasonable times and in a reasonable manner, to inspect facilities and to make all documents (including electronic records) available for review, comparison and/or copying if requested. Participating Institution and Principal Investigator shall notify National Investigator and BioQuest immediately by telephone (with a follow-up by mail) upon, but not later than twenty-four (24) hours after, learning that an Applicable Regulatory Authorities or other regulatory agency inspection is scheduled to take place, or, if there is no prior notice by the Applicable Regulatory Authorities or other regulatory agency, that an inspection has commenced Participating Institution and Principal Investigator shall make all reasonable efforts to coordinate any scheduling of Applicable Regulatory Authorities or other regulatory agency inspections to permit National Investigator and BioQuest and its representatives to attend such inspections.

9 **National Investigator and BioQuest Property.**

National Investigator and BioQuest shall provide the documents necessary for carrying out the activity to the Principal Investigator and Participating Institution at no charge. Participating Institution shall keep all such details and documents in a locked, secured area at all times (provided that all software, if any, may be loaded onto computers with appropriate physical and technical security restrictions) and shall maintain accurate records showing the disposition and return of any document. The documents and other property provided by or on behalf of National Investigator and BioQuest to the Participating Institution or Investigators in connection with this Agreement shall be and remain the exclusive property of the National Investigator and BioQuest. Participating Institution and Investigators shall use documents and other property only for the purposes of this Agreement and shall not use and/or mis-use the documents

National Investigator | BioQuest Solutions | Principal Investigator | Head of Institution

BioQuest Solutions Pvt. Ltd. Bangalore

Dr. RAJIV PARAKH, M S, FRCS
Chairman, Division of Peripheral
Vascular & Endovascular Surgery
Medanta - The Medicity
Sector-38, Gurugram Haryana, India

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

unless authorized in writing to do so by National Investigator and BioQuest. Should any document be damaged or explanted for any reason, Participating Institution and Investigators shall promptly return such documents or information to National Investigator and BioQuest or, at National Investigator and BioQuest's direction, send it to a third party for analysis.

10 **Indemnification.**

10.1 **Indemnification by BioQuest.**
BioQuest here by agrees to indemnify, defend and hold harmless, Participating Institution and Investigators (the "Institution Indemnitees") from and against any and all liability, claims, causes of action, lawsuits, losses, damages, costs, and expenses, including reasonable attorneys' fees and court costs, and other losses (collectively "Claims") asserted by any individual or entity or incurred by any Institution Indemnitee directly resulting from or arising out of the performance of the activity in accordance with the protocol; provided that BioQuest shall not be responsible for any Claims that are the result of: (1) the gross negligence or intentional misconduct of any of the Institution Indemnitees otherwise entitled to such indemnification; (2) except as otherwise specifically provided below, Institution Indemnitees activities under this Agreement conducted contrary to the provisions of this Agreement or the protocol, or outside the scope of the protocol; (3) actions by any Institution Indemnitees in violation of applicable laws or regulations; or (4) unauthorized warranties by any Institution Indemnitees relating to the activity.

10.2 **Indemnification by Participating Institution and Principal Investigator/s.** Participating Institution and Principal Investigator/s hereby agree to indemnify, defend and hold harmless, National Investigator and BioQuest, and as applicable, its respective shareholders, directors, officers, employees, contractors, agents and representatives who are in any manner connected with the Activity (collectively, the "National Investigator and BioQuest Indemnitees") from and against any and all Claims asserted by any individual or entity or incurred by any National Investigator and BioQuest Indemnitees directly resulting from or arising out of the negligence or willful misconduct of Participating Institution or Principal Investigator; provided that Participating Institution and Principal Investigator/s shall not be responsible for any Claims that are the result of: (1) the gross negligence or intentional misconduct of any of the National Investigator and BioQuest Indemnitees otherwise entitled to such indemnification; (2) except as otherwise specifically provided below, National Investigator and BioQuest Indemnitees activities under this Agreement conducted contrary to the provisions of this Agreement or the protocol, or outside the scope of the protocol; (3) actions by any National Investigator and BioQuest Indemnitees in violation of applicable laws or regulations; or (4) unauthorized warranties by any National Investigator and BioQuest Indemnitees relating to the activities.

10.3 In no event will either party be liable for any incidental, special, punitive, exemplary, or consequential damages arising out of or in connection with this Agreement or otherwise, including without limitation, liability for lost profits, business interruption, or loss of business, arising from any cause of action whatsoever, including contract, warranty, tort, or strict liability, even if a party has been notified of the possibility of such damages." The Indemnity or Liability damages payable by either party under this Agreement shall in no event exceed the total value of this agreement.

10.4 The provisions of this Section shall survive the expiration or termination of this Agreement with respect to any loss, damage, injury, or loss of life that occurred during the term of this Agreement.

10.5 **Claim of Indemnification».** The Party claiming a right of indemnification or defense under this Agreement shall provide the indemnifying Party prompt notice (in all events within fifteen (15) days) of any such claim, including a copy thereof, served upon it,

National Investigator | BioQuest Solutions Pvt. Ltd. Bangalore | Principal Investigator | Head of Institution

Dr. RAJIV PARAKH, M S, FRCS
Chairman, Division of Peripheral Vascular & Endovascular Surgery
Medanta - The Medicity
Sector-38, Gurugram Haryana, India

Dr. Raghunandan
Associate Professor
Dept. of Surgery

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Executive Registrar
SGPGIMS,Lucknow

and shall cooperate fully with the indemnifying Party and its legal representatives in the investigation of any matter regarding the subject of indemnification, at the indemnifying Party's expense. The indemnifying Party 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 the indemnifying Party shall not enter into any non-monetary settlement or admit fault or liability on the indemnified Party's behalf without the prior written consent of the indemnified Party, which consent shall not be unreasonably withheld or delayed. In the event a claim or action is or may be asserted, the indemnified Party shall have the right to select and to obtain representation by separate legal counsel. If the indemnified Party exercises such right, all costs, expenses and risks incurred by the indemnified Party for such separate legal counsel shall be borne by the indemnified Party unless the indemnifying Party is adjudicated liable by a court of competent jurisdiction for such injury or death, in which case the indemnifying Party shall be responsible for such indemnified Party's separate legal counsel's costs and expenses.

10.6 National Investigator/ BioQuest shall in addition has subscribed to a clinical trial insurance policy which covers all the registry subjects for bodily injury resulting or alleged to have resulted from the registry, subject to the terms and conditions of the insurance policy.

11 Term and Termination

11.1 **Term.** The term of this Agreement shall commence on the Effective Date and shall continue until all responsibilities of the Parties as described in this Agreement and the protocol have been completed, unless earlier terminated as set forth herein.

11.2 **Termination.** National Investigator and/or BioQuest may temporarily halt or terminate the activity at any time, with or without cause. National Investigator and BioQuest may terminate this Agreement if the Principal Investigator does not meet minimal requirements set forth in the protocol. If National Investigator and BioQuest discovers that Principal Investigator or Participating Institution is not complying with this Agreement, the protocol, or any applicable law or regulation, National Investigator and/or BioQuest may, at its sole discretion: (i) immediately terminate the Principal Investigator's participation in the Activity; or (ii) take other corrective actions as National Investigator and / or BioQuest determines appropriate.

11.3 **Effect of Termination.** Upon termination, the Parties shall notify the IRB that the activity has been terminated, immediately stop and cease conducting procedures in connection with the activity. Principal Investigator and Participating Institution shall return to National Investigator and/or BioQuest any materials and Confidential Information provided for the conduct of the activity. In the event of termination of this Agreement prior to completion of the activity, the Participating Institution, Primary Investigator shall make all reasonable efforts to minimize further costs. National Investigator shall reimburse Principal Investigator for any work performed by Principal Investigator prior to termination and all required follow-up testing.

BioQuest Solutions Pvt. Ltd. Bangalore

National Investigator | BioQuest Solutions | Principal Investigator | Head of Institution

Dr. Raghunandan Prasad, MD
Associate Professor
Deptt. of Radiodiagnosis
SGPGIMS, Lucknow (India)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

12 Ownership.

12.1 **Pre-existing Intellectual Property».** Ownership of inventions, technologies, know-how, ideas, processes, techniques, algorithms, programs, discoveries, improvements, devices, biologics, products, concepts, designs, prototypes, samples, models, technical information, materials, drawings, specifications and other works of authorship existing as of the Effective Date hereof, and all patents, copyrights, trade secret rights and other intellectual property rights therein (collectively, "Pre-existing Intellectual Property"), is not affected by this Agreement, and no Party shall have any claims to or rights in any Pre-existing Intellectual Property of any other Party, except as may be otherwise expressly provided in any other written agreement between two or more Parties.

12.2 **Research Results».** The National Investigator shall solely own all right, title and interest in and to any and all information, data or other materials delivered to the Participating Institution or the Principal Investigator by or on behalf of the National Investigator as well as any derivatives, progeny, or improvements developed therefrom, and all intellectual property rights therein. Further, all data and work product arising out of or relating to the Registry, including, without limitation, the Registry Records, data entered in eCRF, reports, and specimens, and all intellectual property rights therein, shall be the sole property of the National Investigator. Accordingly, the National Investigator shall have, in its sole discretion, the right to publish, disclose, disseminate, and use, in whole or in part, the same for any and all purposes, including, without limitation, in and for submissions to the regulatory agencies, if applicable. If Principal Investigator wants to publish his part, the prior written approval from National Investigator is required.

13 **Confidential Information.**

13.1 **Definition of Confidential Information.**
"Confidential Information" shall be the confidential and proprietary information of National Investigator and BioQuest, and shall mean: (a) the terms and conditions of this Agreement; (b) all information disclosed by or on behalf of National Investigator and BioQuest to Participating Institution, Principal Investigator, or their personnel, including without limitation, the Product, technical information relating to the Product, and all Pre-Existing Intellectual Property of National Investigator and BioQuest; (c) the protocol, information pertaining to the status of the activity, communications to and from the Applicable Regulatory Authorities, information relating to the documents regulatory status and correspondence to or from any clinical events committee or data safety monitoring board; (d) results; and (e) any activity-related information that was previously disclosed to any Party in contemplation of this Agreement or that was subject to a confidential disclosure agreement between two or more of the Parties. Confidential Information shall not include information that: (i) can be shown by documentation to have been public knowledge prior to or after disclosure to the Participating Institution, Principal Investigator, other than through acts or omissions attributable to Participating Institution, Principal Investigator or their personnel; (ii) can be shown by documentation to have been in the possession of Participating Institution, Principal Investigator or their personnel from sources other than National Investigator and BioQuest that did not have an obligation of confidentiality to National Investigator and BioQuest prior to disclosure; or (iii) can be shown by documentation to have been independently developed by Participating Institution, Principal Investigator or their personnel prior to disclosure.

13.2 **Obligations.** Participating Institution and Principal Investigator shall not, and shall require their respective personnel not to, use the Confidential Information for any purpose other than the performance of the activity or disclose the Confidential Information to any third party, except as otherwise expressly permitted by this Agreement or as otherwise required by law or authorized in writing by National Investigator and BioQuest. To protect Confidential Information, Participating

National Investigator | BioQuest Solutions | Principal Investigator | Head of Institution

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Institution, Principal Investigator agree to: (a) limit dissemination of Confidential Information to only those personnel having a "need to know"; (b) advise all personnel who receive Confidential Information of the confidential nature of such information; (c) have appropriate agreements with such personnel sufficient to enable them to comply with the confidentiality and nondisclosure obligations contained herein; and (d) use reasonable measures to protect the information from disclosure.

13.3 **Compelled Disclosure.** In the event that Participating Institution, Principal Investigator receive notice of a third party seeking to compel disclosure of any Confidential Information, they shall provide National Investigator and BioQuest with prompt notice so that National Investigator and BioQuest may assist Participating Institution, Principal Investigator in seeking a protective order or other appropriate remedy. In the event that such protective order or other remedy is not obtained, Participating Institution, Principal Investigator shall furnish only that portion of the Confidential Information which it is advised by its counsel, in consultation with National Investigator and BioQuest, is legally required to be disclosed, and shall exercise its best efforts to obtain reliable assurance that confidential treatment shall be afforded the Confidential Information.

14 **Governing Law and Arbitration**

14.1 This Agreement shall be governed by and construed in accordance with the laws of - India

14.2 **Arbitration.** Any dispute, controversy or claim arising out of or relating to this Deed, or breach, termination or invalidity thereof, shall be referred to binding arbitration in accordance with the country's Arbitration and Conciliation Act, / or equivalent as at present in force, and/or any amendments thereto, from time to time. Parties shall attempt to nominate a sole arbitrator failing which each shall appoint an arbitrator of its choice and the two arbitrators shall appoint the third arbitrator. The place of arbitration shall be Lucknow, India. The proceedings shall be in English language.

14.3 The courts of Lucknow shall have the Jurisdiction to try these cases.

15 **Entire Agreement**

This Agreement constitutes the entire agreement between the parties concerning the subject matter and this Agreement may only be modified or amended in writing and signed by all parties.

16 **Non-Assignment**

Principal Investigator shall not assign rights or duties under this Agreement without the prior written approval of National Investigator and BioQuest. The terms of this Agreement shall be binding upon and inure to the benefit of the Parties hereto and their successors and permitted assigns. Any attempted pledge, transfer, sublicense, or transfer in violation of this paragraph shall be void and of no force or effect.

17 **Notices**

Any notices under this Agreement shall be in writing and delivered to the Parties at the postal addresses set forth below, or to the postal address subsequently provided by a Party in accordance with this paragraph, by (a) first class certified mail, return receipt requested, with notice deemed given three (3) business days following the date of mailing; (b) a nationally-recognized overnight courier service, with notice deemed given on the date of receipt as indicated on the courier's receipt, or (c) by facsimile (with a follow-up by mail):

National Investigator | BioQuest Solutions | Principal Investigator | Head of Institution

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Executive Registrar
SGPGIMS,Lucknow

If to National Investigator	:	**Dr. Rajiv Parakh,** Chairman Division of Peripheral Vascular & Endovascular Sciences, Medanta- The Medicity, Sec-38, Gurgaon, Haryana - 122001, India
If to BioQuest	:	**BIOQUEST Solutions Private Limited,** #24, wellington street, Richmond Town, Bangalore - 560 025, India.
If to Participating Institution	:	**Sanjay Gandhi Postgraduate Institute of Medical Sciences,** New PMSSY Rd, Raibareli Rd, Lucknow, Uttar Pradesh 226014, India.
If to Principal Investigator	:	**Dr. Raghunandan Prasad,** Associate Professor, Department of Radiodiagnosis, Sanjay Gandhi Postgraduate Institute of Medical Sciences, New PMSSY Rd, Raibareli Rd, Lucknow, Uttar Pradesh 226014, India.

18 **Third Party Beneficiaries**
Nothing in this Agreement, whether expressed or implied, is intended to confer any rights or remedies under or by reason of this Agreement on any persons other than the Parties to this Agreement and to their respective successors and assigns.

19 **Independent Contractors**
The Parties agree that the relationship between National Investigator, BioQuest, the Participating Institution and Principal Investigator created by this Agreement is that of independent contractors and that neither the Principal Investigator nor the Participating Institution may create or assume any obligation on National Investigator and/or BioQuest's behalf.

20 **Use of Name or Marks**
Neither Party shall have the right to use the name, symbols, trademarks or service marks of the other Party in advertising or promotional materials or otherwise without receiving the prior written approval of such other Party.

21 **Severability**
If any provision of this Agreement is held invalid, illegal or unenforceable by a court of competent jurisdiction, the remainder of the Agreement shall be valid and enforceable and the Parties shall negotiate in good faith a valid and enforceable substitute provision which most nearly affects the Parties' intent in entering in this Agreement.

22 **Modification; Waiver**
This Agreement may not be altered, amended, or modified in any way except in a writing signed by the Parties. The failure of a Party to enforce any provision of this Agreement shall not be construed to be a waiver of the right of such Party to thereafter enforce that provision or any other provision or right.

23 **Multiple Counterparts.**
This Agreement may be executed in multiple counterparts, each of which shall be deemed to be an original and all of which taken together shall constitute a single instrument.

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

25 **Safety and Reporting.**
The recording of adverse events (AEs) is an important aspect of the Registry documentation. It is the Principal Investigator's responsibility to document all AEs according to the guidelines of the Protocol.

By signing this Agreement, each Party confirms that it has read this Agreement and agrees to all responsibilities and requirements described by each document.

1. **National Investigator**

Name	Title	Signature	Date
Dr. Rajiv Parakh	National Investigator		13-08-2021

2. **BioQuest Solutions Pvt. Ltd**

Name	Title	Signature	Date
Hanumanthu Reddy	Group Head- BRS		07 Apr 21

3. **Principal Investigator**

Name	Title	Signature	Date
Dr. Raghunandan Prasad	Principal Investigator		

4. **Participating Institution**

Name	Title	Signature	Date

National Investigator | BioQuest Solutions | Principal Investigator | Head of Institution 16/8/21

Prof. R. K. DHIMAN
Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences
LUCKNOW-226 014 INDIA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Annexure A: BUDGET AND PAYMENTS SCHEDULE

For each completed patient, PI will receive any amount of Rs. 10000. This amount will be paid as per the schedule detailed below. The fee is inclusive of Institutional overheads, if any.

Set forth milestones will be considered for payment at the submission of an invoices on a quarterly basis to BioQuest and it will be processed after review and approval from National Investigator.

Milestone payments:

Milestone	Value (inclusive of TDS, if any)
Upon enrolment of a patient(s)	50%
Upon Completion of final FU visit	50%

All payment in the above Milestone Table shall be inclusive of Institutional overheads, if any and any applicable taxes will be deducted as per applicable local tax laws. Whereas GST, 18% will be in additional to the above-mentioned investigator fees.

Any Fee charged by Ethics committee will be paid directly by BioQuest on behalf of National investigator.

Payment Recipient and Mailing Address. All cheque shall be made payable to the entity / person mentioned here.

The mailing address for cheque shall be:

Address:

The further details for the payments should be provided as:

Payee Name (Account name)	Director, SGPGIMS, Research Account
Account Number	10095237491
Bank Name	State Bank of India
Branch Name	SGPGIMS, Lucknow
Branch Code	007789
IFSC Code	SBIN0007789
PAN Number*	AAAJS3913N

The Amount paid under this Agreement shall be subject to statutory deduction of tax at source.

National Investigator

BioQuest Solutions

Principal Investigator

10/2/24

Head of Institution

Prof. R. K. [illegible]
Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences
LUCKNOW-226 014, INDIA

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Executive Registrar
SGPGIMS,Lucknow



தமிழ்நாடு तमिलनाडु TAMIL NADU

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C. EDWIN EZHILARAS
STAMP VENDOR
License No. 23/VLR/20
Vellore - 632 001.

10/01/23

CMC
VELLORE

MEMORANDUM OF AGREEMENT -- HYPORT ADJUVANT

This MEMORANDUM OF AGREEMENT is made on this 20th May Two thousand and twenty-three

BY AND BETWEEN Dr Selvamani B, Professor, Department of Radiation Oncology,Christian Medical College, hereinafter referred to as the 'CMC'

AND

Dr Sanjoy Chatterjee, Senior Consultant, Tata Medical Center, Kolkata, hereinafter referred to as'TMC'.

AND

The institution Tata Medical Center, situated at 14, MAR, Rajarhat, New Town, Kolkata-700160, hereinafter referred to as 'TMC'.

This Memorandum of Agreement (MoA) defines the role and responsibilities of the participating agencies, monitoring and other matters related to the HYPORT Clinical Trial

TATA MEDICAL CENTER KOLKATA

NOW THE PARTIES HERE TO AGREE AS FOLLOWS: -

1. **ROLE OF TATA MEDICAL CENTER, KOLKATA**

To provide funds as support / unrestricted grant to the extent of Rs 20,000 per month from 01st June 2023 over a period of 2 years or might be less from the date of signature of MOU to CMCtowards data operator fee and others. This will be bank transfer in the Institution bank accountafter TMC receives a request for transfer every 3 months along with utilization certificate of previous three months.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

2. DURATION OF PROJECT

The duration of the project shall be 2 years from the date the MOU has been sanctioned. The duration of the project could be increased in case the recruitment has not been completed.

3. ROLE OF CHRISTIAN MEDICAL COLLEGE, VELLORE

To utilize the funding received from TMC towards the data operator fees and submit the utilization report signed by authorized signatory and finance head of institution.

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. Dr. Rajesh. B

2. Mrs. Vinolia Vincy. L
Secretary

Signed by Dr. Selvamani B

Professor and Head
Department of Radiation Oncology
Christian Medical College, Vellore

Dr. SELVAMANI B, MBBS, MD, Dip.NB.,
Regn. No. 50921
Professor
Dept. of Radiation Oncology - Unit - III,
Christian Medical College
Vellore-632 004, Tamil Nadu, India.

Witnesses:

1.

2.

Signed by Dr. Sanjoy Chatterjee

Senior Consultant, Radiation Oncology
Tata Medical Center, Kolkata

Signed by Mr. Sanjeev Kumar Agarwal

For TATA MEDICAL CENTER
Sanjeev Kumar Agarwal
Chief Financial Officer

Chief Financial Officer
Tata Medical Center, Kolkata

27/12/23

Signed by Dr. P Arun

Dr. P. Arun
Director
Tata Medical Center
Kolkata

27/12/23

Director
Tata Medical Center, Kolkata

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

Rs. 100

e-Stamp

Certificate No.	:	IN-KA02327940902535T
Certificate Issued Date	:	15-Apr-2021 05:23 PM
Account Reference	:	NONACC (FI)/ kacrsfl08/ PADMANABHANAGAR3/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKACRSFL08754206840993 11T
Purchased by	:	IQVIA RDS INDIA PRIVATE LIMITED
Description of Document	:	Article 12 Bond
Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	IQVIA RDS INDIA PRIVATE LIMITED
Second Party	:	SANJAY GANDHI POST GRADUATE INSTITUTE
Stamp Duty Paid By	:	IQVIA RDS INDIA PRIVATE LIMITED
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

सत्यमेव जयते

BANGALORE CO-OPERATIVE SOCIETY LTD. DRB-3/RSG/02/ 421156/2017-18

IQVIA RDS INDIA PRIVATE LIMITED IN-KA02327940902535T RS. 100 15-APR-2021 05:23 PM

Please write or type below this line

Statutory Alert:

1. The authenticity of this Stamp certificate should be verified at 'www.shcilestamp.com' or using e-Stamp Mobile App of Stock Holding. Any discrepancy in the details on this Certificate and as available on the website / Mobile App 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.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

AMENDMENT NUMBER ONE
TO CLINICAL TRIAL AGREEMENT

This Amendment One (this "**Amendment #1**") to the Clinical Trial Agreement (the "**Agreement**"), dated 07Apr2021 by and between **Sanjay Gandhi Post Graduate Institute of Medical Sciences**, with business address located at Raebareli Road, Lucknow- 226014, Uttar Pradesh, India. ("**Institution**"), and **IQVIA RDS (India) Private Limited,** having a place of business at Omega Embassy Tech Square Marathahalli- Sarjapur Outer Ring Road, Kadubeesanahalli Bangalore- KA- 560103, India ("**IQVIA**") and **Dr. Jayantee Kalita,** with business address at Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow- 226014, Uttar Pradesh, India. ("**Investigator**"), and is effective as of the date last signed below ("**Effective Date**"). All capitalized terms used but not otherwise defined herein shall have the meaning set forth in the Agreement.

WHEREAS, IQVIA, and Institution and Investigator entered into the Agreement, pursuant to which the Parties agreed that Institution would conduct the following clinical trial sponsored by Merck Healthcare KGaA for the conduct of the study with details below:

Protocol Number : MS200527_0082

Principal Investigator : Dr. Jayantee Kalita; and

Protocol Title : "A Phase III, Multicenter, Randomized, Parallel Group, Double Blind, Double Dummy, Active Controlled Study of Evobrutinib Compared with Teriflunomide, in Participants with Relapsing Multiple Sclerosis to Evaluate Efficacy and Safety"

WHEREAS, the parties wish to amend the Agreement due to the Protocol Amendment dated 09 December 2020 / Version 2.0 and effect the required budget changes;

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

1. **Section D,** as found in Attachment A is hereby amended by deleting it in its entirety and replaced with the section below.

DOUBLE BLIND PERIOD

Visit	Cost/Unit (including Overhead) INR
Screening Visit	41414.75
Baseline Visit	47446.75
Week 2	18131.1
Week 4	22293.7
Week 6	18131.1
Week 8	18131.1
Week 10	18131.1
Week 12	35934.6
Week 14	18131.1
Week 16	18131.1
Week 18	18131.1

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Executive Registrar
SGPGIMS,Lucknow

Week 20	18131.1
Week 22	18131.1
Week 24	71007.95
Week 28	18131.1
Week 32	18131.1
Week 36	33757.1
Week 40	18131.1
Week 44	18131.1
Week 48	72515.3
Week 52	7963.8
Week 56	7963.8
Week 60	33757.1
Week 64	7963.8
Week 68	7963.8
Week 72	36523.5
Week 76	7963.8
Week 80	7963.8
Week 84	33757.1
Week 88	7963.8
Week 92	7963.8
Week 96/Early Discontinuation	73000.85
Total Cost Per Patient:	**800823.4**
Week 108*	36338.9
Safety Follow-up	34414.9
AEP**	749.45
Teriflunomide level**	3108.3
Telephone Visit	7963.8

* W108 is applicable only for a subset of participants who have disability progression between 72 and 96 weeks
** AEP and Teriflunomide level in case needed at early discontinuation

* W108 is applicable only for a subset of participants who have disability progression between 72 and 96 weeks
** AEP and Teriflunomide level in case needed at early discontinuation

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OLE PERIOD

Visit	Cost/Unit (including Overhead) INR
Week 2	18131.1
Week 4	18131.1
Week 6	18131.1
Week 8	18131.1
Week 10	18131.1
Week 12	18131.1
Week 14	18131.1
Week 16	18131.1
Week 18	18131.1
Week 20	18131.1
Week 22	18131.1
Week 24	67594.8
Week 28	18131.1
Week 32	18131.1
Week 36	33757.1
Week 40	18131.1
Week 44	18131.1
Week 48	67594.8
Week 52	7963.8
Week 56	7963.8
Week 60	18131.1
Week 64	7963.8
Week 68	7963.8
Week 72	34346
Week 76	7963.8
Week 80	7963.8
Week 84	18131.1
Week 88	7963.8
Week 92	7963.8
Week 96	69587.7
Week 100	7963.8
Week 104	7963.8
Week 108	30342
Week 112	7963.8
Week 116	7963.8
Week 120	34346
Week 124	7963.8

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Week 128	7963.8
Week 132	7963.8
Week 136	7963.8
Week 140	7963.8
Week 144/Early Discontinuation	69587.7
Total Cost Per Patient:	**866395.4**
AEP visit*	2448.55
Teriflunomide level	3108.3
Baseline visit after AEP	71219.2
Baseline visit for female participants not undergoing AEP	4124.9
Week 148 Safety Follow-up	34414.9
Telephone Visit	7963.8

* AEP visit is applicable only for male participants before to enter OLE. It is optional for female.

3. **Section J, Conditional Procedures**. In accordance with the changes outlined above, the Section titled- **Conditional Procedures** of the Budget & Payment Schedule is hereby amended as follows:

J. CONDITIONAL PROCEDURES (WITH INVOICE)

The following conditional procedure costs will be reimbursed on a pass-through basis upon receipt of invoice in the amount indicated in the table below (which includes overhead) and as verified by IQVIA conditional procedures occurred, and the site has completed relevant data entry. Subject number and procedure dates must be included on the invoice for payment to be issued.

Conditional Procedure	Cost/Unit (including Overhead) INR
Optional pharmacogenetics consent; DNA consent	850
Healthy volunteer dummy run MRI informed consent	850
Pregnant partner informed consent	850
Full physical examination: A comprehensive history; A comprehensive physical examination; one set of vital signs; weight	5,645

Lt Col Varun Bajpai VSM
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SGPGIMS,Lucknow

Blood draw, phlebotomy, routine venipuncture for collection of specimen(s), simple for central laboratory (teriflunomide levels if applicable; serum pregnancy if applicable; tuberculosis test; ferritin and transferrin saturation; HIV, HBV and HCV testing; Evobrutinib concentration; Biochemistry; Hematology; Supplemental LFT; Hepatic Panel; Coagulation; Immunoglobulin levels; Novel liver function protein/genomic biomarkes); PD substudy samples if applicable : Includes preparation of specimen; Blood Sampling	1,337
Lab handling and/or shipping of specimen(s) to central laboratory, simple -	677
Urine pregnancy, gonadotropin chorionic (hCG) (BetahCG); qualitative (local lab) -	1,133
Tuberculosis test, cell mediated immunity antigen response measurement; enumeration of gamma interferon-producing T-cells in cell suspension (T-SPOT)(local lab)	2,144
Infectious agent genotype analysis by nucleic acid (DNA or RNA); Hepatitis B virus (local lab); HCV RNA, quantification (local lab)	4,129
Magnetic resonance imaging, brain including brain stem (MRI); with contrast material(s) (eg, proton)	49,099
Interpretation and Report; Magnetic resonance imaging, brain including brain stem (MRI); with contrast material(s) (eg, proton) -	8,291
Magnetic resonance imaging, brain including brain stem (MRI); without contrast material (eg, proton) - healthy volunteer dummy run *	39,628
Copies of Diagnostic Films, Complex - Per Copy - for sharing MRI scans with central reviewer	2,053
Urine collection for local (urinalysis and urine pregnancy if applicable) and central laboratory (microscopis exam if applicable)	342
Lab handling and/or shipping of urine specimen(s) to central laboratory, simple -	455
Single 12-lead ECG: Includes tracing, interpretation and report -	1,901
Health resource utilization -	692
Columbia Suicide Severity Rating Scale, physician administered	1,982
Electronic Extended Disability Status Scale (EDSS); rater-administered -	6,252

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

IN WITNESS WHEREOF, the parties hereto have caused this Amendment #1 to be executed by their duly authorized representatives as of the effective date first set forth above.

AKNOWLEDGED AND AGREED BY THE PARTIES BELOW

IQVIA RDS (INDIA) PRIVATE LIMITED

Signature: _____

Name (Print): Shweta Pradhan

Title: Director & Head, Site Management

Date: 28/Apr/2021

SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES

Signature: _____ 17/5/21

Name (Print): Prof. R K Dhiman

Title: Director, SGPGIMS

Date: _____

Prof. R. K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

INVESTIGATOR

Signature: Dr. Jayantee Kalita

Name (Print): Principal Investigator

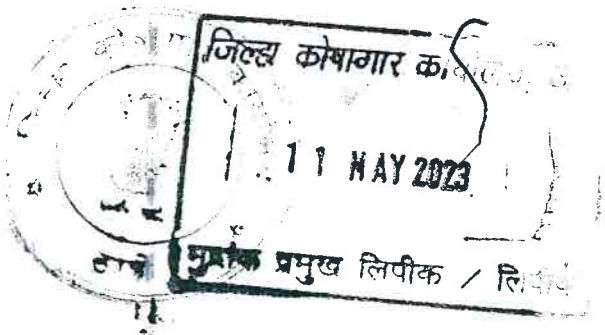
Title: Professor

Date: 07/may/2021

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow



महाराष्ट्र MAHARASHTRA ◐ 2022 ◐ 54AA 348725



Amendment #1
Clinical Study Agreement

This amendment dated 30 March 2023 to the Clinical Study Agreement (the "Amendment") is entered into by and between Sanjay Gandhi Postgraduate Institute of Medical Sciences, a clinical research site with its principal office and place of business at Raibareily Road, Lucknow - 226014, Uttar Pradesh, India ("**Institution**"), Dr. Jayantee Kalita, having an address at Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raibareily Road, Lucknow - 226014, Uttar Pradesh, India ("**Principal Investigator**") and Medpace Clinical Research LLC, located at 5375, Medpace Way, Cincinnati, Ohio 45227 ("Medpace"), collectively, (the "Parties").

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

WITNESSETH:

WHEREAS, the Parties entered into a Clinical Study Agreement as of 28 January 2021 (the "Agreement") pursuant to which Institution is conducting a Study based on Protocol No. VIB0551.P3.S1, entitled "A Randomized, Double-Blind, Multicenter, Placebo-Controlled Phase 3 Study With Open-Label Period To Evaluate The Efficacy And Safety Of Inebilizumab In Adults With Myasthenia Gravis", (the "Protocol"); and

WHEREAS, the Parties desire to amend the Agreement to amend the budget in Schedule A of the Agreement contained therein.

NOW THEREFORE, the Parties hereby agree as follows:

1. Schedule A of the Agreement shall be deleted in its entirety and replaced with the Schedule A appended to this Amendment.

2. All other provisions of the Agreement shall remain unchanged and in effect.

[SIGNATURE PAGE TO FOLLOW]

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(34)

IN WITNESS WHEREOF, the Parties hereto have executed this Amendment by proper persons thereunto duly authorized

FOR MEDPACE, ON ITS OWN BEHALF
AND AS PAYMENT AGENT OF SPONSOR

By: _____

Name: Taher Sadriwala

Title: Sr. Associate Director – Clinical Trial Management

Date: 01/Jun/2023

INSTITUTION

By: _____ 03/07/23

Name: _____

Title: _____

Prof. R.K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Date: _____

Read and Acknowledged by:
Principal Investigator

By: _____

Name: Prof. Jayantee Kalita

Date: 16/Jun/2023

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

MEDPACE
THE ADVANTAGE OF FOCUS

SCHEDULE A

VIELA BIO

PROTOCOL ID: VIB0551.P3.S1

// DR JAYANTEE KALITA //

PROTOCOL VERSION 6.0

SITE: //4105//

SCHEDULE A VERSION: VERSION #2.0

COUNTRY: INDIA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

SCHEDULE A

A1 STUDY BUDGET

Medpace, as Sponsor's payment agent, shall make payment to the payee specified in the Payee Information Table ("Payee") under this Agreement from funds escrowed by Sponsor for services provided according to the payment schedule below. All fees listed include overhead, taxes, and subject stipend or travel reimbursement, as applicable. VAT is not applicable because Medpace Clinical Research, LLC is a US-based corporation. Should any changes to VAT law occur during the term of this Agreement, the party legally responsible shall be liable for VAT. Payments are based on electronic case report forms ("eCRFs"), laboratory data, IVRS data or other specific data source. All amounts shown herein are calculated in INR.

A1.1 Fee for Each Evaluable Subject (Including 25% IOH and 18% GST)

An "evaluable subject" is one who has been enrolled (randomized to treatment) and in whom all the applicable terms and conditions of the Protocol and this Agreement have been satisfied. Randomization occurs at Visit 2/Day 1.

1.1.1	*Randomized Control Period-AcHR-Ab+ Population*	*INR 670,107.00*
1.1.2	*Randomized Control Period-MuSK-Ab+ Population*	*INR 473,031.00*
1.1.3	*Open Label Period*	*INR 554,746.03*

A2 SETUP FEES & VISIT PAYMENTS

☒ Please check box if Payee must submit an invoice to Medpace prior to receiving payment. Payment will be made within forty-five (45) days of receipt of invoice.

A2.1 Setup Fees

2.1.1	*Administrative Fee*	*INR 40,000 + 18% GST*
2.1.2	*Pharmacy Start-Up Fee*	*INR 75,000 + 18% GST*

Payment will be made within forty-five (45) days of:

- Sponsor declaring Institution to be ready for Study Initiation;
- IRB/EC approval; and
- Medpace's receipt of the fully executed Agreement.

A2.2 Ongoing Payments

Payments for Study subject visits, as set forth in Table below, will be paid on a quarterly basis for the actual number of Study subjects for whom eCRFs have been completed less ten percent (10%) of each quarterly payment, which will be withheld until and paid with the final payment. Quarterly payments will be made within forty-five (45) days after the end of each quarter. The quarterly schedule may be offset from the calendar quarter.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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Table 1 - Fees for Completed Clinical Visits for Randomized Control Period- AcHR-Ab+ Population

VISIT	VISIT FEE		25% IOH FEE		VISIT FEE INCLUDING 18% GST	
Visit 1/Screening	INR	30,797	INR	7,699	INR	45,426
Visit 2/Day 1	INR	64,262	INR	16,066	INR	94,786
Visit 3/Day 15	INR	43,778	INR	10,945	INR	64,573
Visit 4/Day 29	INR	34,622	INR	8,656	INR	51,067
Visit 5/Day 57	INR	28,622	INR	7,156	INR	42,217
Visit 6/Day 85	INR	34,784	INR	8,696	INR	51,306
Visit 7/Day 126	INR	27,476	INR	6,869	INR	40,527
Visit 8/Day 183	INR	59,010	INR	14,753	INR	87,040
Visit 9/Day 225	INR	27,950	INR	6,988	INR	41,226
Visit 10/Day 267	INR	34,671	INR	8,668	INR	51,140
Visit 11/Day 309	INR	27,476	INR	6,869	INR	40,527
Visit 12/Day 365	INR	40,862	INR	10,216	INR	60,271
TOTAL PER PATIENT	**INR**	**4,54,310**	**INR**	**1,13,578**	**INR**	**6,70,107**
Remote Visit due to COVID-19	INR	17,592	INR	4,398	INR	25,948

Table 2 - Fees for Completed Clinical Visits for Randomized Control Period- MuSK-Ab+ Population

VISIT	VISIT FEE		25% IOH		VISIT FEE INCLUDING 18% GST	
Visit 1/Screening	INR	30,797	INR	7,699.25	INR	45,425.58
Visit 2/Day 1	INR	64,262	INR	16,065.50	INR	94,786.45
Visit 3/Day 15	INR	43,778	INR	10,944.50	INR	64,572.55
Visit 4/Day 29	INR	34,622	INR	8,655.50	INR	51,067.45
Visit 5/Day 57	INR	28,622	INR	7,155.50	INR	42,217.45
Visit 6/Day 85	INR	34,784	INR	8,696.00	INR	51,306.40
Visit 7/Day 126	INR	27,476	INR	6,869.00	INR	40,527.10
Visit 8/Day 183	INR	56,358	INR	14,089.50	INR	83,128.05
TOTAL PER PATIENT	**INR**	**3,20,699**	**INR**	**80,175**	**INR**	**4,73,031**
Remote Visit due to COVID-19	INR	17,592	INR	4,398.00	INR	25,948.20

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Table 3- Fees for Completed Clinical Visits for Open Label Period

VISIT	FEE	25% IOH	FEE INCLUDING 18% GST
Visit 1/OLE Day 1	INR 27,505.00	INR 6,876.25	INR 40,569.88
Visit 2/OLE Day 15	INR 33,784.00	INR 8,446.00	INR 49,831.40
Visit 3/OLE Day 92	INR 32,310.00	INR 8,077.50	INR 47,657.25
Visit 4/OLE Day 183	INR 55,018.00	INR 13,754.50	INR 81,151.55
Visit 5/OLE Day 275	INR 32,310.00	INR 8,077.50	INR 47,657.25
Visit 6/OLE Day 365	INR 36,810.00	INR 9,202.50	INR 54,294.75
Visit 7/OLE Day 456	INR 29,310.00	INR 7,327.50	INR 43,232.25
Visit 8/OLE Day 547	INR 32,013.00	INR 8,003.25	INR 47,219.18
Visit 9/OLE Day 730	INR 32,013.00	INR 8,003.25	INR 47,219.18
Visit 10/OLE Day 911	INR 32,013.00	INR 8,003.25	INR 47,219.18
Visit 11/OLE Day 1093/ET	INR 33,013.00	INR 8,253.25	INR 48,694.18
TOTAL PER PATIENT	**INR 3,76,099.00**	**INR 94,024.75**	**INR 5,54,746.03**
Safety Follow up	INR 22,199.00	INR 5,549.75	INR 32,743.53

A2.3 Screen Failures

Table 4 - Screen Failures

VISIT OF FAILURE	COST	25% IOH	COST INCLUDING 18% GST
Visit 1/Screening	INR 30,797	INR 7,699.25	INR 45,425.58

Payment for a max of 10 screen failures will be made for whom Medpace has received all appropriate documentation of procedures/visits completed with the next scheduled payment owed to the Payee. Eligible screen failure payment will be based on the order (by date) of when the subject is consented. Payment for additional screen failures must be pre-approve by Medpace/Sponsor.

A2.4 Final Payment

Final payment for all services performed under this Agreement will be paid to Payee by Medpace after:

- Final resolution of all queries;
- Upon final acceptance of all eCRFs;
- The receipt and approval of any outstanding regulatory documents as required by Sponsor;
- The return of all unused Study Drug, Study supplies (including any equipment provided by Sponsor) and Confidential Information to Sponsor; and
- Upon completion of all other applicable conditions set forth in the Agreement.

A2.5 Archiving Fee — 350,000 plus 18% GST

Payable with final payment. The expectation is that the study site will be responsible to maintain study documents for 25 years after site closure unless notified by the sponsor.

The final payment shall be reconfirmed and paid as per the quotation submitted and on receipt of sponsor's approval.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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A2.6 Unscheduled Visit Due to Worsening MG Symptoms (Including 25% IOH) INR 21,118.00 +18% GST

Payable with final payment. An unscheduled visit should be performed if a patient complains of worsening MG symptoms and use of rescue therapy is being considered. This should be performed before the rescue therapy is initiated. This Unscheduled visit should follow the procedures as outlined in the protocol. If an Unscheduled Visit is performed for a different reason, then it is only necessary to perform those specific procedures. Unscheduled Visit must be entered into EDC prior to database lock and visit must occur after randomization. Unscheduled Visit will not be payable if it occurs on the same date as another visit.

Total includes Adverse Events Assessment, Patient Daily Reimbursement, Study Coordinator Fee, and Physician's Fee. All other procedures should be invoiced at cost if completed

A3 INVOICEABLE ITEMS

Payment will be made within forty-five (45) days of receipt of invoice and supporting documentation if applicable and requested.

A3.1 Additional Procedures

Payment will be made for procedures listed below if required by the protocol and not considered as standard of care.

Table 5 – Unitized Procedures

FEES	COST	COST INCLUDING 18% GST
Optional B-cell Repertoire Profiling Substudy	INR 800	INR 944
Optional DNA Sample	INR 800	INR 944

A3.2 OLE - Day 1 Visit INR 70,848 + 18% GST, if applicable

Payable if the OLE - Day 1 visit occurs on a separate date from the Day 365 visit.

A3.3 Rescue Medication

Rescue Medications to be paid at actual cost upon receipt of invoice and supporting documentation, if not covered by a third party as standard of care and costs are reasonable and customary.

A3.4 Additional Study-necessitated Fees

Payee will be reimbursed at actual cost for any other unforeseen but reasonable procedures or costs necessitated by the Study or Protocol (and any amendments thereto) and pre-approved by Medpace/Sponsor.

A3.5 Nominal equipment

Institution may be provided during the course of the Study small items of equipment necessitated by the Study or Protocol and pre-approved by Medpace/Sponsor.

A4 MEDPACE RIGHTS

Medpace reserves the right to suspend payments due to Payee, if Principal Investigator and/or Institution do not complete data entry, query resolutions, and electronic signatures on eCRFs and/or provide regulatory documents to Medpace within timelines defined by the project team. Payments will resume once the missing or incomplete information is resolved.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

A5 MEDPACE INVOICING

All payment inquiries and invoices submitted shall include the Protocol number and Principal Investigator name and be sent to the following:

Email: siteinvoices@medpace.com
Phone: 513-579-9911

Medpace Clinical Research, LLC
Attn: Clinical Operations Site Payments
5375 Medpace Way
Cincinnati, Ohio 45227

All invoices must be submitted to Medpace within ninety (90) days of occurrence or up to thirty (30) days after receipt of the final payment.

A6 PAYEE INFORMATION

All payments made by Medpace as set forth herein shall be payable solely to Payee at the address set forth below. Any such payments which are due to any other party performing services in connection with the Study shall be a matter solely between Payee and such party.

Table 6 - For sites receiving payment by foreign wire transfer

PAYEE INFORMATION	
Beneficiary Name	Director SGPGIMS Research Scheme
Payee Mailing Address	Administrative Building, SGPGIMS, Raebareli Road, Lucknow
Contact Name	Dr. Jayantee Kalita
Email Address	jayanteek@yahoo.com
Bank	State Bank of India
Account №	10095237491
IBAN №	N/A
BIC Code/Swift Code	SBININBB500
IFSC Code (India)	SBIN0007789
Tax ID#**	AAAJS3913N

**Requested for Medpace Accounting tracking purposes only

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

MUTUAL CONFIDENTIALITY AGREEMENT – Protocol no.: 64407564MMY3009 dated 28 April 2023 ("Effective date")

By and Between

1. **Johnson & Johnson Private Limited**, a company with CIN U33110MH1957PTC010928through its pharmaceutical division Janssen, having its corporate office at Arena Space, Behind Majas Bus Depot, Off J.V. Link Road, Jogeshwari (E) Mumbai 400060 ("**J&J**"), and

2. **Dr. Sanjeev** ("**Investigator**"), adult Indian, with professional registration no DLH20160000110KTK residing at Lucknow and presently engaged by Sanjay Gandhi Post Graduate Institute of Medical Sciences, 226014, as a Associate Professor, and

3. **Sanjay Gandhi Post Graduate Institute of Medical Sciences**("**Institution**'), a registered trust/foundation, operating from SGPGIMS, Raebareli Road Lucknow-226014, India

Referred to jointly as "**Parties**" and separately as "**Party**".

Background - Each Party wishes to disclose to the other Parties, Confidential Information in relation to the Study to explore and evaluate the possibility and scope of collaboration and engagement in context of the Study ("**Study Purposes**"), but ensure that the other Parties maintains the confidentiality of its **Confidential Information**.

Now, therefore, in consideration of the premises and the mutual promises and covenants expressed herein, each Party agree as follows:

1. *(a) Confidential Information* shall mean all information (however recorded, preserved or disclosed) disclosed by a Party (hereinafter referred to as "**Disclosing Party**") or its employees, officers, affiliates, representatives or advisers (together, its "**Representatives**") to the other Party or Parties (hereinafter individually referred to as "**Receiving Party**" and jointly referred to as "**Receiving Parties**") and such Receiving Party's Representatives in relation to the Study in any manner. Confidential Information shall include, but not be limited to, scientific, commercial, business, financial, technical data including, drawings, films, documents, analyses, compilations, studies, medical information related to medicinal products, dossiers, product know-how and the like, either orally or in written or electronic format or by demonstration or computer readable media otherwise, irrespective of it being marked or otherwise designated to show expressly or by necessary implication that it is proprietary to the Disclosing Party or that it is prepared by the Disclosing Party or that it belongs to the Disclosing Party, and such confidential information shall include developed intellectual property results and specifications and contents relating to the Study as received by the Receiving Parties and their Representatives.

1. (b) "*Study*" means a clinical trial with respect to Protocol no.:64407564MMY3009 with Protocol Titled: " A Phase 3 Randomized Study Comparing Talquetamab in Combination with Pomalidomide (TalPom), Talquetamab in Combination with Teclistamab (TalTec), and Elotuzumab (IV), Pomalidomide, and Dexamethasone (EPd) or Pomalidomide, Bortezomib (SC), and Dexamethasone (PVd) in Participants with Relapsed or Refractory Myeloma who Have Received at Least 1 Prior Line of Therapy"

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2. *Duty of Receiving Party*. Each Receiving Party here by agrees to keep the Confidential Information received by it in confidence and strictly not to disclose it to any third party or use it for any purpose other than for Study Purposes. However, nothing herein shall prevent a Receiving Party from disclosing the Confidential Information to its Representatives, if such persons need to know such information for Study Purposes, provided that the Receiving Party shall ensure that such Representatives are subject to a confidentiality obligations with respect to such Confidential Information of at least the same level as envisaged under this Agreement. Each Receiving Party agrees that it will be fully responsible, for any breach by its Representatives of their confidentiality obligations with respect to such Confidential Information under this Agreement.

3. *Structure Information*. Unless otherwise mutually agreed in writing between the Parties, the Investigator or Institution shall not identify the chemical structure or molecular composition of J&J's proprietary compound(s) or molecular entity/entities or any data from which J&J's proprietary compound's or molecular entity's chemical structure or molecular composition may be readily determined or elucidated, except if authorized by J&J and shall be disclosed only to those Representatives of Receiving Party who are identified and authorized in writing by J&J to receive such structure, composition or data. For the avoidance of doubt, such structure, composition or data that might be disclosed directly by Principal Investigator to J&J shall not be considered "Confidential Information" of Investigator or Institution or both for any purpose hereunder.

4. *Exceptions*. Each Receiving Party shall not be obligated to maintain in confidence or to refrain from disclosing or using the Confidential Information if such information:

a) was known to the Receiving Party prior to being received from the disclosing party or its Representatives as evidenced by the Receiving Party's written records; or
b) is or without the fault of the Receiving Party (or any of its Representatives) becomes part of the public domain; or
c) is received by the Receiving Party from a third party having to the knowledge of the recipient no obligation of confidence to the other parties hereto; or
d) is independently developed by or on behalf of the Receiving Party without reliance on the information received hereunder as evidenced by the Receiving Party's written records or other competent evidence.

5. *Non–Disclosure/Publicity*. No Party will disclose, and each Party will direct its Representatives, who are aware of the contemplated discussions, not to disclose, publish or disseminate, at any time to any person the identity of the other Parties and the fact that Confidential Information has been made available or that discussions are taking place for Study Purposes or any of the terms, conditions or other facts with respect to Study or Study Purposes, including the status thereof.

6. *Business Acknowledgement*. The Investigator and Institution hereby acknowledge that J&J or its group companies or affiliates may presently have internal development programs relating to the Study, or without recourse to the Confidential Information disclosed hereunder may undertake such development programs, or may receive information on the same or related subject matter from third parties, and may develop and commercialize products and/or services relating to such subject matter independently or in cooperation with such third parties.

7. *Compelled Disclosures*. In the event a Receiving Party or Receiving Parties (or any person to whom it has transmitted the Confidential Information received hereunder) is required by law or legal process to disclose any of such Confidential Information, then the concerned Receiving Party(ies)will (i) provide the Disclosing Party with prompt notice of such event so that the Disclosing Party may intervene to protect the confidentiality of the

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Confidential Information and (ii) at the Disclosing Party's request and expense, use reasonable efforts to obtain assurance that confidential treatment will be accorded to the Confidential Information to be disclosed.

8. *Return of Confidential Information*. All written and electronic documents containing Confidential Information and other confidential material in tangible form including copies thereof in any form irrespective of storage or presentation medium, received by a Receiving Party under this Agreement shall remain the property of the Disclosing Party. Upon request of the Disclosing Party and solely at the expense of the concerned Receiving Party, all such documents (together with any copies or excerpts thereof) and such other material received hereunder shall promptly be either returned to the Disclosing Party or destroyed and the destruction confirmed to the Disclosing Party in writing. Notwithstanding the return or destruction of the documents and materials, each Receiving Party will continue to be bound by its obligations under this Agreement.

9. *No Right or License*. No right or license to use any Confidential Information disclosed hereunder, either express or implied, is granted to the Receiving Parties.

10. *Accuracy of Confidential Information*. Each Receiving Party understands that although the Disclosing Party and its Representatives have endeavored to include in the Confidential Information, information that it believes to be relevant for the purpose of the recipient's evaluation, neither the Disclosing Party nor any of its Representatives have made or make any representation or warranty as to the accuracy or completeness of the Confidential Information.

11. *No Obligation to Pursue Proposed Transaction*. Unless and until a definitive agreement between the parties with respect to Study Purposes has been executed and delivered, no Party will be under any legal obligation of any kind whatsoever with respect to such a transaction by virtue of this or any written or oral expression by any of its representatives, except for the matters specifically agreed to herein.

12. *Survival*. The obligations of Section 2 shall continue for forty-eight months from the Effective Date of this Agreement and for Section 3 shall be in perpetuity or as long as permitted by law.

13. *Governing Law*. Any disputes that may arise from this Agreement or in relation thereto shall be governed under Indian laws and the parties hereby agree to submit themselves to the exclusive jurisdiction of the competent courts in Lucknow. This clause shall survive the expiration or termination of the Agreement

14. *Entire Agreement & Modifications; Severability; Construction*. This Agreement contains the entire agreement between the parties and supersedes all pre-existing agreements, whether oral or written, between the parties respecting its subject matter. Modifications or waivers of this Agreement shall only be effective if made in writing and signed by all the parties hereto. The invalidity of any provision of this Agreement will not affect the enforceability of any other provision hereof. The Parties have jointly negotiated and drafted this Agreement and this Agreement shall be interpreted without presumption favoring or disfavoring any Party by virtue of authorship of any provision of this Agreement. This Agreement shall not be assignable, in whole or in part, by any Party without the prior written consent of the other Parties, and any such assignment without prior written consent shall be considered void.

[*SIGNATURE PAGE FOLLOWS*]

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SGPGIMS,Lucknow

This Agreement is executed in three counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.

For Johnson & Johnson Private Limited

By: Manik Prabhu Nanna

Digitally signed by Manik Prabhu Nanna
DN: c=US, o=JNJ, ou=Subscribers, 0.9.2342.19200300.100.1.1=15298008l, cn=Manik Prabhu Nanna
Reason: I am approving this document.
Date: 2023.04.28 15:03:32 +05'30'
Adobe Acrobat version: 2020.013.20064

Print Name: Dr. Manik Prabhu Nanna
Print Title: Manager-Global Clinical Operation, India
Date:

For Institution

By:

Director 3/5/23
Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226 014, INDIA

Print Name: Dr. R K Dhiman
Print Title: Director Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow

Date:
Institution Seal:

Principal Investigator

By: Sanjeev

Print Name: Dr. Sanjeev
Print Title: Associate Professor

Date: 03/05/2023
Physician Seal:

Dr. SANJEEV
Associate Professor
Department of Hematology
S.G.P.G.I.M.S., Lucknow
U.P.-226014

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Executive Registrar
SGPGIMS,Lucknow



महाराष्ट्र MAHARASHTRA ◐ 2022 ◐ BW 522341

उप कोषागार अधिकारी
कल्याण

NOVARTIS HEALTHCARE PRIVATE LIMITED (FIRST PART) 20 NOV 2020

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences (SECOND PART)

AND

Dr. Dharmendra Bhadauria (THIRD PART)

NOVARTIS HEALTHCARE PRIVATE LIMITED MUMBAI

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

FIRST AMENDMENT TO CLINICAL TRIAL AGREEMENT

This first Amendment is made at Mumbai and entered into on 20 day of Dec, 2023 by and between;

NOVARTIS HEALTHCARE PRIVATE LIMITED, a company incorporated under the Indian Companies Act, 1956 and having its registered office at Inspire BKC, 7th Floor, Bandra Kurla Complex, Bandra (East), Mumbai – 400 051, 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

Sanjay Gandhi Post Graduate Institute of Medical Sciences, located at ***Uttar Pradesh*** ("**Institution**") registered under the provision of the State Legislature Act and having its address at Raebareli road, lucknow-226014, Uttar Pradesh, India which expression shall mean and include its successors and assigns of the SECOND PART;

AND

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

(Novartis, Principal Investigator, and Institution may hereinafter be individually referred to as '**Party**' and are collectively referred as '**Parties**').

WHEREAS

A. By a Clinical Trial Agreement dated 25 Feb 2022 entered into between the Parties hereto ("**Agreement**"), the Principal Investigator and the Institution have agreed to provide certain Clinical Trial related services to Novartis on the terms and conditions contained in the Agreement.

B. Now by this first Amendment, the Parties are desirous of modifying and restating the sub-clause on 'Use of Trial Drug', and 'PUBLICATION' and 'TRANSPARENCY/DISCLOSURE , Modifying Annex-1 (Update in Payment Schedule for Corrected cost) 'clause to amend the Agreement on the terms and conditions herein after appearing.

NOW THIS AMENDMENT WITNESSETH AND IT IS HERE BY AGREED BY AND BETWEEN THE PARTIES AS FOLLOWS:

1. Clause 5.2 (Use of Trial Drug) of the Agreement is modified, and the revised clause 5.2 is as set forth below:

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5.2 Novartis shall provide the Trial Drugs (as defined hereunder) in sufficient quantity to conduct the Trial, unless specified in Protocol that one or more drugs is supplied locally. If the Drugs are supplied locally, Novartis Shall reimburse the Institution. Trial Drugs shall be defined as any investigational drug referred in the Protocol, which can include active ingredient, comparator, or placebo. For purposes of this Agreement only, the Trial Drugs shall be free of charge to the Institution. In all events, the Trial Drug shall remain the sole property of Novartis.

2. Clause 13.1, 13.3, 13.5 and 13.9 are added to the Agreement and the additional clauses are set forth as below:

13.1 The term 'publications' is used interchangeably to refer to peer-reviewed scientific manuscripts (e.g. primary and secondary manuscripts, submitted to scientific or medical journals), scientific congress abstracts, and corresponding posters and oral presentations.
13.3 Novartis follows the ICMJE authorship guidelines (www.icmje.org). All authors must therefore fulfill all four ICMJE authorship criteria during publication development to be included as authors on the publication, as follows:

(a) Substantial contributions to conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND

(b) Drafting the work or revising it critically for important intellectual content; AND

(c) Final approval of the version to be published; AND

(d) Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

13.5 Authors will not receive remuneration for their writing of a publication, either directly from Novartis or through a professional medical writing agency.
13.9 Novartis and its agents may list participating investigators and their institutional affiliations in the acknowledgement section of the manuscript or abstract submitted for publication according to the journal or congress guidelines.

3. Clause 13.4 of the Agreement is modified, and revised clause is set forth as below:

13.4 The list of persons to be designated as primary or secondary author of any publication relating to the Trial shall be determined by mutual agreement prior to drafting the publication.

4. Clause 13.7 of the Agreement is modified and the revised clause 13.7 is as set forth below:

13.7 If the Trial is a multi-centre trial, the first publication of data shall be based on consolidated data from all centres analysed according to the Protocol, unless otherwise agreed in writing by all the Principal Investigators involved in the Trial and by Novartis. Publication of partial data sets shall not be made until the full data is released.

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5. Clause 24.3 is modified and revised clause is as set forth below:

   24.3 It shall be assessed locally if the Provision 24.3 below is required and that it does not contradict with Local Regulations on Data Privacy. The provisions shall be adapted as needed to ensure consistency with Local Regulations on Data Privacy

6. This amendment shall be effective from 10 Jul 2023 and shall be coterminous with the agreement read with the prior addendums/amendments for all intents and purposes.

7. 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. This Amendment shall hereafter be incorporated into and deemed part of the Agreement and any future reference to the Agreement shall include the terms and conditions of this Amendment.

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NOVARTIS HEALTHCARE P. LIMITED MUMBAI

IN WITNESS WHEREOF, the Parties to this Amendment have caused their duly authorized representatives to enter into and execute this Amendment.

Novartis Healthcare Private Limited

By: _____

Name: **Murugahanthan K.**

Title: SSO Country Head

Date: 26 Dec 2023

Sanjay Gandhi Post Graduate Institute of Medical Sciences

By: _____

Name: Prof. R K Dhiman

Title: Director

Acting Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
Lucknow - 226014, INDIA

Date: 20.1.24

PRINCIPAL INVESTIGATOR

By: _____

Name: Dr. Dharmendra Singh Bhadauria

Title: Professor, Department of Nephrology

Date: _____

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SGPGIMS,Lucknow

NOVARTIS HEALTHCARE MUMBAI

Annex1: Payment (and Equipment) Schedule

Financial Break-up

STUDY NUMBER: CLNP023F12301

STUDY NAME: A MULTICENTER, SINGLE-ARM, OPEN LABEL TRIAL TO EVALUATE EFFICACY AND SAFETY OF ORAL, TWICE DAILY LNP023 (IPTACOPAN) IN ADULT ATYPICAL HEMOLYTIC UREMIC SYNDROME (AHUS) PATIENTS WHO ARE NAIVE TO COMPLEMENT INHIBITOR THERAPY

Investigator's Name: Dr. Dharmendra Bhaduria

Institute Name: Sanjay Gandhi Post Graduate Institute of Medical Sciences

Payee Name: Director, SGPGIMS Research Scheme Account

Pan Card Number: AAAJS3913N

GSTIN: 09AAAJS3913N2ZN

Committed Number of Study Subjects: 2

Payment Schedule:

Visits		*Investigator fees*	*HOI (25%)*	*Total per visit cost*
Screening	**SCR**	40547	10137	50684
Core Treatment Period	**W1D1**	9645	2411	12056
	W1D7	7299	1825	9124
	W2	7033	1758	8791
	W3	4157	1039	5196
	W4	9378	2345	11723
	W6	4157	1039	5196
	W8	7832	1958	9790
	W10	4157	1039	5196
	W12	7672	1918	9590
	W14	4157	1039	5196
	W16	6234	1559	7793
	W18	4157	1039	5196
	W20	6234	1559	7793
	W22	4157	1039	5196
	W24	4157	1039	5196
	W26 (EOT/EOS)	11243	2811	14054
Extension Treatment Up To Month 12	**W28**	6234	1559	7793
	W32	6234	1559	7793
	W36	6234	1559	7793
	W40	6234	1559	7793
	W44	6234	1559	7793
	W48	6234	1559	7793
	EOT/EOS	8099	2025	10124
Follow Up	**D7FU**	1332	333	1665
Total Per Patient cost		236314		

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