MGM INSTITUTE OF HEALTH SCIENCES
(Deemed University u/s 3 of UGC Act, 1956)
Grade 'A' Accredited by NAAC
Sector-01, Kamothe, Navi Mumbai - 410 209
Tel 022-27432471, 022-27432994, Fax 022 - 27431094
E-mail : registrar@mgmuhs.com | Website : www.mgmuhs.com

3.2.1 Grants for research projects/clinical trials sponsored by the non-governmental sources such as industry, corporate houses, international bodies, endowments, professional associations, endowment Chairs etc. in the Institution during the last five years (INR in Lakhs)

LIST OF THE PROJECTS WITH MOU/ E -AWRD DOCUMENTS AS PER DVV

Sr.No.	Name of the Projects, Clinical Trial,Endowment, Chairs	Year	Page No.
1	Establishment of MGM Centre of Human Movement Science at MGM School of Physiotherapy	2014-15	1-9
2	Clinical Evaluation of Breath-Based point of care test for diagnosis of Pulmonary Tublerculosis	2015-16	10-15
3	Non Invasive TB Triage & Patient Mapping platform using breath via Low cost titanium dioxide Nanotube sensor	2015-16	16-27
4	The effects of labour and birth positioning on pelvic dimensions: gaining further insight to improve the birth experience	2015-16	28-36
5	Real world, non-interventional, observational study of Venusia Max Cream as Moisturizer in Psoriasis	2016-17	37-53
6	To evaluate efficacy and safety of Bacillus clausii (2 billion spores/5 ml) suspension as an add on therapy to standard of care in acute viral diarrhoea in children	2016-17	54-69
7	"A 24'week, randomised, doubl€'blind, double-dummv parallel group, multi cenire, active'controlled study to evaluatc cfficacy and safety ofremogliflozin etabonate in subjccts with type'2 diabetes mcllitus.	2017-18	70-104
8	Phase 3 Multicenter Double blind study to evaluate the long term safety and efficacy of barciunib in adult patients with atopic dermatitis	2017-18	105-117
9	A Multicenter Randomized double blind placebo controlled study to evaluate the efficacy and safety of baricitinib in adult patients with moderate to severe atopic dermatitis	2017-18	118-132
10	Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization, a phase IV study.	2018-19	133-175
11	Biomechanical analysis and energy expenditure of traditional, chair and wall Suryanamaskar	2018-19	176-188
12	A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Demonstrate the Effects of Sotagliflozin on Cardiovascular and Renal Events in Patients with Type 2 Diabetes, Cardiovascular Risk Factors and Moderately Impaired Renal Function	2018-19	189-223

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ISB

Economically Developing Countries (EDC) Project
Memorandum of Understanding

Please note this document contains guidelines and examples to assist you when filling in each section. The instructions (highlighted in blue italics) should be deleted when completing this application form.

Declaration by the International Society of Biomechanics (ISB):

The ISB is dedicated to supporting international initiatives that will promote research, education, and the provision of healthcare in the field of biomechanics. The objectives of the ISB, with regards to the advocacy of projects in EDC regions, include the following:

- To make the Society truly international.
- To help develop skills of, and/or opportunities for, clinicians and researchers in EDC who do not have the resources available to do so on their own.
- To provide collaborative learning opportunities for students and researchers in developed countries to help them understand the challenges faced in the developing world.
- To enable donating organizations to do something beneficial with equipment that is no longer needed by them.
- To help provide a sustainable initiative that will allow biomechanics skills and knowledge to flourish in developing regions.
- To enable clinicians and researchers in developing countries to solve biomechanics-related problems specific to their own region.

The ISB would like to ensure the long-term sustainability and overall success of all EDC projects. As such, all participants must be clear on the objectives of the EDC participating organization(s) and the supporting organization(s), in addition to the outcomes each party wishes to achieve. This Memorandum of Understanding is intended to help clarify this for all participants. It is also the framework by which the ISB will evaluate the success of the project in the short and long-term and to find out whether the expected outcomes have been achieved, thereby enabling improvement of this process for future projects.

Participants:

Please list all organizations involved in this project (include those that are supporting the EDC participant by way of equipment donations, technical or financial support, or other resources) and their primary contacts.

	Name of Organization	EDC Participant OR	Supporting Organization	Primary Contact(s)	ISB Member Number*	E-mail
1.	*MGM School of Physiotherapy*	☒	☐	*Dr. Rajani Mullerpatan*	*5043*	*rajani.kanade@gmail.com*
2.	*Indian Institute of Technology, Mumbai*	☐	☒	*Prof. B. Ravi* *Mr. Rupesh Ghyar*	*N/A* *In progress*	*b.ravi@iitb.ac.in*
3.	*Cardiff University*	☐	☒	*Prof. Robert van Deursen*	*1974*	*vandeursenR@cardiff.ac.uk*
4.	*International Society of Biomechanics (ISB)*	☐	☒	*John Challis*	*1192*	*jhc10@psu.edu*

* A minimum of one primary contact from each organization must be a member of the ISB.

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Project Proposal:

To be completed by the **EDC participant**:

1. What is the overall mission of your organization *(e.g. to improve the independence and wellbeing of physically disabled people...)* and how does this project help to support it?

The overall mission of MGMIHS is to provide healthcare services, research and higher education particularly in the area of medicine, nursing, physiotherapy and health management. Within physiotherapy/rehabilitation, training and research in the area of Biomechanics is essential to help maximize functional independence of people with physical impairments resulting from a wide spectrum of conditions i.e. repetitive stress, congenital, developmental and degenerative conditions precipitated by traumatic, vascular and pathologic origin. Precise and complete kinesiological assessment of such conditions will guide clinical decision making for accurate conservative, surgical, prosthetic/orthotic and ergonomic management for maximal functional outcome.

2. What is the primary strategic objective(s) of this project? [Please specify details about one or more of the areas listed below. In formulating your objectives, consider specific results you would like to achieve.]

a. Teaching/educational programs:

- To design and seek approval for a postgraduate degree course in Biomechanics designed at a level of global merit (to enable qualified postgraduates to participate in projects conducted worldwide) and local value to meet specific functional needs of our population emerging from a lifestyle influenced by exclusive Indian culture far different from Western lifestyle.
- Establish training for students from various disciplines such as Physiotherapy, Bio-engineering, Mechanical engineering, Prosthetics - Orthotics and Orthopedics at graduate, postgraduate and PhD level.
- Enhance skills in clinical biomechanics of faculty members of MGMSOP

b. Research programs:

- Produce high end research in the area of human movement science related to clinical questions; to offer health care solutions global in nature and specific to the Indian population.

c. Clinical assessment – diagnosis and treatment:

- Provide precise and complete kinesiological assessment of congenital, developmental and degenerative conditions precipitated by traumatic, vascular and pathologic origin which will guide clinical decision making for accurate conservative, surgical, prosthetic/orthotic and ergonomic management.

d. Other (please specify):

(Include additional lines if necessary)

3. What initiatives/actions (project design and/or management strategies) will be implemented to achieve the results outlined in Question 2?

a) Teaching/Educational programs:

- Curriculum for postgraduate course in Biomechanics will be designed and sought approval from MGMIHS and IIT Mumbai.

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- A circular will be sent to Bio-engineering, Mechanical Engineering, Prosthetics and Orthotics and Orthopedics departments within the above mentioned Institutes to inform students from respective disciplines training schedule in biomechanics.
- Training will be imparted to faculty members in form of continuing professional development.

b) Research programs:

- Collaborative research projects between the 3 organizations will be developed to produce high end research studies encompassing fundamental and clinical biomechanics. PhD students will be appointed on appropriate research projects. Broad areas of research are-
  i. Barefoot walking and the risk of plantar ulceration (in collaboration with IIT Mumbai, Cardiff University)
  ii. Foot and knee instability and the development of OA (in collaboration with Cardiff University and the University of Sydney)
  iii. Yoga postures and their effect on the musculoskeletal system (in collaboration with IIT Mumbai and Cardiff University)

c) Clinical assessment –

- Diagnosis and treatment: Information pertaining to available clinical biomechanical evaluation tools will be circulated to various departments within and outside the hospital within Mumbai and Navi Mumbai. Referred patients will be assessed using biomechanical tools to arrive at precise measurement of impairments. Income generated through such services will be used for financial viability of the center. Expenses incurred for annual maintenance of laboratory equipment will be covered partly from the income generated by the center and partly from the funding acquired for research projects.

4. Who will benefit from this project? *(e.g. Students, patients, etc)*

- Undergraduate and postgraduate students from Physiotherapy, Bio- engineering, Mechanical Engineering, Prosthetics and Orthotics and Orthopedics department will benefit from training. Training will be imparted to students within India and across continents. Every effort will be made to enroll students from within India and countries abroad.
- Faculty members from MGMIHS will benefit from skill development in clinical biomechanics
- A Biomechanics Center with expert input from biomechanics specialists worldwide operated in India will offer global merit training at subsidized cost thereby making it affordable for students from several developing countries.
- Patients with congenital, developmental and degenerative conditions of traumatic, vascular and pathologic origin will benefit from biomechanical evaluation.

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5. What are the expected benefits for each group listed in Question 4? *(e.g. Exposure to state-of-the-art methods of...)*

- Students will be exposed to globally used state-of-the-art valid and reliable methods used for biomechanical studiessuch as quantitative movement analysis and plantar pressure measurement. They will receive hands-on training and have opportunities to use various biomechanical tools to conduct research in biomechanics. Such training of global merit will be available at affordable cost to students from developing countries.
- Patients will benefit from precise and complete kinesiological assessment which will guide clinical decision making for accurate conservative, surgical, prosthetic/orthotic and ergonomic management.
- Faculty members will benefit from acquiring skills for biomechanical evaluation which will be applied in both clinical practice and student training.
- The biomechanics center will benefit from financial viability through the above mentioned expected benefits.

6. Please list proposed milestones – associated with the actions, individuals, and benefits given in Questions 3, 4, and 5, respectively – together with a timeline of events. Milestones should include specific outcomes that the collaborators wish to achieve.

Key Milestones	Time period
1. Establish Biomechanics Center: installation of equipment and pilot start	*December 2013*
2. Collaborative research projects	*Already started. Ongoing*
3. Design the curriculum for Masters degree course in Biomechanics and seek approval from the above mentioned contributing organizations	*September 2014*
4. Commence the course in clinical biomechanics	*January 2015*
5. Commencement of clinical service to patients	*March 2014 onwards*

7. What other authority/administrative body, such as government or college administration officials, must approve this initiative to ensure resources are allocated to the intended recipients? Has approval already been sought *(please provide evidence of any approvals)*?

- Administrative/competent authorities of 3 above mentioned institutes have approved development of the research activities proposed at MGM Center for Biomechanics.
- Additionally, approval will be sought for curriculum for Masters Course in Biomechanics by University Grant Commission, India and Academic Council of MGMIHS.
- The opportunity to develop and approve transnational education in association with Cardiff University will be investigated.

8. What commitments will your organization make to ensure:
   a. Recognition of contributions provided by supporting organizations? *(e.g. Website acknowledgment, progress reports)*

- Publications and patents arising out of collaborative projects with Cardiff University and IIT Bombay will be shared by all 3 above mentioned organizations.
- MGMIHS will acknowledge the support and contribution provided by IIT

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Mumbai and Cardiff University on its website.

- Technical support provided by IIT Bombay will be acknowledged in relevant presentations and publications.
- Secondly, IIT Bombay will have an opportunity to conduct clinical trials at MGM Center for Biomechanics in collaboration with host organization which will be acknowledged in related reports.
- MGMIHS will acknowledge the support and contribution provided by IIT Mumbai, Cardiff University, ISB and AMTI on its website and in relevant publications
- MGMIHS will provide agreed upon (to be decided) educational materials to ISB to further share with ISB members in support to the EDC educational program
- MGMIHS will provide a brief "Project History" for the ISB website

b. Long-term sustainability of the project (including personnel required to ensure continuation of project into the future)? *(e.g. Staff training, technical support, security and maintenance, etc)*

- The host organization i.e. MGM Center for Biomechanics will provide ongoing security and maintenance of equipment.
- Technical guidance for equipment selection and experimental data analysis will be provided by II Bombay. The equipment maintenance will be sought via annual maintenance contract from the respective vendors.
- Staff training will continue as an ongoing process which will be partially supported by MGM Center for Biomechanics.
- Any agreed joint transnational education programs would facilitate staff development.
- Income generated through clinical services will aid financial viability of MGM Center for Biomechanics. For e.g. annual maintenance of equipment and expenses incurred towards consumables.
- Income generated through tuition fees for Masters Course in Biomechanics and PhD program will partially support salary of some staff members.
- Income generated through any agreed joint initiatives would be negotiated as appropriate.
- PhD students will be recruited as research assistants on certain projects.

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Supporting Organizations – Commitments and Anticipated Benefits:

What contributions will be made by the supporting organizations? Please list all support that each participant has agreed to provide *(e.g. financial, in-kind, training, etc)*, the period over which they have committed this support, estimated costs for the organization, and how they will benefit *(e.g. publicity)*.

Organization	Commitments	Duration	Estimated Costs	Objectives/Benefits
MGMIHS	*Allotted infrastructure for Biomechanics Center*	*Ongoing*	*Approx 1 million USD*	*Supports objectives outlined on pg 1.*
	Allotted one competent Professor	*Ongoing*	*Salary is paid by MGMSOP (15,000 USD)*	
	Will recruit one research assistant & one laboratory technician	*Ongoing*	*Salary will be paid by MGMIHS (6000 USD)*	
	Already purchased some equipment such as emed pressure platform, activity monitoring system, Silicon coach etc.			
	Staff training	*2 weeks*		
Cardiff University	*Send Prof. van Deursen for 4-visits*	*4 visits:* *Nov 2013* *May 2014* *Nov 2014* *May 2015*	*Covered by ISB*	*Collaborative Research projects.* *Biomechanics lab design, installation of equipment.* *Provide expertise in curriculum design related to clinical biomechanics.*
IIT Bombay	*Technical guidance and collaborative research projects*	*ongoing*		*Using the MGMIHS Biomechanics lab for purpose of clinical testing of the products which are developed by IIT Bombay.*
ISB	*Financial support to send Prof. van Deursen to MGMIHS*	*4 visits*	*7,503 USD*	*Supports objectives outlined on pg 1; acknowledgment in appropriate media; support for development of EDC educational material.*
	Coordinate donation of two second-hand, re-calibrated force platforms from AMTI with technical support for 5 years	*As soon as available*	*Approx. 30,000 USD*	*AMTI acknowledgment in appropriate.* *MGMIHS and ISB media will strengthen relationship with AMTI.*

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Budget

Before any project can be endorsed by the ISB, a detailed budget for all costs involved for each participating organization must be approved by the ISB President, EDC Project Officer, and ISB Treasurer. In the budget, please consider monetary costs involved in establishing/initiating the project plus ongoing costs to ensure the project is sustainable. Please include the budget as a separate document.

Signatures of primary contact from each participating organization:

Name (please print)	Signature	Date
Dr. Rajani Mullerpatan	RPMullerpatan	25 July 2013
Prof. B. Ravi		1 August 2013
Prof. Robert van Deursen		9 August 2013
Prof. John Challis		22nd Oct. 2013

(Include additional lines if necessary)

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VICON

14 Minns Business Park,
West Way, Oxford OX2 0JB
United Kingdom

COMMERCIAL INVOICE

CONSIGNEE:	SHIP TO:
The Dean Mahatma Gandhi Mission Medical College Plot No. 1 & 2 ,Sector – 18 Kamothe Navi Mumbai-410 209	The Dean Mahatma Gandhi Mission Medical College Plot No. 1 & 2 ,Sector – 18 Kamothe Navi Mumbai-410 209 India

Invoice No.	Invoice Date	Customer	Tax ID	Shipment Method
INV9952AM		MGM PT		NNR CIF Mumbai

Contact	Order Date	Payment Terms	
		NOT APPLICABLE	
Purchase Order		Sales Person	Page
CHARITY DONATION		AR-LFS	1/2

Marks & Nos.		Material Description	Quantity	Amount (CIF)
VBMA SYSTEMS	1	VICON BONITA MOTION ANALYSIS SYSTEM (ALONG WITH STANDARD ACCESSORY)	1EA	38,135.00
			Total CIF	38,135.00
		Total Amount in GBP (CIF) :		**38,135.00**

Value declare for Customs purpose , No Commercial Value

Country of Origin : UK

Manufactured by Vicon Motion Systems Ltd.

AMTI BFA SYSTEMS	1	AMTI BIOMECHANICS FORCE PLATE ANALYSIS SYSEM	2SET	36,533.32
		Total Amount in GBP (CIF)	Total CIF	36,533.32

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VICON

14 Minns Business Park,
West Way, Oxford OX2 0JB
United Kingdom

Value declared for Customs purpose , No Commercial Value

Country of Origin : USA (Imported into the UK by Vicon Motion Systems for consolidated shipment)

Manufactured by AMTI

Total value for shipment CIF Mumbai Airport GBP 74668.32

Invoice Certified True & Correct

Vicon Motion Systems Ltd
14 Minns Business Park
West Way
Oxford OX2 0JB
United Kingdom
Tel: +44(0) 1865 261800
Fax: +44(0) 1865 240527

For and on behalf of
VICON MOTION SYSTEMS LTD

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UNIVERSITY OF UTAH SUBCONTRACT

NO. 10040842-01

BY AND BETWEEN

THE UNIVERSITY OF UTAH

AND

SUBCONTRACTOR

This subcontract (Subcontract) is entered into and effective as of Jan. 27th, 2016 by and between the University of Utah, an institution of higher education for the State of Utah ("University") and Mahatma Gandhi Mission Institute of Health Sciences having their principal place of business at MGM Educational Campus, Sector-1 Kamothe, Navi Mumbai 410209("Subcontractor").

RECITALS

WHEREAS, University wishes to have certain services performed in accordance with the scope of work outlined in this Subcontract; and

WHEREAS, the performance of such services is consistent, compatible and beneficial to the role and mission of Subcontractor; and

WHEREAS, Subcontractor is qualified to provide such services required under this Subcontract.

AGREEMENT

NOW, THEREFORE, for and in consideration of the mutual covenants, conditions and undertakings herein set forth, the parties agree as follows:

1. Scope of Work: Subcontractor agrees to perform for University certain services ("Services") described in the Scope of Work set forth in Appendix A, which is attached hereto and incorporated herein by this reference.

2. Period of Performance. This Subcontract commences on January 27, 2016 and will continue until January 31, 2017("Project Period").

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Budget

Sr. No.	Staff	Cost US $
1	Staff Salary, Compensation, Honorarium	44,400
2	Chemicals , Consumables, Test	30,000
3	Transportation of samples, Travel by Investigators	10,600
4	Volunteer Compensation	8,000
5	Ethical Committee Fee	750
6	Insurance	750
7	Overhead	5,550
	Total	1,00,000

The total budget for the project is $1,00,000 and will be allocated based on the milestones as follows:

- Subcontract $ 50,000
- Milestone 2 $ 45,000
- Milestone 3 $ 5,000

Exhibit B – Background IP

IP Owned by the University

- PCT Patent Application: PCT/US2013/067319
  - Titled: Functionalized nanotube sensors and related methods (filed October 29, 2013)
- Trade secrets
  - Titanium dioxide nanotube sensor production and manufacturing
- Data Platform:
  - IP related to the storage, transmission, or mapping of TB data.

IP Owned by Subcontractor

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Annexure 6c:

Permission to Pursue research From Jt Director Health Services, Govt. of Maharashtra, Health Services

Govt.of Maharashtra, Health Services
Jt.Director of Health Services (Leprosy & TB)
"AROGYA BHAVAN" Opp. Vishrantwadi Police Station,
Alandi Road, Yerwada, Pune-411006.

Jt.Director - ☎ (020) 26686955
Dy Director - 26686951
Office - 26686952-54
Fax – 26686956

Section wise e-mail
TB section- stomh@rntcp.org
Lep section - jtlepnms@rediffmail.com
Est section - jdhsest99@gmail.com

No.Jt.DHS/TB&L/RNTCP/Study Project/ /2015
Date - 30/12/2015 674991-94

To
The District TB Officer,
District TB Centre,
Raigad

Sub: Permission to persue Research Project entitled "Clinical Evaluation of a Breath-based Point-of-Care Test for Diagnosis of Pulmonary Tuberculosis".

Ref :- Proposal from MGM Institute of Health Sciences, Kamothe, Dist. Raigad No. MGMIHS:VC:2015-16:290 dated 08/12/2015 (Copy enclosed)

Dr. Sudhir N. Kadam, Vice Chancellor, MGM Institute of Health Sciences, Kamothe has submitted the proposal for permission to conduct research project on "Clinical Evaluation of a Breath-based Point-of-Care Test for Diagnosis of Pulmonary Tuberculosis".

The project is going to conduct a clinical study to evaluate the sensitivity, specificity and ease of use of point-of-care test for diagnosis of pulmonary tuberculosis. The study will include 1050 adult TB suspects. The TB suspects will be given a non-invasive breath test which will be followed by collection of sputum samples.

The clinical study will be conducted in Rural Hospital, Panvel, Sub District Hospital, Karjat and Babasaheb Ambedkar Municipal Hospital, Khopoli.

The study is definitely useful in implementation of RNTCP and is going to help early diagnosis of Tuberculosis. Therefore the Principal Investigator is permitted to conduct a project on "Clinical Evaluation of a Breath-based Point-of-Care Test for Diagnosis of Pulmonary Tuberculosis".

You are directed to permit the Principal Investigator to conduct the breath test on TB suspects and also permit them to collect sputum samples from TB suspects from institutions mentioned above and also co-ordinate in implementing the project.

Jt. Director of Health Services,
(Leprosy & TB) Pune-6.

Copy to – The Medical Consultants – RNTCP ..... (All)

Copy with compliments to – Dr. Sudhir N. Kadam, Vice Chancellor, MGM Institute of Health Sciences, Kamothe

Copy submitted to – The Director of Health Service, Maharashtra State, Mumbai

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MGM INSTITUTE OF HEALTH SCIENCES, NAVI MUMBAI

Project on Non-Invasive TB Triage and Patient mapping Platform Using Breath via Low-cost TiO2 Nanotubes

RECEIPTS AND PAYMENTS ACCOUNT
For the Period 27-01-2016 to 31-03-2019

Receipts	Amount	Amount	Payments	Amount	Amount
To Opening Balances		0.00	**Expenses**		6636484.00
Balance at IDBI Bank A/c No.	0.00		(Consumables, Chemicals etc.)	975390.00	
			Honorarium	3953712.00	
			Travelling & Transport		
To Recurring Receipts		6850820.00	Expenses	862032.00	
Received from University of Utah	6744196.00		Volunteer Compensation	431500.00	
Interest Earned on Bank A/c	106624.00		Ethical Committee Fees	50000.00	
			Overheads	363850.00	
To Non-Recurring Receipts		265459.00			
Advance from MGM Medical College Navi Mumbai	265459.00				
			By Closing Balances		479795.00
			Balance at IDBI Bank A/c No.	479795.00	
Total		**7116279.00**	**Total**		**7116279.00**

Place: Aurangabad
Date: 10-09-2019

FOR ASHOK PATIL & ASSOCIATES
CHARTERED ACCOUNTANTS
FIRM REGN. NO.: 122045 W

Principal Investigator

Finance officer

(CA SAURABH AGRAWAL)
PARTNER
M. NO.: 131312
UDI NO.: 19131312AAAAHS1985

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MGM INSTITUTE OF HELATH SCIENCES
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NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

A - 2

Nanosynth

Names	MAHATMA GANDHI MISSION		
GL Sub Head	10400	Balance	8,713.00 Cr
Opening Bal.	0.00 Cr	Closing Bal.	8,713.00 Cr
Float Balance	0.00 Cr	Funds In Clearing	0.00
Available Amt.	8,713.00 Cr	Eff. Available Amt	8,713.00 Cr
Cust. Status	GEN GENERAL	A/c. Open Date	31-12-2015
A/c. Status	A Active	A/c. Status Date	31-12-2015
Last Purge Date	30-12-2015		

Address	1A CBD BELAPUR		
City	NMU NAVI MUMBAI	State	MH MAHARASHTRA
Country	IN INDIA	Postal Code	400614
Phone No.	27570219 / 27572293	Telex No.	
Email ID	ACCMGMCBD@GMAIL.COM		

Tran. Date	Value Date	Chq. No.	Withdrawl	Deposit	Balance	Narration
23-03-2019	23-03-2019			75.00 Cr	8,713.00 Cr	Int.:23-12-2018 To 23-03-2019
22-12-2018	22-12-2018			75.00 Cr	8,638.00 Cr	Int.:23-09-2018 To 22-12-2018
22-09-2018	22-09-2018			74.00 Cr	8,563.00 Cr	Int.:24-06-2018 To 22-09-2018
23-06-2018	23-06-2018			1,179.00 Cr	8,489.00 Cr	Int.:25-03-2018 To 23-06-2018
11-05-2018	11-05-2018	569883	3,23,051.00 Dr		7,310.00 Cr	MGM INSTITUTE OF HEALTH SCIENCES KAMOTHE
05-04-2018	05-04-2018			3,23,550.00 Cr	3,30,361.00 Cr	BILL ID ^: 181688FTTI01082^

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
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KAMOTHE, NAVI MUMBAI

Tran. Date	Value Date	Chq. No.	Withdrawl	Deposit	Balance	Narration
05-04-2018	05-04-2018		499.00 Dr		6,811.00 Cr	BILL ID ^: 181688FTTI01082^
24-03-2018	24-03-2018			63.00 Cr	7,310.00 Cr	Int.:24-12-2017 To 24-03-2018
23-12-2017	23-12-2017			63.00 Cr	7,247.00 Cr	Int.:24-09-2017 To 23-12-2017
23-09-2017	23-09-2017			71.00 Cr	7,184.00 Cr	Int.:25-06-2017 To 23-09-2017
24-06-2017	24-06-2017			70.00 Cr	7,113.00 Cr	Int.:26-03-2017 To 24-06-2017
25-03-2017	25-03-2017			7,043.00 Cr	7,043.00 Cr	Int.:25-12-2016 To 25-03-2017
16-01-2017	16-01-2017	569882	29,21,145.00 Dr		0.00 Cr	MGM INSTITUTE OF HEALTH SCIENCES KAMOTHE
24-12-2016	24-12-2016			33,021.00 Cr	29,21,145.00 Cr	Int.:25-09-2016 To 24-12-2016
06-10-2016	06-10-2016	569880	35,00,000.00 Dr		28,88,124.00 Cr	MMGM INSTITUTE OF HEALTH SCIENCES
24-09-2016	24-09-2016			41,219.00 Cr	63,88,124.00 Cr	Int.:26-06-2016 To 24-09-2016
01-09-2016	01-09-2016		1,226.00 Dr		63,46,905.00 Cr	^161688FTTI02298 :^ BILL ID
01-09-2016	01-09-2016			30,07,800.00 Cr	63,48,131.00 Cr	^161688FTTI02298 :^ BILL ID
25-06-2016	25-06-2016			18,565.00 Cr	33,40,331.00 Cr	Int.:01-04-2016 To 25-06-2016
06-05-2016	06-05-2016		1,234.00 Dr		33,21,766.00 Cr	^161688FTTI01261 :^ BILL ID
06-05-2016	06-05-2016			33,23,000.00 Cr	33,23,000.00 Cr	^161688FTTI01261 :^ BILL ID

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
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Dr.Shashank D.Dalvi
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(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

తెలంగాణ तेलंगाना TELANGANA

B 506817

Sl. No. 5798 Date 14/05/2015 Rs. 100/-

Sold to Nagendra

S/o Narayana R/o Seebad

For whom M/s IKP Knowledge Park

NAKKA NAGESHWAR
Licensed Stamp Vendor. Lic. No. 15-07-010/2013
Flat No. 211, 2nd Floor, Silver Oak Apartments,
CHERLAPALLY - 500 051 (R.R. Dist.)
Cell : 9949 110 435

Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

For IKP Knowledge Park
Authorised Signatory

GRAND CHALLENGES IN TB CONTROL AWARD AGREEMENT

THIS AGREEMENT is executed at Hyderabad on this 14th day of December 2015

BETWEEN

IKP KNOWLEDGE PARK, a Company registered under the Company's Act, 1956, having its registered office at Genome Valley, Turkapally, Shameerpet, Ranga Reddy District, Hyderabad 500 078 hereinafter referred to as 'IKP' or 'IKP Knowledge Park' (which expression shall mean and include unless repugnant to the context, its successors, assigns and legal representatives) of the ONE PART represented by its authorized representative, Mrs Deepanwita Chattopadhyay, Chairman & CEO.

AND

MGM Institute of Health Sciences, a deemed university registered under Section 3 of UGC Act, 1956, and having its registered office at MGM Institute of Health Sciences, MGM Educational Campus, Sector - 1, Kamothe, Navi Mumbai 410 209 referred to as the 'Recipient' (which expression shall mean and include unless repugnant to the context, its successors, assigns and legal representatives) of the SECOND PART, represented by its authorized representative, Dr. Sudhir N Kadam, Vice Chancellor

For IKP Knowledge Park
Authorised Signatory

Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

ANNEXURE 3

AWARD NO: GCTBC/C2P1/2015/.12/14/06.....

RECIPIENT: "Non-Invasive TB Triage and patient mapping platform using breath via low-cost Titanium Dioxide Nanotube Sensor"

Expense Heads / Month	1	2	3	4	5	6	7	8	9	10	11	12	Total
Capital Expenses	1,520,000												1,520,000
Rentals													-
Consumables	245,000			500,000		425000							1,170,000
Salaries	80000	80000	80000	80000	80000	80000	80000	80000	80000	110000	110000	110000	1,050,000
IP / Legal Expenses													-
Travel	37500	37500	37500	37500	37500	37500	37500	37500	37500	37500	37500	37500	450,000
Test setup													-
Contingency			50000			50000			50000			50000	200,000
Volunteer Compensation			120000			120000			120000				360,000
Utilities	20000	20000	20000	20000	20000	20000	20000	20000	20000	20000	20000	20000	240,000
												Total	4,990,000
Milestone 1		Approvals & Design of trials											
Milestone 2				Healthy volunteers tested									
Milestone 3							Groups 2 to 5 tested						
Milestone 4										Completion of data collecction			
Milestone 5												Final Report	

Budget:

*Excluding service tax

** Regarding Host Government taxes refer 17(C)(1)(C)

B. Funds Disbursement:

Disbursement will be made in 6 tranches at the following times -

Signing of contract - 40%

Month 2 - 20%

Month 4 - 15%

Month 7 - 10%

Month 10 - 10%

Completion of project - 5% **

Expenses will be reimbursed at cost. Recipient will invoice IKP Knowledge Park with service tax as applicable prior to each tranche. Payment to the Recipient shall be subject to deduction of taxes and levies, as applicable from time to time under various laws in India. Payment to the Recipient by IKP shall be released after verification of the Milestones and expenses incurred. In the normal course payment will be released within 30 days from the date of receipt of the Invoice/Bill along with the requisite documents, complete in all respects.

For IKP Knowledge Park

Authorised Signatory

Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

All amounts will be credited by IKP Knowledge Park to the no lien current account No. 0183104000236140 of MGM Institute of Health Sciences, IDBI Bank, IFSC Code IBKL0000183

For IKP Knowledge Park

Authorised Signatory

Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
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NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

IKP

Ashok Patil & Associates
Chartered Accountants

Certificate No.: APA/MGMIHS/16-17/228

Project Title: Non-Invasive TB triage and patient mapping platform using breath via low-cost titanium dioxide nanotube sensor

This is to certify that MGM Institute of Health Sciences has received funds from IKP Knowledge Park for the above captioned project and made expenditure on the said project as per following details:

Receipts

Sr. No.	Budget line	Funds approved for entire project	Funds Released upto 6th January 2017	TDS	Fund Deposited In Bank
1	Fund Received 16/12/2015	49,90,000.00	19,96,000.00	1,99,600.00	17,96,400.00
2	Fund Received 06/02/2016		9,98,000.00	99,800.00	8,98,200.00
3	Fund Received 30/03/2016		7,48,500.00	74,850.00	6,73,650.00
	Total	49,90,000.00	37,42,500.00	3,74,250.00	33,68,250.00

Payment

Sr. No.	Budget line	Funds approved for entire project	Funds Utilized upto 6th January 2017	Balance as per Budget Head
1	Staff Salary	10,50,000.00	10,45,107.00	4,893.00
2	Equipment	15,20,000.00	15,20,000.00	-
3	Consumable	11,70,000.00	8,30,087.00	3,39,913.00
4	Travel	4,50,000.00	2,10,363.00	2,39,637.00
5	Contingency	2,00,000.00	2,53,125.00	(53,125.00)
6	Volunteers' Compensation	3,60,000.00	50,000.00	3,10,000.00
7	Utilities	2,40,000.00	2,38,950.00	1,050.00
	Total	49,90,000.00	41,47,632.00	8,42,368.00

IKP Knowledge Park has released Rs. 37,42,500/- against total sanctioned amount Rs. 49,90,000/-. Thus, so far Rs. 12,47,500/- is receivable from them by MGM Institute of Health Sciences. The excess amount of Rs. 4,05,132/- has been incurred by MGM Institute of Health Sciences out of its own funds and is receivable from IKP Knowledge Park. Also, it has made payment from MGM Medical College, Kamothe funds to the tune of Rs. 2,25,000/- towards travelling expenses and from MGM Institute of Health Sciences Head Office funds to the tune of Rs. 3,10,000/- towards payment of Volunteers' Compensation. These expenses are also receivable from IKP Knowledge Park. Thus, total amount receivable from IKP Knowledge Park against expenditure incurred out of own funds is Rs. 9,40,132/-

This certificate is issued on the basis of audited balance sheet of MGM Institute of Health Sciences as on 31-03-2016, un-audited books of account from 01-04-2016 to 06-01-2017, invoices, bank statement, and Agreement with IKP Knowledge Park produced for our verification and information & explanations given by MGM Institute of Health Sciences.

Date 08-01-2017
Place Aurangabad

For Ashok Patil & Associates
Chartered Accountants
Firm Regn. No. 122045 W

(CA Anand Lodha)
Partner
M. No. 131344

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

Dr.Shashank D Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

A-3 IKP Project

MGM INSTITUTE OF HEALTH SCIENCES

(Deemed University u/s 3 of UGC Act, 1956)
Accredited by NAAC with 'A' Grade
Sector-01, Kamothe, Navi Mumbai - 410 209.

14th December 2015

Bill To:

IKP Knowledge Park
Grand Challenges in TB Control
Genome Valley, Turkapally Village
Shameerpet, Ranga Reddy District
Hyderabad – 500 078.

Item	Service Description	Amount in INR
Award No. GCTBC/C2P1/2015/ "Non-Invasive TB Triage and Patient Mapping Platform using Breath via Low-cost Titanium Dioxide Nanotube Sensor"	Advance payment for fulfillment of the following milestones: **Milestone 1:** 1) To obtain all necessary approvals 2) To procure equipment and supplies 3) To procure sensors 4) To develop and finalize clinical trial protocols 5) To develop and finalize data collection protocol 6) To develop study design.	(40% of Rs. 49,90,000 as in agreement) Amount: Rs. 19,96,000.00 40% of Project Amount
	Service Tax (@14%)	Nil
	Total	Rs. 19,96,000.00

PAN Card No.: AACTM0014C
Bank Account Details :
Name of Beneficiary : MGM Institute of Health Sciences
Account No.: 0183104000236140
Bank & Address: IDBI Bank, IDBI Building Plot No. 39/40/41 Sector 11, CBD Belapur, Navi Mumbai. IFSC Code: IBKL0000183

For MGM Institute of Health Sciences

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
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Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

for Vice Chancellor
(Dr Chandan Puri)

Philomena

From: MVP Varma [varma@ikpknowledgepark.com]
Sent: Wednesday, December 16, 2015 2:20 PM
To: Chander Puri
Cc: Vineet IKP; Philomena
Subject: Re: IKP Project

Dear Dr. Chander Puri,

GCTBC C2P1 1st Tranche has been processed.

Please confirm the receipt.

Please find below the breakup:

1.Invoice Amount-Rs.19,96,000.
2.TDS-Rs.1,99,600.
3.Paid amount-Rs.17,96,400.

Date:-
IDBI Bank A/c No - 0183104000236140
Rs- 1796400/- Recd

Regards,

Varma

On Tue, Dec 15, 2015 at 1:04 PM, Chander Puri <chander.puri@rediffmail.com> wrote:
Thanks Mr Varma. In voice is being sent. Regards, Chander Puri

On Tue, 15 Dec 2015 12:35:08 +0530 MVP Varma wrote
>Dear Dr. Chander Puri,
Please raise an invoice for 1st Tranche.
Regards,
Varma
On Fri, Dec 11, 2015 at 3:43 PM, MVP Varma wrote:
Dear Dr. Chander Puri,
Please find attached the invoice format for reference.
Let me know if you have questions.
Regards,
Varma
On Fri, Dec 11, 2015 at 3:35 PM, Vineet IKP wrote:
Thanks Sir,
We will wait for it. Meanwhile you can coordinate with Mr. Varma who will guide you on the format for raising the first invoice.
Regards,
Vineet
On Fri, Dec 11, 2015 at 3:29 PM, Chander Puri wrote:
Dear Vineet

Looks like the Contract Document has still not been delivered to you.

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
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Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

IKP TB Proje

Bhimrao Patil

From: Philomena [pvcr@mgmuhs.com]
Sent: Monday, February 08, 2016 5:30 PM
To: 'Varma MVP /IKP/HYD'
Cc: 'Bhimrao Patil'; chander.puri@rediffmail.com
Subject: RE: Second Invoice

Sir,

Noted your e-mail message. We will confirm after checking with our bank by tomorrow.

Thanks and regards
Philomena D'silva

Rs- 898200/- Recd in Bank dated :06/02/16..

From: Varma MVP /IKP/HYD [mailto:varma@ikpknowledgepark.com]
Sent: Monday, February 08, 2016 3:42 PM
To: Philomena
Cc: Chander Puri; Vineet /IKP/BLR
Subject: Re: Second Invoice

Dear Philomena,

We have processed 2nd tranche. Please confirm.

Please find below the breakup:

1. Amount-Rs.9,98,000.
2. TDS-Rs.99800.
3. Paid amount-Rs.898200.

Regards,

Varma

On Wed, Feb 3, 2016 at 5:26 PM, Philomena <pvcr@mgmuhs.com> wrote:

Sir,

Forwarding herewith attached scanned copy of revised Invoice.

Sorry for the inconvenience caused to you.

Thanks and regards

Philomena D'silva

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

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MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

From: Varma MVP /IKP/HYD [mailto:varma@ikpknowledgepark.com]
Sent: Wednesday, February 03, 2016 1:00 PM
To: Philomena
Cc: Vineet IKP; Chander Puri
Subject: Re: Second Invoice

Dear Philomena,

Please check the invoice amount.

2nd Tranche is 20% of Project cost (4990000)=9,98,000.

Regards,

Varma

On Wed, Feb 3, 2016 at 12:35 PM, Philomena <pvcr@mgmuhs.com> wrote:

Dear Sir,

Please find attached scanned copy of the Invoice. Original we will send by courier today.

Thanks and regards

Philomena D'silva

Secretary to Pro Vice Chancellor (Research)

MGM Institute of Health Sciences

(Deemed University u/s 3 of UGC Act 1956)

Post Box No.06, 3rd Floor, MGM Educational Complex

Plot No. 1 & 2, Sector -1, Kamothe

Navi Mumbai - 410 209.

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
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(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

1KP

Transactions Inquiry

A/c. No	**0183104000236140**	CCY / SOL ID	**INR / 183**
Names	**MGM INSTITUTE OF HEALTH SCIENCES**		
GL Sub Head	**10400**	Balance	**3,26,159.00 Cr**
Opening Bal.	**0.00 Cr**	Closing Bal.	**3,26,159.00 Cr**
Float Balance	**0.00 Cr**	Funds In Clearing	**0.00**
Available Amt.	**3,26,159.00 Cr**	Eff. Available Amt	**3,26,159.00 Cr**
Cust. Status	**GEN GENERAL**	A/c. Open Date	**08-10-2015**
A/c. Status	**A Active**	A/c. Status Date	**08-10-2015**
Last Purge Date	**07-10-2015**		

Address	**3RD FLOOR MGM MEDICAL COLLEGE SECTOR 18 KAMOTHE**		
City	**NMU NAVI MUMBAI**	State	**MH MAHARASHTRA**
Country	**IN INDIA**	Postal Code	**410209**
Phone No.	**27422471 / 27421994**	Telex No.	
Email ID	**mgmuniversity@yahoo.com**		

Tran. Date	Value Date	Chq. No.	Withdrawl	Deposit	Balance	Narration
30-12-2016	30-12-2016			2,53,125.00 Cr	3,26,159.00 Cr	MGM INSTITUTE OF HEALTH
24-12-2016	24-12-2016			1,191.00 Cr	73,034.00 Cr	Int.:25-09-2016 To 24-12-2016
19-12-2016	19-12-2016	539480	19,800.00 Dr		71,843.00 Cr	RAJESH KUMAR SUMAN
16-12-2016	16-12-2016	539478	40,000.00 Dr		91,643.00 Cr	RASAYANI :- HARAPRIYA KAR
16-12-2016	16-12-2016	539476	40,000.00 Dr		1,31,643.00 Cr	HARAPRIYA KAR
15-12-2016	15-12-2016	539477	14,620.00 Dr		1,71,643.00 Cr	POONAM PATIL
15-12-2016	15-12-2016	539481	14,620.00 Dr		1,86,263.00 Cr	POONAM PATIL
14-12-2016	14-12-2016			1,00,000.00 Cr	2,00,883.00 Cr	MGM
08-12-2016	08-12-2016	539475	3,723.00 Dr		1,00,883.00 Cr	AKSHAR STATIONARY

Dr. Rajesh B. Goel
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KAMOTHE, NAVI MUMBAI

Tran. Date	Value Date	Chq. No.	Withdrawl	Deposit	Balance	Narration
07-11-2016	07-11-2016	539474	300.00 Dr		1,04,606.00 Cr	METRO STATIO
28-10-2016	28-10-2016	539467	19,800.00 Dr		1,04,906.00 Cr	RAJESHKUMARSUMAN
28-10-2016	28-10-2016	539470	5,317.00 Dr		1,24,706.00 Cr	ABLYCHEM LABORATORIE
27-10-2016	27-10-2016	539473	35,824.00 Dr		1,30,023.00 Cr	RAVRAY COMPUTER
26-10-2016	26-10-2016	539472	55,706.00 Dr		1,65,847.00 Cr	RUSH CHEM
24-10-2016	24-10-2016	539471	27,450.00 Dr		2,21,553.00 Cr	GENEX LIFE SCIENCES
24-10-2016	24-10-2016	539469	75,040.00 Dr		2,49,003.00 Cr	Mr VILAS DAULAPPA IN
19-10-2016	19-10-2016	539466	40,000.00 Dr		3,24,043.00 Cr	HARAPRIYA KAR
14-10-2016	14-10-2016	539468	14,620.00 Dr		3,64,043.00 Cr	POONAM PATIL
13-10-2016	13-10-2016			3,74,250.00 Cr	3,78,663.00 Cr	MGM INSTITUTE OF HEALTH SCIENCES
13-10-2016	13-10-2016	539463	7,856.00 Dr		4,413.00 Cr	SETIA MANINDER SINGH
07-10-2016	07-10-2016	539464	1,600.00 Dr		12,269.00 Cr	PRADIP VISHWAS POTD
05-10-2016	05-10-2016	539465	8,970.00 Dr		13,869.00 Cr	CHANDER PURI
30-09-2016	30-09-2016	539462	25,419.00 Dr		22,839.00 Cr	SYMPHONYTRAVEL
30-09-2016	30-09-2016			25,000.00 Cr	48,258.00 Cr	MGM INSTITUTE OF HEALTH SCIENCES
24-09-2016	24-09-2016			5,224.00 Cr	23,258.00 Cr	Int.:26-06-2016 To 24-09-2016
23-09-2016	23-09-2016	539461	57,500.00 Dr		18,034.00 Cr	CEPHEID INDIA PRIVAT
23-09-2016	23-09-2016	539459	19,800.00 Dr		75,534.00 Cr	RAJESHKUMARSUMAN
20-09-2016	20-09-2016	539458	40,000.00 Dr		95,334.00 Cr	HARAPRIYA KAR
19-09-2016	19-09-2016	539460	14,620.00 Dr		1,35,334.00 Cr	POONAM PATIL
26-08-2016	26-08-2016	467307	7,988.00 Dr		1,49,954.00 Cr	TANGENT SERVICES
26-08-	26-08-	5394	1,00,000.00		1,57,942.00	MGM MEDICAL COLLEGE &

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KAMOTHE, NAVI MUMBAI

Tran. Date	Value Date	Chq. No.	Withdrawl	Deposit	Balance	Narration
2016	2016	55	Dr		Cr	HOSPITAL
25-08-2016	25-08-2016	539457	19,575.00 Dr		2,57,942.00 Cr	Mr VILAS DAULAPPA IN
25-08-2016	25-08-2016	539454	1,750.00 Dr		2,77,517.00 Cr	KHOPOLI XRAY CENTRE
20-08-2016	20-08-2016	539451	19,800.00 Dr		2,79,267.00 Cr	RAJESH KUMAR SUMAN
20-08-2016	20-08-2016	467306	91,125.00 Dr		2,99,067.00 Cr	LAB INDIA
19-08-2016	19-08-2016	467309	2,53,125.00 Dr		3,90,192.00 Cr	INTERNATIONAL MARKET
18-08-2016	18-08-2016	539450	40,000.00 Dr		6,43,317.00 Cr	HARAPRIYA KAR
18-08-2016	18-08-2016	539453	13,830.00 Dr		6,83,317.00 Cr	Mr VILAS DAULAPPA IN
17-08-2016	17-08-2016	467310	2,800.00 Dr		6,97,147.00 Cr	VARSHA PATIL
12-08-2016	12-08-2016	539452	14,620.00 Dr		6,99,947.00 Cr	POONAM PATIL
11-08-2016	11-08-2016	539449	2,600.00 Dr		7,14,567.00 Cr	M S ARUN ARTS
26-07-2016	26-07-2016	467303	40,000.00 Dr		7,17,167.00 Cr	HARAPRIYA KAR
21-07-2016	21-07-2016	467304	19,800.00 Dr		7,57,167.00 Cr	RAJESHKUMARSU
16-07-2016	16-07-2016	467300	5,715.00 Dr		7,76,967.00 Cr	Mr VILAS DAULAPPA IN
16-07-2016	16-07-2016	467301	25,271.00 Dr		7,82,682.00 Cr	SYMPHONYTRAVEL
15-07-2016	15-07-2016	467297	2,131.00 Dr		8,07,953.00 Cr	RESHCON HEALTHCARE P
15-07-2016	15-07-2016	467298	9,629.00 Dr		8,10,084.00 Cr	LAB INDIA
15-07-2016	15-07-2016	467299	8,696.00 Dr		8,19,713.00 Cr	LAB INDIA
14-07-2016	14-07-2016	467305	12,788.00 Dr		8,28,409.00 Cr	PATIL POONAM DH
12-07-2016	12-07-2016	467302	5,607.00 Dr		8,41,197.00 Cr	NAVI MUMBAI -BELAPUR :- SAMIR PACHPUTE
25-06-2016	25-06-2016			12,281.00 Cr	8,46,804.00 Cr	Int.:01-04-2016 To 25-06-2016
17-06-2016	17-06-2016	467288	6,527.00 Dr		8,34,523.00 Cr	AUTOCAL SOLUTIONS PV

Dr. Rajesh B. Goel
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MGM INSTITUTE OF HELATH SCIENCES
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Dr.Shashank D.Dalvi
Vice Chancellor
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Tran. Date	Value Date	Chq. No.	Withdrawl	Deposit	Balance	Narration
2016	2016			Cr	0 Cr	097/IKP KNWLDG PARK BIRAC
23-03-2016	23-03-2016	467272	19,800.00 Dr		8,52,079.00 Cr	RAJESH KUMAR SUMAR
23-03-2016	23-03-2016	467268	19,800.00 Dr		8,71,879.00 Cr	RAJESH KUMAR SUMAN
22-03-2016	22-03-2016	467271	40,000.00 Dr		8,91,679.00 Cr	HARAPRIYA KAR
21-03-2016	21-03-2016	467269	4,845.00 Dr		9,31,679.00 Cr	SAMEER PACHPUTE
21-03-2016	21-03-2016	467273	12,788.00 Dr		9,36,524.00 Cr	POONAM PATEL
12-02-2016	12-02-2016	467266	12,788.00 Dr		9,49,312.00 Cr	POONAM PATIL
12-02-2016	12-02-2016	467265	40,000.00 Dr		9,62,100.00 Cr	HARAPRIYA KAR
06-02-2016	06-02-2016			8,98,200.00 Cr	10,02,100.00 Cr	RTGS/ICICR52016020600798472/IKP KNWLDG PARK BIRAC
04-02-2016	04-02-2016	467264	1,72,500.00 Dr		1,03,900.00 Cr	LABINDIA HEALTH CARE PVT
04-02-2016	04-02-2016	467263	15,20,000.00 Dr		2,76,400.00 Cr	LABINDIA HEALTH CARE PVT
16-12-2015	16-12-2015			17,96,400.00 Cr	17,96,400.00 Cr	RTGS/ICICR52015121600709990/IKP KNWLDG PARK BIRAC

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L'INSTITUT INDO-CANADIEN SHASTRI INDO-CANADIAN INSTITUTE

SHASTRI RESEARCH GRANT (SRG)
Final Report 2015-2016

This report contains three sections, i.e. Section A , B and C.
Section A is to be filled in by the Lead Applicant (and Co-Applicant).
Section B and C are to be filled in by the Canadian and Indian Student/ Research Assistant respectively (when applicable).

SECTION: A

1	Name of Lead Applicant: Dr. Andrea Hemmerich Telephone (land): 613-533-2648 Mobile: 613-301-6354 Fax: 613-533-6489 E-mail: andrea.hemmerich@queensu.ca	Name of Co-Applicant: Dr. Nancy Fernandes Pereira Telephone (land): 91-022-22031879/22087422 Mobile: 9820524750 Fax: 22087422 E-mail: nancyfernandesltcn64@gmail.com
	Name of Lead Applicant's Institution: Queen's University Mailing Address of Lead Institution: 130 Stuart St., Kingston, ON, K7L 3N6, Canada	Name of Co-Applicant's Institution: S.N.D.T. Women's University Mailing Address of Co-Applicant's Institution: Leelabai Thackersey College of Nursing, S.N.D.T.Women's University, New Marine Lines, Churchgate, Mumbai 400 020
2	Name of Canadian student or research assistant (if any): Ms. Emily Geens	Name of Indian student or research assistant (if any): Ms. Shobha Gaikwad
	Name of the Institution: Queen's University Academic Level: Undergraduate Subject of Study: Kinesiology (continuing in Midwifery) Mailing Address : Kingston ON Telephone (land): Mobile: Fax: E-mail: 12elsg@queensu.ca	Name of the Institution: Leelabai Thackersey College of Nursing,S.N.D.T.Women's University,New Marine Lines,Churchgate,Mumbai 400 020 Academic Level: PhD Subject of Study: Labour comfort- Obstertric Nursing Mailing Address : Same as above Telephone (land): 91-022-22031879/22087422 Mobile: 9892130703 Fax: 22087422 E-mail: shobha.gaikwad14@gmail.com
3	Project Title: The effects of labour and birth positioning on pelvic dimension: gaining further insight to improve the birth experience	
4	Project Period: From: Jan 2016 To: Nov 2016	

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3	Project Title: The effects of labour and birth positioning on pelvic dimension: gaining further insight to improve the birth experience	
4	Project Period: From: Jan 2016 To: Nov 2016	
5	a) Please give a brief summary of your project including key research questions.(300 words) Obstructed labour is a leading cause of maternal and newborn mortality. In India where maternal mortality rates are among the highest globally, squatting – a position shown to increase pelvic dimensions – is also more common during daily life. The primary objective of this project was to use a motion capture device to investigate the effects of birthing position on pelvic dimensions in a group of non-pregnant, Indian subjects. A secondary objective was to better understand rural Indian women's current experiences and aspirations around childbirth. A human motion analysis study conducted at the MGM Centre of Human Movement Science (India) will enable calculation of clinically-relevant pelvic dimensions from digitized landmarks using an optical motion capture system. Dynamic analysis of motion, including joint loading and muscle activity, will help explain pelvimetry findings. Three-dimensional positional information generated by the MRI will be used to validate the pelvimetry measurements from motion capture equipment in upright and supine positions. A field study in the rural community of Wauanje allowed investigators to gain insight into actual practices related to childbirth in rural India; women who had recently given birth and obstetrics care providers within the community were asked to guide us through their birth experiences. b) Please describe the major findings-results. (350 words) A) Human motion analysis Magnetic resonance imaging (MRI) data were collected from three participants at Queen's University's MRI Facility. MRI measurements have demonstrated an increase in all pelvic dimensions in the kneel-squat position (used to simulate an upright birth posture) when compared with supine. The largest increase in the sagittal plane was the anteroposterior outlet (0.45 cm) and in the transverse plane the bituberous diameter (0.25 cm). Analysis of laboratory digitizing trials from which pelvimetry measurements are estimated must be further refined to improve accuracy in all positions. Data from three participants demonstrate the greatest consistency between MRI and laboratory measurements in the standing and lithotomy positions. Preliminary results from motion trials show substantial hip and lumbosacral joint extension moments in squatting (greater than 100 Nm and 60 Nm, respectively), while a flexion moment is exhibited at the lumbosacral joint in the all-fours position. Such moments could potentially open the pelvic outlet in squatting while increasing the inlet anteroposterior diameter in all-fours. Further analysis is required to evaluate forces acting on the pelvis in the supine position. Laboratroy digitizing and motion analysis data have been collected from 30 participants to date. B) Perceptions of childbirth in a rural Indian community Interviews were conducted with five healthcare personnel -- including one auxiliary nurse midwife (ANM) and four accredited social health activists (ASHA workers) -- as well as seven mothers in Wavanje village's community centre. Mothers generally described pleasant experiences; the ANM with over 30 years of experience and ASHA workers described normal deliveries without complications and were confident with their skills. Delivery positions were always supine (lying on their backs); neither care providers nor women were aware of other methods of delivery. A tour of the primary health sub-centre in the village revealed sparse surroundings with only the bare minimum in medical technology resources. Only one labour room and one small delivery room having two beds was available for a community serving approximately 4000 people. Pharmacological pain medication is not available at the sub-centre and women have very little space to move around once inside the facility. Instrumental deliveries, including caesarean section, were not conducted at the sub-centre, but rather at the tertiary care facility, MGM Hospital, Kalamboli, located half an hour away from the village. c) How did you measure the results? (250 words) A) MR images were acquired using a 3-Tesla Siemens scanner from each subject in two positions: kneel-squat (yoga child's pose) and supine. Images were segmented and 3D reconstructed using Mimics software. Clinically	

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	Number of Canadian faculty members visiting to India	1 Postdoctoral fellow. (1 faculty member's visit was supported by a separate grant)
	Number of Indian faculty members visiting to Canada	0
	Number of Canadian and Indian students or research assistants involved in your project (if any)	1 Canadian, 4 Indian
	Number of Canadian students visiting India (if any)	0
	Number of Indian student visiting Canada (if any)	0
8	What are your plans for your institutions' future research collaboration based on the activities completed under this project? Further addressing maternal health through women's empowerment, for example, introducing women to squatting position during delivery in rural Indian community (teach and facilitate delivery in squatting position).	
9	What other research collaboration activities are being planned by your institution over the coming 12 to 18 months? 1. Further qualitative field work. Possibilities include: - interviewing Indian women and care providers who have experienced complications during childbirth that occur more commonly in India; - comparison with Canadian women's experiences; - comparative study of birthing experience among two different economic strata. 2. Refinement of quantitative analysis methods; finalizing analyses of quantitative data.	
10	Please describe how dissemination of project information and showcasing of research/project results are done at various levels throughout the project period. (400 words) Local (Canada) - presentations at Queen's University, Ottawa Birth and Wellness Centre; Local (India): - Wauanje Community Centre; plan to conduct a workshop to disseminate the findings to health care providers so that it can be incorporated into practice. - Presentations and discussions with students at SNDT Women's University and MGM Institute of Health Sciences about the research. International - ISB2017 conference, peer-reviewed journals (not during project period).	
11	Is there any success stories with your research/project that you would like to share? Please attach relevant photographs. The seed for this project was initially planted before the birth of my daughter while considering the link between various cultural birthing practices and biomechanical benefits to maternal health. Including the qualitative research component to ensure the relevance and long-term impact of the overall project was crucial. The three-way collaboration between Nancy Fernandes Pereira (SNDT University), Rajani Mullerpatan (MGM Inst of Health Sciences), and my postdoctoral supervisor and I at Queen's University was actualized through the Shastri Research Grant. Travelling to India to meet with my collaborators solidified our mutual understanding of goals and strategies and allowed me to better understand the context of our work. This collaboration was further enhanced through new relationships developed with students and colleagues of the primary collaborators, which will -- undoubtedly! -- pave the way for future research together. - Andrea Hemmerich, August 2016 (Photograph of collaborators prior to Wauanje village visit in April is attached.)	
12	Were there any reports, publications or other educational materials produced as a result of the project? If so, please attach a copy of these documents to your report (Please note that the Institute reserves the right to use relevant information from those documents in its public communication without any further consultation) SNDT report (attached); Conference and journal publications for both qualitative and quantitative parts of the study are anticipated.	

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13	Please attach 2-3 high resolution digital photographs from your SRG project that could be featured in the Shastri Institute's public communication (i.e., annual report, newsletters, etc.) Photos attached: Yes: Yes
14	Please provide a quote based on the experience of your SRG project work that could be used by the Institute for the above purposes. Simplicity of expectation and experience of birthing: a natural process (as viewed by women in rural India). The SRG provided an opportunity for both Canadian and Indian researchers to understand women's birthing experiences from a cultural and biomechanical perspective.
15	**Please note the following for your Financial Reporting:** - **Fill in and attach the financial report form available on the website.** - **Submit scanned copies of all invoices and proof of payments to support your financial report.**
16	Signatures

Signature of Lead Applicant	Signature of Co-Applicant
Date: 07 DEC 2016.	**Date:** 07 Dec 2016

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MGM Institute's University Department of Physiotherapy

Sector-1, Kamothe, Navi Mumbai – 410209

Receipt & Payment Details for the Indocanatian Shastri Foundation

DT	RECEIPT	AMT	PAYMENT	AMT
09/09/2016	GRANT RECEIVED FROM *Indocanatian Shastri Foundation BY NEFT IN BANK*	99367.00	By Petrol & Disel Exp	2100.00
17/11/2016	CASH RECEIVED	2100.00	Petrol & Disel Exp	7000.00
23/11/2016	CASH RECEIVED	7000.00	Store & Consumables (purchased Voltage Convertor for machine)	2750.00
2/2016	CASH RECEIVED	2750.00	Computer Exp (purchased Pen Drive 64GB)	1200.00
16/12/2016	CASH RECEIVED	1200.00		
			Postage Exp (paid to Jet Air Express pvt ltd for custom+courier charges to buy Hard markers from Vicon motion system Ltd)	4560
			Balance from project	94807.00
		112417.00		112417.00

Accountant

Principal

Director

Dr. Rajesh B. Goel
Registrar
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Tranactions Inuiry

A/c. No	**0306104000079417**	CCY / SOL ID	**INR / 306**
Names	**MGM CENTRE FOR HUMAN MOVEMENT SCIENCES**		
GL Sub Head	**10400**	Balance	**1,19,017.00 Cr**
Opening Bal.	**0.00 Cr**	Closing Bal.	**1,19,017.00 Cr**
Float Balance	**0.00 Cr**	Funds In Clearing	**0.00**
Available Amt.	**1,19,017.00 Cr**	Eff. Available Amt	**1,19,017.00 Cr**
Cust. Status	**GEN GENERAL**	A/c. Open Date	**13-05-2016**
A/c. Status	**A Active**	A/c. Status Date	**13-05-2016**
Last Purge Date	**12-05-2016**		

Address	**3RD FLOOR MGM MEDICAL COLLEGE SECTOR 18 KAMOTHE**		
City	**NMU NAVI MUMBAI**	State	**MH MAHARASHTRA**
Country	**IN INDIA**	Postal Code	**410209**
Phone No.	**27422471 / 27421994**	Telex No.	
Email ID	**mgmuniversity@yahoo.com**		

Tran. Date	Value Date	Chq. No.	Withdrawl	Deposit	Balance	Narration
09-09-2016	09-09-2016			99,367.00 Cr	1,19,017.00 Cr	NEFT-1699204494VO1009-QUEENS U
04-08-2016	04-08-2016			14,000.00 Cr	19,650.00 Cr	NAVI MUMBAI - BELAPUR :- CASH RECEIPT
06-07-2016	06-07-2016	171301	3,038.00 Dr		5,650.00 Cr	HINDUSTAN ENTERPRISE
04-07-2016	04-07-2016	171302	6,000.00 Dr		8,688.00 Cr	MEAL BOX
25-06-2016	25-06-2016			38.00 Cr	14,688.00 Cr	Int.:13-05-2016 To 25-06-2016
03-06-2016	03-06-2016			6,000.00 Cr	14,650.00 Cr	NAVI MUMBAI - BELAPUR :- CASH RECEIPT
02-06-2016	02-06-2016			8,650.00 Cr	8,650.00 Cr	NAVI MUMBAI - BELAPUR :- CASH RECEIPT

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MGM SCHOOL OF PHYSIOTHERAPY

Sector-1, Kamothe, Navi Mumbai – 410209

MGM/ SOP/ 253 /2019 Date : 11/6/2019

To,
The Registrar
MGM Institute of Health Sciences,
Kamothe, Navi Mumbai.

Through,
Research Director
MGM Institute of Health Sciences
Kamothe, Navi Mumbai.

Subject : Utilization of funds received for project entitled "The effects of labour and birth positioning on pelvic dimensions: gaining further insight to improve the birth experience"

Respected Sir,

This is to bring to your kind notice that, MGM School of Physiotherapy was working on a collaborative project with Queens University, Canada and SNDT Women's University , Mumbai entitled "The effects of labour and birth positioning on pelvic dimensions: gaining further insight to improve the birth experience" which was funded by Indo Canadian Shastri Foundation.

In view of completion of the project, funds amounting to INR 1,12,417 were deposited in MGM Center of Human Movement Science account..
May we request sanction for utilization of funds as proposed below:

Sr No	Header of Utilization	Beneficiary	Amount in INR
1	University Share – 15 % of total Research grant	MGM Institute of Health Sciences	16,863.00
2	Research Associate on the project	Dr Bela Agarwal(PT)	15,000.00
3	Research Student on the project	Dr. Triveni Shetty(PT)	15,000.00
4	Research co-ordinator for Wavanje Village visit	Dr Jyoti Parle(PT)	5,000.00
5	2 Marker Sets (70-80 markers)	MGMCHMS	42,944.00

Sector 1, Kamothe, Navi Mumbai , E-mail: mgmschoolofphysiotherapy@gmail.com

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6	Hard disk and EMG amplifier	MGMCHMS	17,610.00 * (already spent)
		Total	1,12,417.00

We thank you for your continued support.

Kind Regards,

Dr. Rajani Mullerpatan
Professor – Director

Professor - Director
MGM School of Physiotherapy
MGMIHS, Navi Mumbai

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16/12/2016	CASH RECEIVED	1200.00	Postage Exp (paid to Jet Air Express pvt ltd for custom+courier charges to buy Hard markers from Vicon motion system Ltd)	4560
			Balance from project	94807.00
		112417.00		112417.00

Accountant

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INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

सत्यमेव जयते

Certificate No.	:	IN-KA03262010744535P
Certificate Issued Date	:	18-Mar-2017 11:29 AM
Account Reference	:	NONACC (FI)/ kaksfcl08/ COX TOWN/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKAKSFCL0855290968587626P
Purchased by	:	BIOQUEST SOLUTIONS PVT LTD
Description of Document	:	Article 12 Bond
Description	:	AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	Dr HEMANGI RAJIV JERAJANI
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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----------Please write or type below this line----------

OBSERVATIONAL STUDY SITE AGREEMENT

This Observational Study Site Agreement ("Agreement"), having an effective date of 18-Mar-2017 ("Effective Date"),
between
Dr. Hemangi Rajiv Jerajani, an individual, having an address at MGM Medical College & Hospital, Sector 18, Kamothe, Navi Mumbai-410209, will serve as the principal investigator ("herein after referred to as Principal Investigator"),

Confidential H.R.J

Bioquest Solutions Pvt. Ltd. Bangalore

And

the institution at MGM Medical College & Hospital, located at Sector 18, Kamothe, Navi Mumbai-410209, ("herein after referred to as Institution")

(collectively, Principal Investigator and Institution, with its personnel, officers, board members, affiliates and agents, shall herein after be referred to as "SITE"),

And

BioQuest Solutions Pvt. ltd, with a principal place of business at #24, Wellington St, Richmond Town, Bengaluru, Karnataka 560025. (herein after referred to as the CRO)

CRO, Site, and Principal Investigator are each individually referred to herein as a "Party" and collectively referred to herein as the "Parties."

RECITALS

WHEREAS, by separate MSA dated_____, Dr. Reddy's Laboratories Limited (collectively, with its personnel, officers, board members, affiliates and agents, "SPONSOR"), with a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500034, has engaged CRO, a contract research organization, acting as an independent contractor, to act on behalf of SPONSOR for the purposes of transferring certain obligations in connection to this Agreement, said obligations including negotiation and execution of the Agreement and payment administration of grant amounts in coordination with the SPONSOR and;

WHEREAS, CRO, acting as an independent contractor on behalf of SPONSOR, desires to coordinate an observational study entitled **"Real world, Non-interventional, Observational Study of Venusia® Max Cream as Moisturizer in Psoriasis"** ("the Study"), which shall be conducted according to SPONSOR's Protocol Number GGI-VENUSIA -11-16 ("Protocol") incorporated herein by this reference; and

WHEREAS, SPONSOR has developed an investigational product candidate designated as Venusia Max ("Investigational Product"); and

WHEREAS, SITE has acquired expertise in conducting research evaluations including observational studies; and

WHEREAS, SPONSOR and CRO wish to engage the SITE to facilitate and carry out the Study; and

WHEREAS, SITE has sufficient authority, competence and experience in conducting observational studies and, having reviewed the Protocol, and sufficient information regarding the Investigational Product related to the Study, desires to so participate in the Study as more particularly described in this Agreement; and

Dr. Rajesh B. Goel
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NAVI MUMBAI- 410 209

HRG

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

BioQuest Solutions PVT. LTD. Bangalore

WHEREAS, SITE is willing to undertake the Study for SPONSOR according to the terms, conditions and covenants hereinafter set forth.

NOW THEREFORE THIS AGREEMENT WITNESSETH, that in consideration of the mutual covenants herein contained and other good and valuable consideration exchanged between the Parties, the receipt and sufficiency whereof is hereby acknowledged by the Parties hereto, the parties covenant and agree as follows:

ARTICLE 1

Statement of Work

1.1 SITE will take appropriate direction and supervision from CRO in connection with monitoring, supervision, and carrying out of the Study.

ARTICLE 2

Period of Performance

2.1 The performance of this Agreement shall be from the Effective Date till the date of termination of the Study by SPONSOR, unless earlier terminated in accordance with Article 12 of this Agreement.

ARTICLE 3

Conduct of the Study

3.1 The SITE agrees to conduct the Study in strict accordance with the Protocol attached to this Agreement as Attachment B, as amended from time to time, in accordance with the terms and conditions of this Agreement, and all applicable local laws and regulations applicable to the territory in which the Study is being conducted which is [mention the territory in which the Study is conducted] (herein after collectively referred to as, "Applicable Law").

3.2 The Study will be supervised by the Principal Investigator, who will personally be responsible for the direction of the research and the conduct of the Study in accordance with the applicable policies of the SITE, which the Principal Investigator and Institution represent and warrant are not inconsistent with (1) the terms of this Agreement, (2) the Protocol, (3) generally accepted standards of good clinical practice, and (4) Applicable Law. Principal Investigator shall conduct the Study and use his/her best efforts to complete the Study in a professional manner in accordance with the highest standards in the industry and in strict adherence to sub-parts (1) – (4) of this Article 3.2. If the Study is conducted by a team of individuals including Sub-investigator(s), the Principal Investigator shall be responsible for all Sub-investigators and Study team members utilized in any manner, in connection with the

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Study, and SITE shall instruct each Sub-investigator and team member to follow the direction of the Principal Investigator and otherwise adhere strictly to the Protocol.

3.3 SITE will notify CRO immediately if Principal Investigator is unable to continue as principal investigator for the Study. Institution further agrees that no other investigator may be substituted for the Principal Investigator without the prior written approval of CRO. If for any reason, Principal Investigator is unable to serve as principal investigator, and a successor acceptable to CRO/SPONSOR is not available, this Agreement shall be terminated as provided for in Article 12.2.

3.4 As required by Applicable Law, prior to initiation of the Study, SITE shall ensure that the Protocol has been reviewed and approved by the appropriate Ethics Committee ("EC") and shall provide CRO with evidence of such EC approval pertaining to the: (i) the Protocol and/or any subsequent modifications thereof, and (ii) the informed consent form and/or any subsequent modifications thereof.

3.5 As required by Applicable Law, SITE shall obtain the informed consent of patients to participate in the Study prior to said participation, and shall document the Study patients' informed consent by securing from each patient, his or her signature upon an informed consent form that complies with Applicable Law and is approved by an appropriate Ethics Committee ("EC"), a copy of which shall be retained by the SITE. The Study patient shall also receive a signed copy of the informed consent. Further, the name, medical history, and any and all information relating to a Study patient obtained as a result of or in connection with his or her participation in the Study shall be held in strictest confidence and trust, and shall not be disclosed or transferred to third parties except as expressly permitted by this Agreement or the Protocol.

3.6 SITE shall ensure that Study patients have agreed to participate in the Study as defined by the Protocol to be conducted at the Institution's facilities in compliance with Applicable Law.

3.7 SITE shall undertake to ensure that all Study patients are adequately informed of the aims, methods, anticipated benefits and potential hazards of the Study and the circumstances under which their personal data might be disclosed to relevant third parties including, but not limited to, CRO, SPONSOR and/or its affiliates, competent authorities, and/or ethics committees, in accordance with the requirements for such information as set forth in the Protocol prior to including any subject in the Study.

3.8 Institution and Principal Investigator hereby represents that neither: (a) has a conflict of interest that would affect the conduct of the Study; (b) has received any offer by SPONSOR, CRO and/or their respective representatives or affiliates, of any extra benefit for participation in the Study, including offers to family members. Further, SITE agrees to promptly notify CRO if it becomes aware of any conflict of interest that arises during the term of this Agreement. SITE not enter into any financial security transaction based on the Study data or the Study results. Without limiting the foregoing, SITE acknowledges that as of the date of this Agreement, neither Institution nor Principal Investigator are parties to any oral or written

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contract or understanding with any third party which (i) is inconsistent with this Agreement nor SITE's performance hereunder or (ii) will in any way limit or conflict with SITE's ability to fulfill its obligations under the terms of this Agreement. SITE further represents that it will not knowingly enter and will instruct its sub-investigators not to knowingly enter into any such conflicting agreements during the term of this Agreement

3.9 Adverse Events. SITE shall report to CRO and EC with a copy to SPONSOR, any death, life threatening, or serious adverse event, or other event as specified by the Protocol. Such notification shall be given promptly, and in no instance later than twenty-four (24) hours of becoming aware of such an event and shall be made in accordance with the procedures outlined in the Protocol concerning the reporting of adverse events.

3.10 No changes or revisions in the Protocol shall be made unless first mutually agreed upon in writing by SPONSOR and/or CRO and the SITE, and reviewed and approved by the EC in accordance with Applicable Law. If any changes in the Protocol affect the charge for research conducted in the Study, the SITE shall submit a written estimate of the charges for CRO's and SPONSOR'S prior written approval.

ARTICLE 4

Payment

4.1 In consideration of the work performed by SITE, payments shall be made to the SITE by CRO for evaluable Study patients in accordance with the terms of Attachments A; subject however, to the following terms and conditions:

4.1.1 In the event of early Study termination by SPONSOR, CRO, or the EC, as contemplated under Section 12 herein, the Institution will be reimbursed in full for completed Study patients except that Institution shall not be reimbursed in full or in part for any breach of this Agreement under Section 12.CRO shall reimburse Institution on a prorated basis for enrolled Study Subjects that are terminated early due to Sponsor, CRO, or EC termination of the Study. CRO will compensate Institution for services provided up to the effective date of termination and for any services provided after termination that are necessary to safeguard subject safety or comply with Applicable Law, rules, regulations or CRO requirements.

4.1.2 CRO reserves the right to temporarily withhold payment to Institution if it is determined from a monitoring visit or audit that there are significant errors in the Case record forms (CRFs) or where CRF's were not completed and/or provided to CRO in a timely manner.

ARTICLE 5

Record Keeping and Access

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Confidential

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5.1 Institution and Principal Investigator shall prepare, maintain and retain complete, current, organized, and legible Study documents relating to the performance of the Study which are required to be retained under Applicable Law and the Protocol (collectively, "Study Records") for each Study patient no later than ten (10) days after a visit. SITE shall respond to all data queries within seven (7) days from the date of such request. SITE will ensure that all personnel take appropriate measures to prevent unauthorized access to the electronic data capture system including maintaining confidentiality of their passwords.

5.2 Authorized representative(s) of CRO and SPONSOR, after arranging in advance with the Principal Investigator and the SITE, shall be allowed during regular business hours, and at reasonable intervals, to examine and inspect SITE facilities utilized in the performance of the Study, and to inspect and copy all Study data, records, and work products related to the Study, for purposes of assuring compliance with Applicable Laws, the Protocol, and the terms of this Agreement. Audits shall be at no additional cost to CRO/SPONSOR provided such audits are at mutually agreed intervals and do not significantly alter Institution's ability to meet any deadlines delineated in this Agreement.

5.3 Subject to ownership of intellectual property under Article 8 and SITE's right to publish under Article 6, all results, data, reports, documents, information and the like generated in connection with the Study shall be the property of SPONSOR and shall be delivered promptly to SPONSOR. After the required retention period under applicable law for the Study, SPONSOR will have the option (i) to have the records returned to Sponsor, (ii) to have the records destroyed, or (iii) to continue having the documentation stored as set forth herein (at no additional cost).

5.4 Regulatory Inspections and Audits.

A governmental or regulatory authority (including but not limited to representatives of the FDA or other international health agency or regulatory body, having similar regulatory authority over the subject matter of the Study) may, at reasonable times, examine and inspect the facilities being used to conduct the Study. In the event SITE is notified of any such regulatory inspection of SITE's records, facilities, equipment, or procedures, or other materials (including CRFs and patient medical records to the extent allowed by the informed consent document or other legal disclosure authorization), or request for access to the Principal Investigator and/or any sub-investigators to discuss the Study, SITE shall promptly notify CRO and shall provide CRO with copies of any reports issued by any such regulatory authority, and allow CRO to review and comment on any SITE response to such authority. If Institution is found deficient in any manner and reasonable efforts to correct the deficiency are ineffectual, CRO, in its sole discretion, shall either terminate SITE's continued participation in the Study and/or take such corrective actions as may be agreed between SPONSOR and CRO. It is further agreed that if Institution is notified that the Study is to be the subject of an audit, SITE shall promptly inform CRO and SPONSOR. If a formal response to any audit is required, Institution agrees to permit representatives of SPONSOR to review and comment on such response.

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ARTICLE 6

Publications

6.1 Neither Institution nor the Principal Investigator shall register the Study or Study results on any publicly accessible forum. Institution and Principal Investigator hereby acknowledge and agrees that the CRO/SPONSOR has the right to use the Study results in any manner deemed appropriate to CRO's/SPONSOR's business interests, both during, and following termination of this Agreement and/or the Study.

6.2 The obligations described in this Section shall survive the expiration or termination of the Agreement.

ARTICLE 7

Confidentiality and Use Restrictions

7.1 CRO and/or SPONSOR will disclose to Principal Investigator and Institution, including its employees, agents, directors, and representatives, certain information furnished in any form, including written, verbal, visual, electronic or in any other media or manner, any information that a party would reasonably consider to be confidential or proprietary including, but not limited to, information concerning the Investigational Product, this Agreement, the Protocol, Study results, processes, know-how, discoveries, inventions, compilations, business or technical information, other materials prepared by either Party or their respective affiliates and representatives, containing or based in whole or in part, on any information furnished by the CRO and/or SPONSOR, and the procedures for carrying out the Study, (collectively, "Confidential Information"). SITE will keep, such Confidential Information in confidence and shall not use it for the benefit of nor disclose it to others, except as required by the Study or as defined in the Protocol and will at all times, refrain from any other acts or omissions that would reduce the value of CRO's/SPONSOR's Confidential Information. SITE agrees to ensure that its employees, agents, contractors, representatives, or affiliates (including members of the Study team), who have access to Confidential Information are bound by an obligation of non-disclosure and shall procure non-disclosure agreements with such parties with the same breadth of coverage as provided for in this Section 7. SITE's obligations of confidentiality shall not apply to that part of the Confidential Information that SITE is able to demonstrate by documentary evidence: (i) already in the public domain prior to receipt of such information by SITE, or (ii) that becomes lawfully part of the public domain through no act on the part of the SITE, and/or its employees, agents, and representatives; or (iii) is obtained from a third party without an express obligation of confidence; or (iv) where required by applicable law, regulation, legal process, or other applicable judicial or governmental order to disclose, provided that, should the SITE be required to make such disclosure, where legally permissible, SITE shall provide the SPONSOR and CRO with prompt written notice of such request or requirement so that SPONSOR and CRO may, at its sole expense, seek an appropriate protective order prior to such disclosure; and where SITE is compelled to disclose, SITE shall only disclose that portion of the Confidential Information that SITE is compelled to disclose and will exercise

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reasonable efforts to obtain assurance that confidential treatment will be accorded to that portion of the Confidential Information disclosed; or (v) is approved by CRO/SPONSOR with written authorization for disclosure by the SITE.

7.2 SITE shall return, retain or destroy all Confidential Information to CRO/SPONSOR at their request, at no additional cost, and under all circumstances except where retention of same is required by Applicable Law.

ARTICLE 8

Intellectual Property (IP)

8.1 For the purpose of this Agreement the term "Intellectual Property" or "IP" shall means all patents, trademarks, designs (whether or not registered) and applications therefor, present and future copyright, trade secrets, rights in know-how and other rights of confidence and all other rights of a similar nature or having equivalent or similar effect to any of these which may subsist anywhere in the world. Intellectual Property that either party owned prior to execution of this Agreement, or develops independently of the Study (without the use of SPONSOR IP and/or Confidential Information), is that Party's separate property and is therefore, not affected by this Agreement. Neither party has any claims to, or rights in such intellectual property of the other party.

8.2 The Parties agree that the SPONSOR owns the proprietary rights (whether or not protectable by patent, copyright or other intellectual property rights) to the Study and/or Study data or materials and other reports required to be generated and submitted to the SPONSOR pursuant to the Protocol, and any data compiled therein, or any discovery, concept, or idea arising out of the Study, including but not limited to any/all Intellectual Property and Confidential Information provided to Institution and/or Principal Investigator relating to the Study, or any inventions, mechanisms, substances, works, trade secrets, know-how, methods, or techniques (including improvements), tangible research products, any intellectual property conceived and reduced to practice, made or developed, the Investigational Product, formulation of the Investigational Product, device, or biologic, including its administration or use, alone or in combination with any other drug or device and any related assay or biomarker, or any improvements or methods of using such Investigational Product, existing or pending patents and patent applications, records or compilations of information (excluding records/compilations set forth in Section 8.3 herein), Study data, including records produced by Institution and/or Investigator, innovations of any kind made in performance or carrying out of the Study, and the Protocol, and the like, either of which, in whole or in part, relating to the Study, derived from the use or access to SPONSOR's Confidential Information, or developed conceived or reduced to practice during the course of conducting the Study (collectively, "SPONSOR IP"). The Parties agree that title, interest and rights to any SPONSOR IP shall remain the sole property of the SPONSOR. The parties further agree that neither party will have any proprietary or other ownership rights in any such SPONSOR IP, but that such rights in and to the following will remain with SPONSOR, subject only to the right of Institution and Principal Investigator to use such information for: (i) Institution's own internal, non-commercial research and for

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educational purposes provided such use does not violate SPONSOR's confidentiality rights or impede commercialization; and (ii) if required during the Study, for the provision of standard of care medical treatment for a Study patient, without jeopardizing the SPONSOR's Intellectual Property Rights on such subject matter. This Agreement shall not be deemed or construed to convey or transfer any of such intellectual property rights to SITE except insofar as necessary to permit SITE to conduct the Study which is the subject of this Agreement. SPONSOR and SITE acknowledge that the SPONSOR, owns the proprietary rights to the formulation of the Investigational Product, existing or pending patents and patent applications, trade secrets, know-how, and confidential information related to the Investigational Product and that these and all other proprietary rights shall remain the sole property of the SPONSOR.

8.3 Without SPONSOR's prior written approval, SITE will not knowingly use in the Study, any of its own or any third-party intellectual property that may interfere with SPONSOR's rights to any SPONSOR IP and/or Study Invention. Except as stated elsewhere in the Agreement, the Parties expressly authorize the use and grant a royalty-free license to their respective intellectual property to the other Party and to SPONSOR, to the extent necessary to accomplish the purposes of the Study.

8.4 The SITE will not transfer the Investigational Product or related information to any third party, or otherwise make the Investigational Product or related information available to any investigator other than those listed in the SPONSOR'S Protocol, nor to any clinic or medical facility for use with patients not properly enrolled in the investigational Study, and hereby acknowledges that the SITE shall not use or exploit the results of the Study for any purpose other than that contemplated by this Agreement.

8.5 The obligations described in this Section shall survive the expiration or termination of the Agreement.

ARTICLE 9

Use of Names

9.1 Neither party shall be permitted to use the name, trademark, trade name, logo, or any adaptation thereof, of the Sponsor and/or either Party hereto, in any news or publicity release, policy recommendation, advertisement, promotional material, promotional activity, or in any other commercial fashion, without the prior written consent of the other Party or where applicable, of SPONSOR subject, however, to the following:

9.1.1. CRO/Sponsor may, without prior consent, identify Institution and Principal Investigator as the entity and/or persons conducting the Study;

9.1.2. CRO/SPONSOR may disclose the name of the Institution and the Principal Investigator to investors or potential investors or as required by local laws or security exchange regulations.

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9.1.3. SITE may, without prior consent, disclose their participation in the Study (but only with respect to the indication, treatment period) and may disclose SPONSOR as the source of funding for the Study as well as the Protocol title as necessary to comply with regulatory, academic, and governmental reporting requirements. SITE will not issue and will ensure the Study staff will not issue, any information or statement to the press or public, including but not limited to advertisements for the enrolment of Study patients, without, where appropriate, the review and prior written consent of the CRO and/or SPONSOR.

9.2. Nothing in this Article 9 shall be construed as prohibiting CRO/SPONSOR from submitting reports with respect to the Study to a governmental agency as required by law.

ARTICLE 10

Data Protection and Privacy

10.1 SITE shall undertake to ensure:
10.1.1 that data obtained from the Study patients in connection with the Study is utilized for no purposes other than as outlined in the Protocol and that SITE shall cause such data to be managed in accordance with Applicable Law;

10.1.2 compliance with Applicable Law on the protection of individuals with regard to the processing and free movement of personal data;

10.1.3 that all Study patients are properly informed that the data collected from them may be considered personal data and to obtain from such Study patients written consent to the processing, disclosure, and transfer of this data by SITE, CRO, and SPONSOR;

10.1.4 to provide information as requested by SPONSOR and CRO, to authorize the processing and storage of certain personal identifying information and data concerning a Study patient and/or SITE, and other site personnel involved in the Study for the purpose of fulfilling legitimate business requirements relating to the Study, meeting regulatory requirements, as well as for the purpose of evaluating SITE for inclusion in future studies; and

10.1.5 to obtain the consent of Study team members and all other personnel involved in the Study for the processing of their personal data as required by Applicable Law.

ARTICLE 11

Debarment

11.1 Principal Investigator and Institution hereby certify that they have not been debarred under (a) Applicable Law and (b) or excluded from participation in any government health care program. In the event that during the term of this Agreement, Principal Investigator or Institution (i) becomes debarred or excluded or (ii) receives notice of an action or threat of an

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action with respect to its debarment or exclusion, SITE shall notify SPONSOR and CRO immediately.

11.2 In the event that SITE becomes aware of the debarment/exclusion or threatened debarment/exclusion of any individual, corporation, partnership or association providing services to SITE which directly or indirectly relate to activities under this Agreement, SITE shall notify SPONSOR and CRO immediately. Upon the receipt of such notice by SPONSOR or CRO, or if SPONSOR or CRO otherwise becomes aware of such debarment/exclusion or threatened debarment/exclusion, the provisions of Section 12.2 shall apply.

ARTICLE 12

Termination

12.1 Performance under this Agreement may be terminated by SPONSOR or CRO for any reason or no reason upon thirty (30) days written notice to SITE. Performance may be terminated upon thirty (30) days prior written notice by the SITE if circumstances beyond its control preclude continuation of the Study. However, termination of this Agreement shall not relieve SITE of its obligations under Articles 5, 6, 7, 8 and 9 of this Agreement or any other obligation which is specifically expressed to survive expiry or termination. Other than in cases of termination for breach of this Agreement by SITE, CRO on behalf of SPONSOR shall make all payments due hereunder to SITE for actual costs, non-cancellable commitments incurred in the performance of the research, which have accrued up to the date of such termination, or, in case of a termination of this Agreement pursuant to Section 12.2 (f), up to the date of receipt of such final rejection. Should Institution have received higher payments than the payments due according to the work already performed, Institution shall reimburse the balance to CRO.

12.2 Performance under this Agreement may be terminated by SPONSOR or CRO immediately upon written notice without any further action or notice by either party, in the event (a) SITE ceases operations, is insolvent or unable to pay its debts when they become due; (b) of negligence or wilful misconduct by SITE or its employees, contractors or agents which impacts or reasonably may impact the Study; (c) SITE's breach of this Agreement, or obligation and/or warranty hereof; (d) for reasons related to Study patient safety as determined by SPONSOR and/or CRO; (e) the Principal Investigator ceases or is unable to serve and a successor acceptable to SPONSOR or CRO cannot assume his/her duties within a reasonable period of time; (f) in case any regulatory or legal authorization necessary for the conduct of the Study is finally rejected; (g) in the event that Principal Investigator or Institution becomes debarred, threatened with debarment or any similar proceeding, is excluded from being able to participate in any such Study, and/or utilizes the services of a third party directly or indirectly in order to perform obligations related to the activities under this Agreement that has been debarred, threatened with debarment or any similar like proceeding.

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12.3 Except as otherwise provided above, where either party fails to perform any of its material non-monetary obligations under this Agreement, and does not cure such breach within thirty (30) days of receipt of written notice of such default, then the non-defaulting party, at its option, may terminate this Agreement by giving written notice of termination to the defaulting party. In such event, this Agreement shall terminate on the date specified in such notice.

12.4 Upon completion, termination (early or otherwise), suspension or discontinuation of the Study or upon the request of CRO, Institution and Principal Investigator will immediately cease Study activities and complete its normal Study completion responsibilities in an orderly and safe manner, of which shall include but is not limited to:(i) cooperate promptly and diligently in an orderly and safe manner, in the wind down of the Study, allowing SPONSOR and/or CRO access to records and facilities for Study close-out procedures, requiring Investigator to complete any actions required by the role of Investigator, and transferring to CRO all Study data and, if applicable, the administration and conduct of the Study; (ii) allowing Sponsor and/or CRO access to records and facilities for Study close-out procedures, and requiring Investigator to complete any actions required by the role of Investigator; and (iii) Immediately delivering to the CRO and/or SPONSOR, all Confidential Information, except for copies to be retained in order to comply with Institution's archiving obligations or for evidential purposes.

ARTICLE 13

Liability/Indemnification/Insurance

13.1 CRO. CRO shall be liable for and agrees to indemnify and hold Institution harmless from and against, any and all any/all claims, damages, liabilities and losses (including reasonable attorney's fees and expenses) (collectively, "Losses") arising out of CRO's negligent act, omission or wilful misconduct.

13.2 Institution. Institution shall be liable for, and agrees to indemnify and hold the CRO and Sponsor harmless from and against, any and all Losses caused by or attributable to Institution's (including Investigator), and/or any of its affiliates, subsidiaries, employees (including sub-investigators), officers, directors, contractors, sub-contractors, consultants or agents (collectively, "Representative(s)"): (i) negligent acts, omissions, wilful or intentional and/or professional malfeasance or misconduct of any Representative(s) involved in the Study; and (ii) breach of any of the terms of this Agreement or for violation of Applicable Law.

EXCEPT WITH RESPECT TO A PARTY'S INDEMNIFICATION OBLIGATIONS IN SECTIONS 13.1 AND 13.2 OR OTHERWISE SEPARRATELY AGREED IN WRITING, NEITHER PARTY SHALL BE LIABLE FOR ANY SPECIAL, INCIDENTAL, PUNITIVE, INDIRECT OR CONSEQUENTIAL DAMAGES OF ANY KIND, INCLUDING LOST PROFITS, WHETHER OR NOT A PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS OR DAMAGE.

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13.3 Insurance

Institution represents that it will maintain general and professional liability insurance and if applicable, workers compensation insurance, covering Institution's liability and the liability of its employees (including, Investigator and sub-investigator(s)) and its trustees, officers, agents, or directors, in amounts sufficient to adequately cover its obligations hereunder. Institution shall maintain such coverage for the duration of this Agreement and if the policy is claims-made, for two (2) years thereafter. Institution will provide evidence of all such coverage upon request. Institution will notify CRO within twenty (20) days of any notice of cancellation, non-renewal, or material change in its insurance coverage.

13.4 The obligations described in this Section 13 shall survive the expiration or termination of the Agreement.

ARTICLE 14

Miscellaneous

14.1 Assignment and Succession

This Agreement and the rights and obligations hereunder granted to and undertaken by CRO may be assigned by CRO and/or SPONSOR without prior written approval of SITE. Neither this Agreement, the obligations hereunder nor the rights granted to the SITE under this Agreement shall be assignable or otherwise transferable by the SITE without the prior written consent of CRO. Any such assignee of the SITE shall be bound by the terms hereof as if such assignee were the original party hereto. Any assignment in violation of this provision shall be deemed null and void and of no effect.

14.2 Independent Contractor Status

In the performance of this Agreement the Principal Investigator and Institution shall be independent contractors with respect to CRO and SPONSOR. Neither Principal Investigator nor Institution is authorized to act as the agent for CRO or SPONSOR. CRO and SPONSOR shall not be bound by the acts of the Principal Investigator or Institution.

14.3 Notices

Any notices concerning the administration of this contract which are required or permitted by this contract shall be delivered by hand, sent by mail, or by facsimile to the following party:

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Quest Solutions Pvt. Ltd. Bangalore

to INSTITUTION:

Institution Address:
MGM Medical College & Hospital
Sector 18, Kamothe, Navi Mumbai-410209

Attention: Dr. Hemangi Jerajani

Telephone:9820031483

To INSERT CRO NAME/ADDRESS:

BioQuest Solutions Pvt Ltd
#24, Wellington street, Richmond town
Bangalore - 560025

and to SPONSOR at:

Dr. Reddy's Laboratories, Limited
8-2-337, Road No. 3, Banjara Hills
Hyderabad, Telangana 500034 (INDIA)
Fax: +914049002999

or to such other addresses as specified by the Parties in writing.

14.4 Applicable Law

This Agreement shall be governed by the laws of India. Any proceeding arising out of or relating to this Agreement shall be brought in the courts located in Hyderabad. Each of the Parties irrevocably submits to the exclusive jurisdiction of such court in any such proceeding, waives any objection it may now or hereafter have to venue or to convenience of forum, agrees that all claims with respect to this Agreement shall be heard and determined on in such court, and agrees not to bring any claim arising out of or relating to this Agreement in any other court.

14.5 Impossibility and Waiver

In the event that any further lawful performance of this Agreement or any part thereof by any party hereto shall be rendered impossible by or as a consequence of any law or administrative ruling of any government, or political sub-division thereof, having jurisdiction over such party, such party shall not be considered in default hereunder by reason of any failure to perform occasioned thereby.

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

BioQuest Solutions Pvt. Ltd. Bangalore

14.6 Force Majeure

Any delays in or failure by either party in performance of any obligations hereunder shall be excused if and to the extent caused by such occurrences beyond such party's reasonable control, including but not limited to acts of God, strikes, or other labor disturbances, war, whether declared or not, sabotage, and other causes, whether similar or dissimilar to those specified which cannot reasonably be controlled by the party who failed to perform.

14.7 Conflict between Agreement and Protocol

If the event provision of this Agreement conflicts with a provision of the Protocol relating to the conduct of the Study, the Protocol shall take precedence on matters of medicine, science and Study conduct. This Agreement takes precedence in any other conflicts.

14.8 Third Party Beneficiaries

Notwithstanding any other provision in this Agreement to the contrary, the Parties agree that the SPONSOR is an intended third-party beneficiary of this Agreement and shall have the full right to enforce any and all obligations owned to it as through it were a party to the Agreement.

14.9 Severability

The provisions of this Agreement shall be deemed severable. Therefore, if any part of this Agreement is rendered void, invalid or unenforceable; such rendering shall not affect the validity and enforceability of the remainder of this Agreement unless the part or parts which are void, invalid or unenforceable as aforesaid shall substantially impair the value of the whole agreement to either party.

14.10 Integration and Amendment

This Agreement sets forth the entire agreement between the parties and merges all prior communications relating to the subject matter contained herein and may not be modified, amended or discharged except as expressly stated in this Agreement or by a written agreement signed by the parties hereto.

14.11 Warranties

Principal Investigator and Institution, for itself and its officers and directors, warrant and represent that they: (a) possess the necessary resources, skills, expertise and training to complete the Protocol professionally and competently; (b) are familiar with current laws and regulations related to the Study, and maintain a program for regularly updating their familiarity and compliance with such laws and regulations; (c) are licensed and in good standing with all necessary and appropriate government agencies; (d) have never been disciplined or debarred by any government agency; (e) have never been convicted of a

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felony; (f) are not currently the subject of any regulatory, civil or criminal investigation; and (g) shall maintain and provide evidence upon request comprehensive general liability insurance, professional liability insurance and worker's compensation insurance.

14.13 Counterparts

This Agreement may be executed in any number of counterparts, each of which counterparts, when so executed and delivered, shall be deemed to be an original, and all of which counterparts, taken together, shall constitute one and the same instrument. Facsimile and PDF signatures shall be treated as original signatures.

14.14 Headings

Headings are used in this Agreement for convenience only and shall not affect any construction or interpretation of this Agreement.

IN WITNESS, WHEREOF, the parties hereto have caused this Agreement to be executed in duplicate as of the date and year first above written.

to INSTITUTION:

PRINCIPAL INVESTIGATOR

By: H.R. Jerajani

Printed Name: Dr. H.R. Jerajani

Title: Professor & HOD, Dept of Dermatology

Reg. No. MMC 37586

Professor and H.O.D.
Department of Skin and VD
MGM Medical College
Kamothe, Navi Mumbai

BioQuest Solutions Pvt. Ltd

By: _____

Printed Name: Gautam. V. Sathia

Title: MD & CEO.

INSTITUTION

By: _____

Printed Name: Dr. G.S. Narshetty

Title: Dean

Dean.
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

MGM Institute Of Health Sciences (HO) University

Head Office- 3rd Floor, MGM Education Complex,
Plot No-1 & 2,Sect-1,Kamothe,Navi Mumbai.

Biqquest Solutions Pvt Ltd

Ledger Account

1-Apr-2017 to 31-Mar-2018

Date		Particulars	Vch Type	Vch No.	Debit	Credit
15-11-2017	Dr	**(as per details)**	IDBI Receipts	392		1,20,000.00
		Convocation Fees	**1,000.00 Cr**			
		IDBI Bank S A/c-0183104000132763	**1,09,000.00 Dr**			
		T D S Receivable 2017-2018	**12,000.00 Dr**			
		Being fees collection report of Misc DCR REC. Dt-15/11/2017 Rs. 108000/-received from Biqquest Solution Pvt Ltd				
						1,20,000.00
	Cr	**Closing Balance**			1,20,000.00	
					1,20,000.00	**1,20,000.00**

Actual Amount 120000/-
Less: TDS 12000/-
108000/-

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KAMOTHE, NAVI MUMBAI

महाराष्ट्र MAHARASHTRA ◑ 2017 ◑ RW 447661

प्रधान मुद्रांक कार्यालय, मुंबई
प.मु.वि.क्र. ८०००००३
- 5 MAY 2017
सक्षम अधिकारी

AGREEMENT FOR FUNDING/ FACILITATING INVESTIGATOR INITIATED STUDY

श्री. उ. को. पाटील

This Funding / Facilitating Investigator Initiated Study agreement ("Agreement") is made as of this 05th day of May 2017(the "Effective Date") by and among

Wockhardt Limited a Company organized and existing under the Indian Companies Act, 1956 and having its registered office at D-4, MIDC, Chikalthana, Aurangabad-431006, and Global headquarters at Wockhardt Towers, Bandra-Kurla Complex, Bandra East, Mumbai – 400 051, which expression shall unless repugnant to the context or to the contrary to the meaning thereof, be deemed to mean and/or include its successors in business and permitted assigns ("Wockhardt") and

Dr Nimain C Mohanty associated as Professor of Paediatrics with Mahatma Gandhi Medical College (MIHS) situated at Sector 1 Kamothe, Navi Mumbai 410209, Maharashtra India.

Wockhardt is a pharmaceutical Company engaged inter alia in the business of manufacturing and/or marketing of various active pharmaceutical ingredients and pharmaceuticals in finished dosage forms.

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KAMOTHE, NAVI MUMBAI

Investigator is an individual from a health care institution engaged inter alia in the business of undertaking clinical studies including but not limited to Interventional clinical studies, Prospective observational clinical studies, Retrospective (records based) human subject research. Investigator has also represented that it has obtained all licenses, authorizations and permissions required under law for providing the services contemplated under this agreement and that all such licenses, authorizations and permissions are in full force and effect, at present and during the term of this agreement.

For Investigator Initiated Study (IIS), Wockhardt would fund/ facilitate the Investigator Initiated Study in form of Grants, investigational products, resources, materials or support in developing study documents and/ or manuscript/ poster based on the study results IIS from time to time, to support the conduct of investigator-initiated study entitled "A prospective, randomised, parallel group, single centre study to evaluate efficacy & safety of Bacillus clausii (2 Billion Spores per 5 mL) suspension as an add on therapy to standard of care in acute viral diarrhea in children" by the Investigator at the Institution.

Wockhardt, Institution and Investigator agree as follows:

I) Responsibilities of Investigator and Institution

a. The Investigator shall conduct IIS (as defined below) at the Institution mutually agreed upon by Wockhardt and Investigator specified in writing from time to time, in accordance with this Agreement, IIS proposal, Protocol for the study, Good Clinical Practices (GCP) and all applicable laws, rules and regulations and with the standard of care customary in the area of clinical research.

b. Institution will ensure that the investigator complies with Institution's policies and procedures, including any applicable financial policies as well as applicable regulations. Institution will notify Wockhardt if there is any conflict between the terms of this agreement or any Investigator Initiated Study (IIS) Concept/ Proposal form and any such policy or procedure or applicable regulations and the parties will attempt to reach and appropriate accommodation.

c. IIS will be conducted by the investigator at the institution with the necessary prior approval and ongoing review of all appropriate and necessary review authorities and in accordance with all requirements of the institution and all applicable laws and regulations.

d. Each IIS would be conducted in accordance with the protocol developed by the Investigator. If required, Investigator can also request Wockhardt to extend its support in protocol and other essential document preparation on submission of its idea or proposal in "Outline of Investigator Initiated Study (IIS) Concept/ Proposal" form.

e. Investigator agrees not to implement any deviation from or changes to the Protocol without prior ethics committee approval, except as necessary to protect the safety, rights or welfare of a patient enrolled in the Study.

f. Investigator shall promptly report to Wockhardt any significant developments that may occur during the Study, including but not limited to adverse events, serious adverse events related to Wockhardt's investigational product. In case of serious adverse events, Investigator shall address any further information request by Wockhardt's Pharmacovigilance department to meet applicable regulatory requirements.

g. Investigator and the institution agree to permit representatives of Wockhardt and other regulatory authorities having jurisdiction over the Study to examine at any reasonable time during normal business hours (i) the facilities where the Study is being conducted, (ii) raw study data and (iii) any other relevant information necessary for Wockhardt or 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. Investigator shall notify Wockhardt immediately if regulatory authority schedules or, without scheduling, begins such an inspection.

Investigator is an individual from a health care institution engaged inter alia in the business of undertaking clinical studies including but not limited to Interventional clinical studies, Prospective observational clinical studies, Retrospective (records based) human subject research. Investigator has also represented that it has obtained all licenses, authorizations and permissions required under law for providing the services contemplated under this agreement and that all such licenses, authorizations and permissions are in full force and effect, at present and during the term of this agreement.

For Investigator Initiated Study (IIS), Wockhardt would fund/ facilitate the Investigator Initiated Study in form of Grants, investigational products, resources, materials or support in developing study documents and/ or manuscript/ poster based on the study results IIS from time to time, to support the conduct of investigator-initiated study entitled "<<IIS project title>>" by the Investigator at the Institution.

Wockhardt, Institution and Investigator agree as follows:

I) Responsibilities of Investigator and Institution

a. The Investigator shall conduct IIS (as defined below) at the Institution mutually agreed upon by Wockhardt and Investigator specified in writing from time to time, in accordance with this Agreement, IIS proposal, Protocol for the study, Good Clinical Practices (GCP) and all applicable laws, rules and regulations and with the standard of care customary in the area of clinical research.

b. Institution will ensure that the investigator complies with Institution's policies and procedures, including any applicable financial policies as well as applicable regulations. Institution will notify Wockhardt if there is any conflict between the terms of this agreement or any Investigator Initiated Study (IIS) Concept/ Proposal form and any such policy or procedure or applicable regulations and the parties will attempt to reach and appropriate accommodation.

c. IIS will be conducted by the investigator at the institution with the necessary prior approval and ongoing review of all appropriate and necessary review authorities and in accordance with all requirements of the institution and all applicable laws and regulations.

d. Each IIS would be conducted in accordance with the protocol developed by the Investigator. If required, Investigator can also request Wockhardt to extend its support in protocol and other essential document preparation on submission of its idea or proposal in "Outline of Investigator Initiated Study (IIS) Concept/ Proposal" form.

e. Investigator agrees not to implement any deviation from or changes to the Protocol without prior ethics committee approval, except as necessary to protect the safety, rights or welfare of a patient enrolled in the Study.

f. Investigator shall promptly report to Wockhardt any significant developments that may occur during the Study, including but not limited to adverse events, serious adverse events related to Wockhardt's investigational product. In case of serious adverse events, Investigator shall address any further information request by Wockhardt's Pharmacovigilance department to meet applicable regulatory requirements.

g. Investigator and the institution agree to permit representatives of Wockhardt and other regulatory authorities having jurisdiction over the Study to examine at any reasonable time during normal business hours (i) the facilities where the Study is being conducted, (ii) raw study data and (iii) any other relevant information necessary for Wockhardt or 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. Investigator shall notify Wockhardt immediately if regulatory authority schedules or, without scheduling, begins such an inspection.

h. Investigator agrees to maintain records and data related to the IIS in compliance with all applicable laws and regulations.

i. An adverse event is considered to be an unintended and noxious clinical occurrence or laboratory test result observed in a Subject receiving a drug, which is related in time but not necessarily caused by the administration of the Study Material. It is considered as "serious" if the adverse event is life - threatening, requires or prolongs hospitalization, causes persistent relevant disability or incapacity, consists of congenital anomaly, results in death or requires intervention to avoid any of the mentioned serious medical outcomes. Furthermore, any event is to be evaluated if that event could affect the safety of the Subject or the conduct of the Study. The Institution and Investigator is obliged to inform Ethics committee and of any adverse events or serious adverse events occurring during IIS in accordance with the applicable rules and regulations.

j. The progress and results of the IIS will be collected, analyzed, and adequately reported to Wockhardt by the Investigator, including, at a minimum, submission of periodic progress, final study report and safety information.

k. The Investigator takes full responsibility for the design, initiation, management, data analysis and reporting of the study (including local regulatory obligations). Based on scientific merit and request by the IIS investigator, Wockhardt may consider providing on a case-by-case basis additional support (e.g., laboratory analysis, vendor for data management).

l. The provision of funding or facilitation by Wockhardt does not create any liability, explicit or implicit, on Wockhardt in respect of the manpower engaged in the Project by the Investigator or Institution.

m. In case of unilateral decision by any Investigator or Institution to abandon the project of any of the terms and conditions, the unutilized amount to be paid back to Wockhardt or for breach of any of the terms and conditions by any Investigator or Institution, the entire amount released by Wockhardt with interest to be paid back.

n. Cooperate with the Monitoring Committee / Wockhardt / its representative by providing it the requisite information and if requested, access to the premises where the project activity is being carried out;

o. Assist wherever necessary, the Monitoring Committee / Wockhardt / its representative with requisite technical inputs / facilities to help accomplish the objectives of the project;

p. Abide by the decision of the Monitoring Committee / Wockhardt / its representative on the assessment of the progress in the project and the modification in the objectives, outputs, milestones, targets, funding, as also the foreclosure of any activity or subproject;

q. In case of reorganization of Institution through merger, acquisition, termination, closure etc, the Institution undertakes to settle the Wockhardt's fund, even prior to initiating such measures.

II) Responsibilities of Wockhardt

a. Wockhardt agrees to provide funding or facilitation to the Investigator Initiated Study IIS as mutually agreed upon by the Investigator and Wockhardt and as mentioned in Outline of Investigator Initiated Study (IIS) Concept/ Proposal form. IIS Grants would be provided to the Institution and not directly to the Investigator. IIS Grants shall be solely used for the purpose as defined in this agreement.

b. Wockhardt will monitor the IIS investigators compliance and adherence to their contractual obligations related to disclosure of IIS findings, agreed upon milestones, and safety information reporting.

c. Wockhardt does not request any subject level data that could include protected health information as that termed defined in the privacy rule enacted pursuant to the health insurance portability and accountability ACT of 1996 from IIS supported with IISG from Wockhardt. However, Wockhardt shall gain access to the IIS data generated from IIS supported by Wockhardt that included protected health information for the purpose of ensuring that the funds/ facilitation is being utilized by the investigator and institution for the IIS as per the terms of this agreement. Wockhardt will take appropriate measures to protect the confidentiality and security of that protected health information during this process.

III) Financial Conditionalities

a. The Institution shall ensure that the Wockhardt's funds of the project are utilized only for the project as per this Agreement. Without the approval of Wockhardt, the institution will not affect re-appropriation of funds from one budget head to other.
b. The institution shall immediately refund to Wockhardt any funds released by Wockhardt remaining with it unutilized on foreclosure or completion of the project.
c. Wockhardt shall retain the right to transfer the capital assets acquired (with Wockhardt funds) during the tenure of the project or after completion of the project.
d. The provision of the loan/grant to the institution does not create any liability explicit / implicit on Wockhardt of the manpower engaged by the industry for the project.

IV) IIS Review Committee

a. IIS Review Committee shall monitor the project for achieving the defined objectives in the time and costs projected. The terms of reference to the IIS Review Committee are:

    i. To review and examine the progress of the project in conformance with the deliverables/milestones, targets and objectives set as contained in the agreement;
    ii. revising the funding support to any / or all implementing parties;
    iii. To advise on issues related to publications and securing of IPR individually or severally by the implementing parties; and
    iv. Any other matter as referred to by Wockhardt

V) Completion

The project envisaged shall be deemed to have been successfully completed, as assessed by IIS Review Committee. In case, during the tenure of the project, it is found that the project or any project component is not likely to lead to successful completion, the IIS Review Committee may decide to foreclose the project or the project component as warranted. The decision of the IIS Review Committee is fully binding on all the participants.

VI) Term and Termination

a. The term of this Agreement shall begin on the Effective Date and terminate upon the completion of the Study and the submission of all information and reports as described in the Protocol or upon expiry of two (2) years, whichever is later, unless sooner terminated as provided herein. The validity period of this Agreement may be extended or amended or renewed by express mutual consent of the parties conveyed in writing.

b. The Agreement may be terminated by the Wockhardt at any time upon thirty (30) days prior written notice, except that the Investigator may terminate the Study immediately upon written notice to the other parties if necessary to protect the health, welfare or safety of any research subject.

c. That Wockhardt will terminate this Agreement if there is a material breach of this Agreement and also there is violation of clauses VII, VIII, X, XI of this Agreement.

d. In the event that Wockhardt receives notice from Investigator or otherwise becomes aware that a debarment action has been brought against or threatened against Investigator, Wockhardt may terminate this Agreement immediately. In the event of termination hereunder, Investigator shall without undue delay deliver to Wockhardt all data required under this Agreement.

e. Total grant payable by Wockhardt pursuant to this Agreement shall be equitably prorated for actual work performed to the date of termination with any unexpended funds previously paid by Wockhardt to Investigator being refunded to Wockhardt.

f. Upon termination or expiration of this Agreement, neither Investigator/Institution nor Wockhardt shall have any further obligations under this Agreement, or in the case of termination or expiration of a IIS proposal, under such Proposal, except that (a) Investigator/Institution shall terminate all Services in progress in an orderly manner as soon as practical and in accordance with a schedule agreed to by Wockhardt , unless Wockhardt specifies in the notice of termination that Services in progress should be completed, (b) Investigator/Institution shall deliver to Wockhardt any Materials in its possession or control that was supplied by Wockhardt for the IIS, (c) Wockhardt shall pay Investigator/Institution any monies due and owing Investigator/Institution, up to the time of termination or expiration, for Services actually performed, all authorized expenses actually incurred (as specified in the applicable IIS proposal) and any additional fees associated which were duly approved by Wockhardt with the termination, (d) Investigator / Institution will refund or adjusted /reduced invoice of any payment made by Wockhardt for which Investigator/Institution is not able to provide the Services and e) Investigator/Institution shall immediately return to Wockhardt all Wockhardt's Confidential Information and copies thereof provided to Investigator/Institution under this Agreement or under any IIS proposal which has been terminated or has expired.

VII) Intellectual Property / Ownership and Use of Data .

a. All clinical data, case report forms, documents, information, clinical specimens and results prepared and developed by the Investigator in connection with the IIS or this Agreement whether in written or electronic form (collectively the "Information") shall remain the property of Investigator or Institution. However, Investigator shall provide brief summary of results of the IIS to Wockhardt and permit Wockhardt to use the same any way it deems legally appropriate. Further, investigator and institution agrees to provide Wockhardt a copy of any article/ abstract/ poster published or presented based on the resulted on this IIS for their internal use.

b. All Materials provided to Investigator/ Institution by Wockhardt for the performance of Services and all associated intellectual property rights shall remain the exclusive property of Wockhardt. Investigator/ Institution shall use materials provided by Wockhardt under any IIS proposal solely for rendering the Services under the applicable IIS proposal. Wockhardt will provide Investigator/ Institution with any relevant occupational safety information known by Wockhardt, including a Material Safety Data Sheet (MSDS). Any Materials remaining upon completion of the Services under IIS proposal shall be, at Wockhardt's direction, either returned to Wockhardt or destroyed.

c. In the event that Investigator/ Institution conceives, produces and/or reduces to practice inventions relating to any Material transferred to Investigator/ Institution in the course of or in connection with the Services, including without limitation any new uses or formulations of or improvements to such Material, the parties hereto acknowledge and agree that Wockhardt shall share, title and interest in such improvements and shall share all related documents to the Wockhardt without any cost.

d. Investigator/Institution hereby assigns and agrees to share with Wockhardt title to the Results, including any intellectual property rights embodied in or derived from such Results (whether or not protectable under patent, copyright, trade secret or similar laws).

e. Investigator/Institution shall maintain all materials and all other data and documentation obtained or generated by Investigator/ Institution in the course of IIS duration hereunder, including all computerized records and files (the "Records") in a secure area reasonably protected from fire, theft and destruction and shall make them available for review by Wockhardt as and when requested.

f. All Records shall be (i) retained by Investigator/ Institution for a period of five (5) years, or as a matter of law or regulation or (ii) disposed of, at their discretion, unless such Records are otherwise required to be stored or maintained by Investigator/ Institution as a matter of law or regulation. In no event shall Investigator/ Institution dispose of any such Records without first giving Wockhardt sixty (60) days' prior written notice of its intent to do so for the purpose of any verification or review prior to disposal as it deems appropriate. Notwithstanding the foregoing, Investigator/ Institution may retain copies of any such Records as are reasonably necessary for regulatory or insurance purposes, subject to Investigator/ Institution's obligation of confidentiality.

VIII) Confidential Information

a. The Investigator/ Institution ("Receiving Party") acknowledges that certain confidential information and data relating to the Wockhardt ("Disclosing Party") and its activities shall be furnished in connection with the purpose. Such information and data shall hereinafter be referred to as "Confidential Information" and shall include collectively and individually all or any proprietary and confidential information and data in any form whether oral, written or in electronic form relating to plans, products, intellectual property (including but not limited to information related NCE, patents, patent applications, trademarks, copyrights, know-how, rights on software and rights on databases), analyses, projects, processes, testing methods, technical data, formulations, techniques, trade secrets, know-how, data, reports, methodology, equipment, systems, marketing, information regarding sources of supply, business plans and the existence or scope of activities of any research, development, manufacturing, marketing or other projects of Wockhardt (including negative developments), research or development activities, non public corporate information and all technical or scientific information or know-how of Wockhardt relating to the purpose. Information disclosed by Disclosing Party to Receiving Party in the course of the discussions between the Parties shall constitute "Confidential Information".

b. The Receiving Party agrees that the Confidential Information disclosed by the Disclosing Party under this Agreement shall remain confidential and it shall not without the Disclosing Party's prior written consent disclose the same to any third party nor shall use the same for any purpose other than the fulfilment of its obligations under the terms of this Agreement.

c. Confidential Information will not include information that:

(i) is known to the Receiving Party, as evidenced by the Receiving Party's written records, before receipt of it under this Agreement

(ii) is disclosed to the Receiving Party by a third party having a right to make such disclosure; or

(iii) is or becomes part of the public domain through no fault of the Receiving Party; or

(iv) is independently developed by or for the Receiving Party, without recourse to such Confidential Information disclosed under this Agreement as evidenced by the Receiving Party's written records.

d. The Receiving Party agrees that:

(i) It will not use any Confidential Information received from a Disclosing Party except for the purposes of performing this Agreement.

(ii) It shall maintain Confidential Information of the Disclosing Party in strict confidence and follow the procedures to prevent unauthorized disclosure or use of the Disclosing Party Confidential Information and prevent it from becoming disclosed or being accessed by unauthorized persons.

(iii) It shall immediately advise the Disclosing Party of any unauthorized disclosure, loss, or use of Confidential Information

The Receiving Party may disclose the Confidential Information if required by law or by any court, tribunal, regulator or other authority with competent jurisdiction, provided to the extent practically possible and permissible under the law, gives notice to the Disclosing Party of such disclosure and shall disclose only that portion of Confidential Information which is required to be disclosed under the law. The Receiving Party agrees not to disclose any Confidential Information received from the Disclosing Party to any third party without the prior written consent of the Disclosing Party, except to its Affiliates, employees, agents, consultants, subcontractors, directors and officers on a need to know basis to effectuate the purpose of this Agreement (a "Representative"); provided, that in every Representative of the Consultant shall be informed of the confidentiality provisions of this Agreement.

e. The Receiving Party shall within fifteen (15) days of written request either before or after termination of this Agreement (for whatever reason), return to the Disclosing Party all materials, Confidential information (in whatever form) incorporating, embodying or recording any such Confidential Information in its possession or control and, if requested by the Disclosing Party, certify in writing that it has done so.

f. The confidentiality and non-use obligation under this Agreement shall survive for period of this Agreement and for a period of [10 (ten)] years following its expiration or termination.

IX) Investigator Initiated Study Grants (IISG)

a. Wockhardt agrees to provide funds/ facilitation to the investigator, Investigator Initiated Study (IIS) in accordance with IIS proposal and as amended from time to time upon mutual agreement and in writing.

b. No component of the IIS funds/ facilitation will be provided to the investigator until Wockhardt has received the necessary documents identified in IIS proposal form.

c. Investigator will use IIS funds solely for the purpose of the Investigator Initiated study specified in this agreement. IIS funds will not be used to pay physician referring potential subjects for enrolment in the study. At the completion of the study, investigator will confirm in writing that Wockhardt IIS funds have been used only to support the Investigator Initiated study.

d. If a particular IIS proposal calls for Wockhardt to provide a Wockhardt Product/ other medicines/ equipment/ materials, Wockhardt will provide, free of charge, sufficient supplies of the same to conduct the Study as per mutual agreement documented in proposal.

e. Investigator will maintain appropriate control of the Wockhardt Product/ other medicines/ equipment/ materials and will not provide it to anyone else except research staff who are directly involved in investigator initiated study conduct.
f. Except for, and limited to, the use specified in the Protocol &/or proposal form for the applicable Study, Wockhardt grants Investigator no express or implied intellectual property rights in the Wockhardt Product or in any methods of making or using the Wockhardt Product. Investigator will use Wockhardt Product/ other medicines/ equipment/ materials only as specified in the Protocol &/or proposal form for the applicable Study. Any other use of the Wockhardt Product/ other medicines/ equipment/ materials constitutes a material breach of this.
g. Investigator will not charge study subjects for Wockhardt Products/ other medicines/ equipment/ materials.

X) Investigator/ Institutions Representations, Warranties & obligations.

a. The Investigator/ Institution confirms having obtained the written approval of the appropriate authority/authorities for the study Protocol prior to conduct of such study.
b. The Investigator/ Institution shall not at any time during or after the expiration of the term divulge or allow to be divulged to any person any confidential information relating to the business or affairs of Wockhardt or any of the Material/ Product or the trials or studies conducted pursuant to this Agreement without the prior written consent of the Wockhardt. Further, if any confidential information was disclosed to the Investigator/ Institution prior to the date of this Agreement in anticipation of the parties entering into this Agreement, such confidential information shall be subject to the terms and conditions of this Agreement.
c. Investigator/ Institution shall take all reasonable precautions in dealing with the Material/Product and with any information documents and papers provided to it by Wockhardt so as to prevent any unauthorized person from having access to such Product, information, documents or papers or to any report on or records of any non-clinical/ Clinical Studies carried out.
d. Investigator/ Institution shall conduct the clinical studies in compliance with rules/ guidances issued by the competent authority and to the Protocol agreed to by Wockhardt and given approval by such competent authority.
e. Investigator/ Institution agrees to apply quality control to each of data handling and ensure that all data provided by it to Wockhardt is reliable.
f. Investigator/ Institution agrees that time is the essence of the contract and undertakes to complete the studies within the term as specified in each IIS proposal.
g. Investigator/ Institution undertakes not to terminate the trials prematurely without the consent of Wockhardt.
h. Investigator/ Institution warrants that it has qualified and experienced personnel to assume responsibility for the proper conduct of the studies/ trial and shall maintain a list of such qualified persons to whom it has delegated significant trial related duties.
i. Investigator/ Institution warrants that it is thoroughly familiar with the appropriate use of the Material/ Product.
j. Investigator/ Institution warrants that it is aware of and shall comply with the Guideline for Good Clinical Practice and other regulatory requirements.
k. Investigator/ Institution warrants that it shall submit the protocol to appropriate authority/authorities for approval and start the study only after the approval from appropriate authority/authorities is obtained.

l. Investigator/ Institution warrants that it is aware that the Wockhardt has agreed to provide its services/ funds/ products based upon the aforesaid declarations and warranties.

XI) Investigator initiated Study Data and Publication Rights

a. Investigator shall share the data generated from investigator initiated study with Wockhardt for but not limited to support data management, clinical study report preparation, manuscript publication/ abstract or poster presentation.

b. Investigator can publish the results of the investigator initiated Study ("Study Data"), and use study data generated from the investigator initiated study for their own research and educational purposes and programs after obtaining written consent from Wockhardt. Any third party other than the investigator and Wockhardt, will not use or permit others to use non-public or unpublished raw Study Data from any Study that involves the use of a Wockhardt Product for the commercial benefit of any third party.

c. Investigator shall have the right, consistent with academic standards, to publish or present the results of the Study provided that the manuscript, abstract or other material proposed to be published or presented ("Proposed Publication") shall be submitted to Wockhardt at least sixty (60) days prior to submission for publication or presentation to permit Wockhardt to request removal of any Confidential Information contained therein and to protect its rights to any patentable Invention. Wockhardt shall complete its review within thirty (30) days after receipt of the Proposed Publication. If Wockhardt believes that any Proposed Publication contains any information relating to any patentable Invention, the disclosure of such Proposed Publication shall be delayed for up to two (2) years from the date of receipt of the Proposed Publication to permit the filing of a patent application. If Wockhardt believes that any Proposed Publication contains Confidential Information, Wockhardt shall so notify Investigator, and they shall remove any such Confidential Information prior to publication or presentation.

d. Investigator will comply with recognized ethical standards concerning publications and authorship.

e. Investigator will disclose Wockhardt's support of the Study in any publication of Study results

f. If Wockhardt wishes to disclose results or other study information, Study Data or parts or all of the Study Report earlier than indicated above, Wockhardt may submit a request to Investigator in writing. Investigator will consider any such request in good faith. Any such request must identify the results or other Study information, Study Data or parts of the Study Report that Wockhardt wishes to disclose and how and where it would be disclosed. In any publication by Wockhardt of the results of the Study, Wockhardt will acknowledge the roles and efforts of Investigator in the Study.

XII) Indemnification

a. Wockhardt shall take the full responsibility of any issues/ events related to the Wockhardt product, when it is used within limits of recommendations of product's latest package insert/ leaflet and indemnify investigator against all losses, claims, or damages arising from such usage of the Wockhardt product within the investigator initiated study or otherwise, except that the foregoing indemnity shall not apply to any liability arising from investigator's intentional deviation or omission or negligence in the performance of its obligation under this agreement or any use of the product beyond recommendations of product's latest package insert/ leaflet.

b. Wockhardt shall guarantee that no Wockhardt product/ other medicines/ equipment/ materials shipped to investigator in connection with the Study covered by this Agreement will be adulterated or mislabelled.

c. Investigator agrees to keep all accountability of all Wockhardt product/ other medicines/ equipment/ materials

d. Investigator and Institution agrees at their own cost and expense to indemnify, defend and hold harmless Wockhardt and its Affiliates, employees, officers, and directors (Wockhardt Indemnities) from and against any and all losses, costs, expenses and damages, including but not limited to reasonable attorney's fees, based on a personal injury and/or for damage to or loss of property incurred as a result of Investigator/ Institution its officers', directors', agents', or employees'(including Principal Investigator's, and Sub-Investigators') (i) breach of its obligations including violation of clause VII, VIII, X, XI of this Agreement under this Agreement, including, but not limited to the Protocol; (ii) negligence or malfeasance or nonfeasance; and (iii) breach of any applicable local, state or federal law(s), rule(s), or regulation(s), including, but not limited to, applicable Regulatory Authority regulations, ICH-GCPs and other governmental requirements or any other governmental authority or agency (iii) from all actions, suits, claims, or demands brought by any third party based on or arising under this Agreement to the extent that such loss is caused by the negligence or willful misconduct or any use of the Wockhardt product beyond recommendations of product's latest package insert/ leaflet by the Investigator, Institution, their employees or agents.

e. Neither party will be liable for any loss or damage, including loss of profits, loss of goodwill or any other special, incidental, indirect or consequential damages whatsoever (and whether caused by the negligence of either party or its employees or agents or otherwise) arising out of or in connection with any act or omission of either party whether for breach of contract, tort (including negligence and strict liability), or otherwise relating this Agreement.

XIII) Insurance.

a. Investigator shall maintain such professional liability and other insurance as shall be reasonably necessary to insure himself against any claim or claims for damages, whether arising by reason of personal injury or death occasioned directly or indirectly in connection with the Study or services provided under this Agreement. Investigator shall provide evidence of such coverage to Wockhardt upon request.

XIV) Force Majeure.

a. A party shall be excused from performing its obligations under this Agreement to the extent its performance is delayed or prevented by any cause beyond such party's reasonable control, including but not limited to, acts of God, fire, explosion, disease, weather, war, insurrection, civil strike, riots, government action, or power failure (a "Force Majeure Event") provided the affected party gives the other party prompt written notice of the occurrence of any Force Majeure Event and the nature and the extent to which the affected party will be unable to perform its obligations under this Agreement. The affected party agrees to use commercially reasonable efforts to correct the Force Majeure Event as quickly as possible, to perform its obligations under this Agreement to the extent feasible given the Force Majeure Event, and to give the other party prompt written notice when it is again fully able to perform its obligations. Performance shall be excused only to the extent of and during the reasonable continuance of such Force Majeure Event, provided that the Wockhardt may terminate this Agreement if such Force Majeure Event continues for a period of ninety (90) days or more. Any deadline or time for performance specified in this Agreement or the Protocol which falls due during or subsequent to the occurrence of a Force Majeure Event shall be automatically extended for a period of time equal to the period of the Force Majeure Event

XV) Agreement Modification.

a. This Agreement may not be altered, amended or modified except by a written document signed by all the parties.

XVI) Assignment.

a. This Agreement may not be assigned by the Investigator without the prior written consent of Wockhardt.

XVII) Successors and Assigns.

a. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns.

XVIII) Notice

a. 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 Wockhardt:	Attn: Dr. Hanmant Barkate Wockhardt Limited Wockhardt Towers, Bandra Kurla Complex, Bandra (East), Mumbai 400051, Maharashtra, India Facsimile:022 -26534242
If to Institution:	Attn: Dr . G.S. Narshetti MGM MEDICAL COLLEGE (MIHS), Sector 01 Kamothe, Navi Mumbai 410209, Maharshtra India. Facsimile: 022-27431093
If to Investigator	Attn: Dr. Nimain C Mohanty MGM MEDICAL COLLEGE (MIHS), Sector 01 Kamothe, Navi Mumbai 410209, Maharshtra India. Facsimile: 022-27431093

XIX) Severability.

a. If any provision of this Agreement shall be declared invalid for any reason whatsoever, that decision shall not affect any other provision of this Agreement, which shall remain in full force and effect; and to this end the provisions of this Agreement are hereby declared severable.

XX) APPLICABLE LAW AND COMPETENT COURTS

This Agreement shall be governed by Laws of India, under exclusive jurisdiction of courts of Mumbai.

If any question of dispute shall at any time during the term or thereafter arise between the Parties with respect to the validity, interpretation, implementation or alleged material breach of any provision of this Agreement or the rights or obligations of the Parties hereunder, or regarding any question including the question as to whether the termination of this Agreement by either Party has been legitimate, then the Parties shall attempt to settle such dispute amicably between them. In the event that such dispute has not been amicably settled within sixty (60) days, then such a question or dispute shall be referred to and finally resolved by arbitration under the Arbitration and Conciliation Act 1996, (as amended from time to time). The seat of the

arbitration shall be Mumbai. All proceedings of such arbitration, including without limitation, any agreements or awards, shall be in the English language.

XXI) Entire Agreement.

a. This Agreement constitutes the entire agreement between the parties and supersedes all prior agreements and understandings whether written or oral relating to the subject matter of this Agreement.

IN WITNESS WHEREOF, each of the parties hereto has caused this Agreement to be executed by its duly authorized representative as of the date written above.

[WOCKHARDT LIMITED]

By: 09/05/2017

Name: Dr. Hanmant Barkate

Its: Vice President – Medical Affairs

[INSTITUTION]

By:

Dean.
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

Name: Dr . G.S. Narshetti

Its: Dean – MGM Medical College, Kamothe.

[INVESTIGATOR]

By: 9/5

Name: Dr. Nimain C Mohanty

Its: Principal Investigator

Professor
Dept. of Paediatrics
MGM Medical College & Hospital,
Navi Mumbai

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

WOCKHARDT LTD

Wockhardt Towers, Bandra Kurla Complex,
Bandra (E), Mumbai – 400051, India

Payment Advice

MGM Medical College Navi Mumbai Res
Sector 01
Kamothe,Navi Mumbai
Mumbai
410209

Value Date : 04-Jun-2019

Cheque DD No : 2500003754
Bank Reference No. : CMS1140060111
UTR No. : ICICR22019060400474757

Your Account With Us : 749421

Dear Sir/Madam,

We have initiated your payment through RTGS to IDBI BANK, SECTOR 11,BELAPUR,NAVI MUMBAI Branch, Account no. 0183104000166669 with the IFSC CODE IBKL0000183 for the amount of Rs. 233,640.00 (Rupees Two Lakh Thirty-Three Thousand Six Hundred and Forty Only) towards settlement of your following bills

Kindly provide one time confirmation that the account has been correctly credited. Ignore if already sent.
Kindly Email to agholam@wockhardt.com and SAdhikari@wockhardt.com

SAP Document No	SAP Document Date	Vendor Bill No	Bill Date	Booked	Deduction	Payable Amount
3100115874	04/02/2019	5	14/02/2019	259,600.00	-25,960.00	233,640.0
Net Amount						233,640.0

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

Computer Advice hence does not require signature

WOCKHARDT LTD.

Wockhardt Towers, Bandra Kurla Complex,
Bandra (E), Mumbai – 400051, India

Payment Advice

MGM Medical College Navi Mumbai Sector 01 Kamothe,Navi Mumbai Mumbai 410209 Your Account With Us : 749421	Value Date : 09-06-2017 Cheque DD No. : 2500009366 Bank Reference No : CMS598854825 UTR No : ICICR22017060900503217

Dear Sir / Madam,

We have initiated your payment through RTGS to IDBI BANK, SECTOR 11,BELAPUR,NAVI MUMBAI Branch, Account No 0183104000166669 with the IFSC CODE IBKL0000183 for the amount of Rs. 450000.00 (Rupees Four lakhs fifty thousand) towards settlement of your following bills.

Kindly provide one time confirmation that the account has been correctly credited.Ignore if already sent.
Kindly Email to agholam@wockhardt.com and kmukherjee@wockhardt.com

Bill No.	Bill Date	Vendor Bill No.	Vendor Bill	Booked	Deduction	Payable Amoun
3100006367	20170510	ZEEBON R -01	20170606	500,000.00	-50,000.00	450,000.00

Net Amount 450,000.00

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

Zeebon R IIS study payment Inbox

Devang Parikh <DParikh@wockhardt.com>
to me, Colette, Rohee, Agam, Gaurav

Mon, Nov 26, 3:40 PM (21 hours ago)

Dear Dr. Mohanty

Greetings from Wockhardt!

Thank you very much for your support in scientific and academic activities of Wockhardt.

Regarding Zeebon R IIS study conducted by you and your team, payment for first four milestones has been cleared as per the details mentioned in below table.

Sr. No.	PI Name	Hospital Name	Payment type	Amount (Rs.)	Submission date	Received amount (Rs.)	Received date	Mode of Payment
1	Dr. Nimain Mohanty	MGM Hospital	2nd instalment	129800	22-Jun-18	116820	17-Aug-18	NEFT/RTGS
2	Dr. Nimain Mohanty	MGM Hospital	3rd instalment	129800	22-Jun-18	116820	17-Aug-18	NEFT/RTGS
3	Dr. Nimain Mohanty	MGM Hospital	4th instalment	129800	16-Aug-18	116820	12-Sep-18	NEFT/RTGS

We request you to kindly share the invoice for the last (fifth) milestone amounting for 259,600 Rs.
Please find attached draft invoice which needs to be printed on institute letterhead and signed & dated by the PI.

Once again, we extend our sincere gratitude and look forward for long-term relationship.

Thanks & Regards,
Dr. Devang Parikh MD

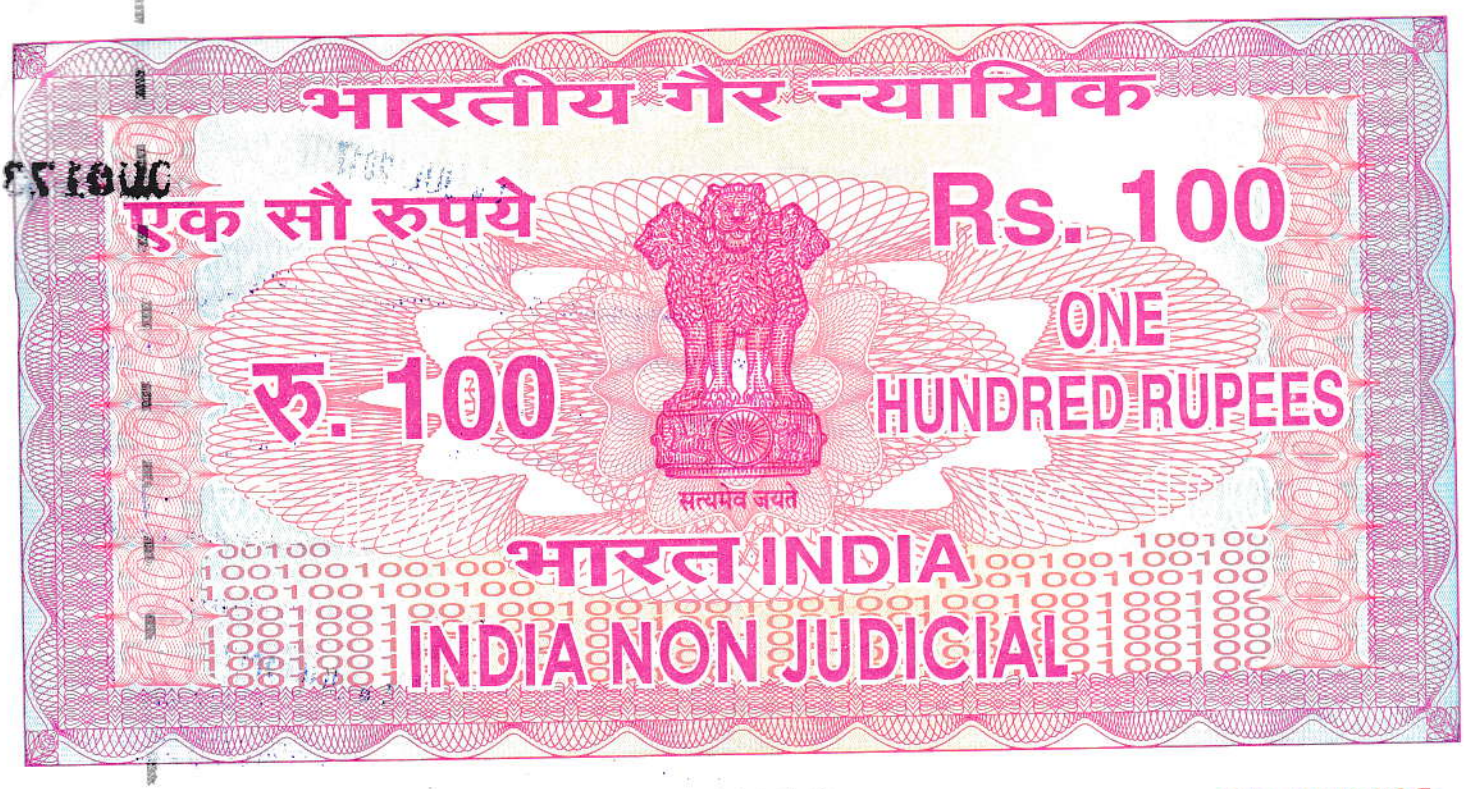
Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

Ach Branch
MGMMC, Kamothe

Please verify and confirm.
We need to ensure complete
utilisation of funds in order
to claim the 5th and final
disbursement in the attached format,
Printed on our letter head.
Thanks & regards

27.11.18
DY



महाराष्ट्र MAHARASHTRA ◑ 2017 ◑ SD 028225

प्रधान मुद्रांक कार्यालय, मुंबई
प.म.वि.क. 4000095
-7 JUL 2017
सक्षम अधिकारी

श्री. प्र. ना. चिंचघरे

CLINICAL TRIAL SERVICE AGREEMENT

DATED 14TH DAY OF JULY 2017

BETWEEN

GLENMARK PHARMACEUTICALS LIMITED

AND

MAHATMA GANDHI MISSIONS MEDICAL COLLEGE AND HOSPITAL

AND

DR. DEEPAK BHOSALE

AND

GRAPECITY RESEARCH SOLUTION LLP

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai- 410 209

INPLCT155421

14 JUL 2017

000174

जोडपत्र - १ Annexure - I

प्रतिज्ञापत्रासाठी Only for Affidavit

मुद्रांक विकत घेणाऱ्याचे नाव Glenmark Pharmaceuticals Ltd.

मुद्रांक विकत घेणाऱ्याचे रहिवाशी पत्ता Glenmark House, B D Sawant Marg, Chakala, Off Western Express Highway, Andheri - (E), Mumbai - 400099

मुद्रांक विक्रीबाबतची नोंद वही अनु. क्रमांक ____________ दिनांक ____________

मुद्रांक विकत घेणाऱ्याची सही

परवानाधारक मुद्रांक विक्रेत्याची सही

परवाना क्रमांक : ८०००९५

मुद्रांक विक्रीचे ठिकाण/पत्ता : अंधेरी कोर्ट बार असोसिएशन

एम. एम. कोर्ट, अंधेरी रेल्वे स्टेशनच्या बाजूला

अंधेरी (पूर्व), मुंबई - ४०० ०६९

14 JUL 2017

शासकीय कार्यालयासमोर /न्यायालयासमोर प्रतिज्ञापत्र सादर करणेसाठी आवश्यक नाही. (शासन आदेश दि. ०१/०७/२००४ नुसार)

ज्या कारणासाठी ज्यांनी मुद्रांक खरेदी केला त्यांनी त्याच कारणासाठी मुद्रांक खरेदी केल्यापासून ६ महिन्यात वापरणे बंधनकारक आहे.

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

CLINICAL TRIAL SERVICE AGREEMENT

This Clinical Trial Service Agreement ("**Agreement**") is made on this 14th day of July 2017

Between

Glenmark Pharmaceuticals Limited, a company incorporated under the laws of India having its registered office at B/2 Mahalaxmi Chambers, 22, Bhulabhai Desai Road, Mumbai – 400 026, India and its corporate office at Glenmark House, B. D. Sawant Marg, Chakala, Andheri (E), Mumbai – 400099, India (hereinafter referred to as "**Glenmark**" which expression shall unless repugnant to the context or meaning thereof shall be deemed to mean and include its successors and permitted assigns) of the **FIRST PART**;

And

Mahatma Gandhi Missions Medical collage and Hospital an institution incorporated under the laws of India having its registered office at N-6, CIDCO, Aurangabad-431003, Maharashtra, India (hereinafter referred to as the "**Institution**" which expression shall unless repugnant to the context or meaning thereof shall be deemed to mean and include its successors and permitted assigns) of the **SECOND PART;**

And

Dr. Deepak Bhosale, aged around 41 years, Indian, residing at Flat No 201, Regency Royal, surana Nagar, Aurangabad-431003, Maharashtra, India (hereinafter referred to as the "**Investigator**" which expression shall unless repugnant to the context or meaning thereof shall be deemed to mean and include his heirs and legal representatives) of the **THIRD PART.**

And

Grapecity research Solution LLp., a firm having address at Prakash Housing Society, Block No 2, Thergaon , Pune, Maharashtra, India (hereinafter referred to as the "**SMO** " which expression shall unless repugnant to the context or meaning thereof shall be deemed to mean and include his heirs and legal representatives) of the **FOURTH PART.**

"Glenmark", "Institution", "SMO" and Investigator" are hereinafter collectively referred to as the "Parties" and severally as a "Party".

WHEREAS:

Glenmark is *interalia* engaged in the business of discovery, development, manufacturing, distribution and sales of pharmaceutical products;

The Institution is a private and is *interalia* engaged in in carrying out clinical trials;;

The Investigator is engaged in carrying out clinical research/studies/trials;

The SMO is a site management organization engaged in carrying out various activities during a clinical trial;

Glenmark has approached the Institution and the Investigator to provide the Services in accordance with the provisions herein below which the Institution and the Investigator are willing to provide on the terms and subject to the conditions of this Agreement;

Pursuant to the aforesaid, the Parties are desirous to spell out the terms and conditions in writing to give effect to the aforesaid understanding.

IN CONSIDERATION OF THE PAYMENTS AND MUTUAL PROMISES AND COVENANTS CONTAINED HEREIN AND WITH THE INTENT TO BE LEGALLY BOUND HEREBY, THE PARTIES HEREBY AGREE AS FOLLOWS:

1. **GENERAL DEFINITIONS & INTERPRETATION**

In this Agreement the following capitalised terms shall, unless the context requires otherwise, have the following meanings:

1.1. "**Adverse Event**" 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 Adverse Event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom or disease temporarily associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) Product;

1.2. "**Commencement Date**" means the date on which the Investigator commences its activities in accordance with this Agreement;

1.3. "**Confidential Information**" means the proprietary and/or confidential information of any Party, howsoever disclosed, which relates to the subject matter of this Agreement including without limitation technical information, business information, information relating to the conduct of the Trial, the Subjects of the Trial, Trial Material, Know-How, methodology, trade secrets, results, processes, sequences, structure and organization of the Trial, the Protocol, the Trial Materials and information relating to the Investigational Products etc. and information included within this definition by virtue of Sections 10 and 13;

1.4. "**Consent Form**" means the patient information sheet & consent form required to be voluntarily completed by every Subject/Patient participating in the Trial (and/or a relative or legal guardian of the Subject or any other person or authority required by law at each Site) after having been informed of all aspects of the Trial. The Consent Form shall be approved by Glenmark and Ethics Committee prior to use at the Site;

1.5. "**Co-investigator**" means one or more resident doctors / consultants with the Institution appointed by the Investigator at each Site as per the provisions of law and approved by Glenmark; who will lead, co-ordinate and run the Trial at the Site;

1.6. "**CRF**" means a printed, optical, or electronic document designed to record all of the Protocol required information to be reported to Glenmark on each Trial Subject/Patient;

1.7. "**Eligible Subject**" means a person who meets all the eligibility criteria as set out in the Protocol for enrolment of a subject/patient into the Trial at the time of selection;

1.8. "**Ethics Committee**" means the ethics committee/independent review board constituted according to GCP and local laws and regulations and having authority over the conduct of any clinical Trial at the Site and that is ultimately responsible for approving the conduct of the Trial and associated Protocol;

1.9. "**GCP**" means a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected;

1.10. "**ICH**" means the International Conference on Harmonisation. The Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) specifies the unified standards to facilitate the mutual acceptance of clinical data by the regulatory authorities of Europe, Japan and North America together with such other good clinical practice requirements as are specified in Directive

2001/20/EC and Directive 2005/28/EC or the Code of Federal Regulations relating to medicinal products for human use and as may otherwise be applicable in the territory where the Site is located;

1.11. "**Ineligible Subject**" means a person who does not meet the eligibility criteria as set out in the Protocol for enrolment of a subject into the Trial;

1.12. "**Inspection(s)**" means the act by a Regulatory Authority of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority(ies) to be related to the clinical Trial and that may be located at the Site of the Trial, at Glenmark's facilities, or at other establishments deemed appropriate by the Regulatory Authority(ies);

1.13. "**Investigational Product**" means a pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use;

1.14. "**Investigator**" shall have the same meaning as assigned herein above and who shall be responsible for the conduct of the clinical Trial at a trial Site;

1.15. "**Intellectual Property Rights**" means all intellectual property rights throughout the world (both present and future) including without limitation copyrights, trademarks, designs, patents, database rights, Know-How and all other rights or forms of protection of a similar nature or having equivalent or the similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered and including applications for registration of any of them for their entire term and any applicable extensions;

1.16. "**Know-How**" means all technical and other information which is not in the public domain including but not limited to information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, procedures, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, clinical data, manufacturing data and information contained in submissions to Regulatory Authorities;

1.17. "**Protocol**" means the document that describes the objective(s), design, methodology, statistical considerations, and organization of the Trial as more specifically laid down in **Annexure 1** hereto and shall include amendments (written description of a changes(s) to or a formal clarification of a Protocol) made by Glenmark at its sole discretion from time to time;

1.18. "**Regulatory Authority**" means any governmental or regulatory authority responsible for granting health approval, clinical trial authorisations and licences, import and/or export licences or any other relevant approval, permission or licence necessary for the conduct of a trial and those that conduct Inspections of sponsors, contract research organisations, Sites/Institutions/Investigators etc.;

1.19. "**SAE**" means any untoward medical occurrence that at any dose that: results in death, is life threatening (actual or hypothetical), requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, is a medically significant event;

1.20. "**Services**" means and includes the services to be performed according to the terms of this Agreement and the Protocol by the Investigator directly or through the Institution, Co-investigator etc. and conduct and performance of the Trial pursuant to ICH GCP and as more fully outlined in **Annexure 2** hereto;

1.21. "**Site**" means the location(s) where Trial related activities are actually conducted;

1.22. "**Site File**" means the file maintained by Investigator at each Site and the file maintained in-house by Glenmark containing the documentation specified in Section 8 of ICH GCP or as may otherwise be required by any other local rules, laws, regulations, directives or guidance;

1.23. "**Subject**" means a person who is enrolled in the Trial as an Eligible Subject and a recipient of the Investigational Product;

1.24. "**Termination Date**" means the date when the Parties have performed their respective obligations under the Agreement or if terminated earlier in accordance with the terms and conditions of this Agreement, then such earlier date;

1.25. "**Trial/Study**" means any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms Trial and Study are synonymous;

1.26. "**Trial Materials**" means the Investigational Product, the Protocol, case report forms, Consent Forms, placebos, trial aids, and any other material that is used in, or arises out of, the conduct of the Trial;

1.27. Headings used or mentioned in this Agreement are for convenience only and do not affect the interpretation of the sections;

1.28. In this Agreement unless the context requires otherwise:

1.28.1. words importing the singular include the plural and vice versa and reference to one gender includes all genders;
1.28.2. reference to any individual or person includes a corporation, partnership, joint venture, association, authority, state or government and vice versa;
1.28.3. any phrase introduced or preceded by the terms "include", "including" and "in particular" or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding these terms unless preceded by the term "explicitly".

1.29. Recitals and Annexures hereto constitute an integral part of this Agreement.

2. TERM

2.1. This Agreement shall come into force on the Commencement Date and shall remain valid until the Termination Date.

3. GENERAL OBLIGATIONS OF THE INSTITUTION & INVESTIGATOR

3.1. The Institution and the Investigator hereby represents and warrants that it has the expertise, facilities and all appropriate registrations, licenses, permits and authorisations necessary to provide the Services and more particularly to conduct the Services to the highest of the professional Standards mentioned **Annexure 3** and in accordance with this Agreement.

3.2. Throughout the Term the Institution and the Investigator shall:

3.2.1. provide the Services as per the terms of this Agreement and as more fully outlined in **Annexure 2** hereto;

3.2.2. appoint appropriate and professionally trained, experienced and qualified personnel at their sole responsibility, risk and cost to perform the Services under this Agreement;

3.2.3. use all reasonable endeavours to ensure the smooth running of the Services at all times as per the Standards mentioned in **Annexure 3** and Timelines mentioned in **Annexure 4;**

3.2.4. will ensure that all employees/study team perform the Services in accordance with the terms of this Agreement and the Standards mentioned in **Annexure 3** and Timelines mentioned in **Annexure 4:**

3.2.5. provide the data required by Glenmark pursuant to and in furtherance of the Services;

3.3. The Institution and the Investigator will at all times permit Glenmark and/or its nominees to conduct monitoring/audit at such intervals as required by Glenmark of all Services provided by the Institution and the Investigator under this Agreement including all records and documents relating to the Services, and any equipment or materials supplied and/or maintained by the Institution and the Investigator in connection therewith and the Institution and the Investigator will provide such assistance as reasonably requested by Glenmark in connection therewith.

3.4. The Institution and the Investigator will immediately notify Glenmark of any notified Inspections affecting or potentially affecting the Services provided to Glenmark.

4. GENERAL RESPONSIBILITIES

4.1. Glenmark shall assist and support the Institution and the Investigator in its performance of the Services as more particularly laid down in Annexure 2 hereto.

4.2. The Parties understand and agree that the Investigator may from time to time appoint the SMO to assist him in carrying out the Services (or any part thereof).

5. GENERAL OBLIGATIONS OF THE PARTIES

5.1. Parties understand, acknowledge and agree that they will work together and co-operate with the other in order to comply, as closely as possible, with the estimated Trial timeline annexed hereto as **Annexure 4**.

5.2. Parties further understand, acknowledge and agree that prior to or at any time during the course of the Trial, Glenmark may amend or vary the Services and/or the Protocol. In such an event:

5.2.1. The Investigator will co-operate with Glenmark to promptly incorporate and act upon such amendments in its performance of the Services going forward including undertaking further Site monitoring and audits, training of personnel at each Site, seeking approvals to the amendments as appropriate from the Ethics Committees;

5.2.2. Parties will negotiate in good faith any amendments do modifications in price and payment in **Annexure 5**, if applicable and required having regard to the impact of the changes in light of the previous scope of Services and the Protocol.

5.3. Should there be any inconsistency between the Protocol and the other terms of this Agreement, the terms of the Protocol shall prevail to the extent of such inconsistency.

6. PAYMENT

6.1. In consideration of the performance of the Services by the Institution and the Investigator pursuant to this Agreement, the Institution and Investigator have requested Glenmark to make the payments to the SMO, and Glenmark has agreed to make payments to the SMO as per **Annexure 5** hereto. The SMO shall submit to Glenmark for payment, pursuant to the following terms, an invoice for those sums identified in **Annexure 5** when the relevant event or time period set out in **Annexure 4** occurs.

6.2. Glenmark will pay the SMO all sums properly invoiced in accordance with Section 6.1 and **Annexure 5** within 30 days of receipt of such invoice.

6.3. Glenmark may suspend payment of an invoice if it raises a bona fide dispute as to the accuracy of any invoice submitted by the SMO. If the dispute cannot be resolved between the Parties it will be referred to arbitration in accordance with Section 17.2.

7. INDEMNIFICATION

7.1. The Institution and the Investigator hereby jointly and severally undertakes to indemnify, defend and hold Glenmark, its successors and assigns, its officers, directors, employees harmless agents against all losses, damages, costs, expenses and other liabilities, including reasonable attorney's fees and court costs, incurred by it on its own account or any third party claim, action or proceeding to which Glenmark may be subject which arises out of or results from or may be payable by virtue of:

7.1.1. any failure of the Institution, Investigator, its affiliates, contractors or agents, Co-Investigator, to perform the Trial in accordance with the Protocol, ICH-GCP, local regulatory requirements; and/or

7.1.2. improper or negligent administration or use of the Investigational Product during the course of the Trial ; and/or

7.1.3. any breach of Section 10 and/or 13 or other terms of this agreement; and/or

7.1.4. any negligence, misconduct, malpractice, material deviation, breach or non-compliance of any provisions of this Agreement by the Institution and/or the Investigator, its affiliates, contractors or agents, Co-Investigator, the project manager and the SMO; and/or

7.1.5. due to infringement of the Intellectual Property Rights of Glenmark or a breach of any warranty, representation, covenant or obligation.

7.2. Notwithstanding the above, Glenmark shall assume no liability for any case in which written informed consent and an authorization regarding personal data in accordance with applicable law was not given by the patient involved Protocol amendments (if any) were not approved by the Regulatory Authority.

7.3. Glenmark hereby undertakes to indemnify Institution, Investigator, its affiliates, contractors, agents or the Co-Investigator against all losses, damages, costs, expenses and other liabilities, including reasonable attorney's fees and court costs, arising out of, or in connection with, any injury to a person (including death) arising solely from the Investigational Product due to negligence of Glenmark, except to the extent the same is caused by the negligence, misconduct, malpractice or breach or non-compliance by the Institution and/or the Investigator, Co-Investigator or its officers, directors, employees or agents of the terms of the Protocol, the terms of this Agreement or any applicable laws, regulations, guidelines and generally accepted standards.

7.4. Any Party hereto seeking indemnification for itself or on behalf of those other parties specified hereunder ("**Indemnified Party**") shall notify the other Party ("**Indemnifying Party**") in writing reasonably promptly after the assertion against the Indemnified Party of any claim under the indemnity or allegation by a third party in respect of which the Indemnified Party intends to base a claim for indemnification hereunder ("**Claim**"), but the failure or delay so to notify the Indemnifying Party shall not relieve the Indemnifying Party of any obligation or liability that it may have to the Indemnified Party except to the extent that the Indemnifying Party demonstrates that its ability to defend or resolve such Claim is adversely affected by such unreasonable delay or failure.

7.5. The Indemnifying Party shall have the right, upon written notice given to the Indemnified Party within thirty (30) days after receipt of the notice from the Indemnified Party of any Claim to assume the defence or handling of such Claim, at the Indemnifying Party's sole expense, in which case the provisions of Section 7.6 below shall govern.

7.6. The Indemnifying Party shall select external legal counsel reasonably proficient and experienced within the field of the dispute giving rise to the Claim in connection with conducting the defence or handling of such Claim, and the Indemnifying Party shall keep the Indemnified Party reasonably apprised of the status of such Claim. The Indemnifying Party shall not, without the prior written consent of the Indemnified Party, agree to a settlement of any Claim which leads to liability or creates any financial or other obligation on the part of the Indemnified Party for which the Indemnified Party is not entitled to full indemnification hereunder. The Indemnified Party shall fully cooperate with the Indemnifying Party and shall be entitled to appoint its own counsel to observe and report on but not participate in the Claim at its own expense. Notwithstanding the foregoing, in the event the Indemnifying Party fails to conduct the defence or handling of any Claim in good faith after having assumed such defence or handling, then the provisions of Section 7.8 below shall govern.

7.7. If the Indemnifying Party does not give written notice to the Indemnified Party, within thirty (30) days after receipt of the notice from the Indemnified Party of any Claim, of the Indemnifying Party's election to assume the defence or handling of such Claim, the provisions of Section 7.8 below shall govern.

7.8. Subject to Sections 7.5, 7.6 and 7.7, the Indemnified Party may, at the Indemnifying Party's expense, select external legal counsel reasonably proficient and experienced within the field of the dispute giving rise to the Claim in connection with conducting the defence or handling of such Claim and defend or handle such Claim in such manner as it may deem appropriate, provided, however, that the Indemnified Party shall keep the Indemnifying Party timely apprised of the status of such Claim and shall not settle such Claim without the prior written consent of the Indemnifying Party, which consent shall not be unreasonably withheld or delayed. If the Indemnified Party defends or handles such Claim, the Indemnifying Party shall fully cooperate with the Indemnified Party and shall be entitled to participate in the defence or handling of such Claim with its own counsel and at its own expense.

7.9. The Indemnified Party will only be entitled to claim under the indemnity for a Claim provided that it has not made any admission of liability or culpability without having first obtained the prior written consent of the Indemnifying Party.

8. LIMITATION OF LIABILITY

8.1. Save for the provisions of Section 8.2 below, notwithstanding any other provision in this Agreement, in no event shall either Party be liable, whether in contract, tort, under an indemnity, misrepresentation, negligence or otherwise, for any remote, indirect, incidental or consequential damages arising out of or in connection with this Agreement, or any performance, non-performance or breach of any provision hereof. However, it is understood and agreed that claims, actions, lawsuits or other proceedings made by third parties being the subject of the indemnification obligation under Section 7 shall not be considered as indirect, consequential, special or incidental damages.

8.2. Nothing in this Agreement will act as or seek to restrict, limit or exclude any liability for (i) death or personal injury caused by negligence; (ii) liability for fraud or fraudulent misrepresentation; (iii) negligence or misconduct; or (iv)any liability for breach of implied undertakings or conditions which cannot be excluded or limited by contract.

9. INSURANCE

9.1. Institution and the Investigator shall secure and maintain in full force and effect throughout the performance of the Trial insurance or self-insurance coverage for medical malpractice and general liability in amounts appropriate to the conduct of his/her business. Institution and the Investigator shall also require any subcontractor to secure and maintain such coverage for his/her/its activities related to the Trial. Certificates evidencing such insurance will be made available for examination upon request by Glenmark.

10. CONFIDENTIAL INFORMATION AND PUBLICITY

10.1. All data, documents and information whether written or orally supplied or disclosed by Glenmark to the Institution and/or the Investigator, including but not limited to Confidential Information and the Materials, Documents and all other data including that derived from the Services, in whatsoever form, shall be the exclusive property of Glenmark and shall be treated as strictly confidential and shall not be disclosed to any person except to the extent that any such disclosure is necessary to be disclosed to that person in connection with the proper performance of this Agreement. The Parties understand, acknowledge and agree that all results and data from the Services in whatever form are the exclusive property of Glenmark and cannot be:

10.1.1. used by the Institution and/or the Investigator or its Co-Investigators, agents, employees or consultants etc. other than pursuant to the performance of the Services; or,

10.1.2. disclosed by Institution and/or the Investigator or its Co-investigators or any of its employees, agents, personnel etc. to any person including directly or indirectly to any person other than Glenmark or to persons who are authorised, in writing by Glenmark in advance, to receive such information.

10.2. The Institution and/or the Investigator will take all precautionary measures to ensure compliance of this Section 10 by its employees, agents, consultants and personnel to whom Confidential Information is required to be disclosed under the terms of this Agreement. The Institution and/or the Investigator will ensure that all its employees, agents, consultants, and personnel are bound by obligations no less onerous than those contained herein before any disclosure of such Confidential Information to them.

10.3. A breach of this Section 10 by the Investigator or any of the Investigator's agents, employees or contractors shall constitute a material breach by the Investigator of this Agreement.

10.4. The restrictions and obligations under this Section 10 shall not apply to any information which:

10.4.1. at the time of disclosure, is freely and lawfully in the public domain or thereafter lawfully becomes part of the public domain;

10.4.2. is in the possession of the Institution and/or the Investigator prior to the first disclosure of such information by Glenmark or its agent and the Investigator and Institution are not under any obligation of confidence in respect of such information;

10.4.3. other than pursuant to the Services, is independently and without any reference (whether direct or indirect) to the Confidential Information generated by the Investigator and/or Institution as can be demonstrated by contemporaneous written documents without any obligation of confidence owed in respect of such new information;

10.5. In the event the Institution and/or the Investigator must disclose in order to comply with an applicable mandatory and enforceable legal obligation or to the extent ordered by a court of competent jurisdiction exercising its right of authority over the Institution and/or the Investigator (subject to entry of an appropriate protective order), provided that if the Institution and/or the Investigator is required by such law, regulation or order to make any such disclosure of Confidential Information, they shall give reasonable notice to Glenmark of such disclosure requirement and will use its best efforts to secure confidential treatment of such Confidential Information required to be disclosed.

10.6. Any inventions or improvements whether patentable or unpatentable which are conceived of, discovered, or developed by the Institution and/or the Investigator, its Affiliates or by any person claiming through them in any way derived from, related to, based on, or resulting from the use of the Confidential Information ("Derivative Intellectual Property") shall be promptly disclosed to Glenmark. Any such Derivative Intellectual Property shall be the sole property of Glenmark. The Institution and/or the Investigator, its affiliates and any person claiming through them shall do all acts and things as shall be necessary to vest all right, title and interest therein in Glenmark. The Institution and/or the Investigator shall keep the said Derivative Intellectual Property confidential

in accordance with this Agreement. The Institution and/or the Investigator therefore undertakes that they will not reverse engineer, decompile or dissemble the Confidential Information or make any variant out of the Confidential Information and strictly use or abide by the terms of this Agreement.

10.7. Notwithstanding the performance or the discharge for whatever reason including breach of this Agreement, the provisions of this Section 10 shall remain in full force and effect in perpetuity.

10.8. Institution and the Investigator will preserve all Confidential Information including periodic backup of computer files, to prevent the loss or alteration of Glenmark's study data, documentation, and correspondence. At Glenmark's request or on expiry or upon termination of this Agreement, the Investigator and Institution shall return all the Confidential Information received in pursuance to this Agreement including all information disclosed orally and shall also destroy or erase all the electronic files, copies, notes, memorandum, extracts, which contains, reflects or is derived from the Confidential Information of Glenmark.

11. REPRESENTATIONS AND WARRANTEES

11.1. Each Party represents, warrants and covenants for itself to the other that:

11.1.1. 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;

11.1.2. it has the power and authority to enter into and perform its obligations under this Agreement;

11.1.3. this Agreement has been duly authorised, executed and delivered by it and constitutes a valid and binding obligation enforceable against it in accordance with its terms;

11.1.4. neither the execution and delivery of this Agreement, nor the performance by such Party of its obligations hereunder 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 other agreement, indenture, 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.

11.1.5. it will perform its obligations hereunder in accordance with all applicable federal, international, state or local law or regulation.

11.2. The Institution and Investigator represent and warrant that they will not enter into any other agreement(s) which would interfere or prevent performance of the obligations described herein.

11.3. The Institution and Investigator represents and warrants that they have the facilities, professional, technical and clerical staff, experience and expertise sufficient in quality and quantity to perform the Services and the Trial pursuant to the Protocol within the time frame set forth herein.

11.4. Debarment Certification: the Investigator and Institution jointly and/or severally represent and warrant that the Investigator, its employees, the Co-Investigator and/or any agents, contractors, sub-contractors etc. carrying out any of the Services have not been debarred under any law. In the [illegible]

[illegible]

11.5. Compliance with Laws: the Institution and Investigator represent and warrant that all the Services performed and provided by the Institution and Investigator, the Co-Investigator and/or any agent, contractor, sub-contractor shall fully comply with all applicable central, state, and local laws, rules and/or regulations, as may be amended from time to time.

11.6. Inconsistent Obligations: the Institution and Investigator represent and warrant that the responsibilities and obligations assumed by the Institution and Investigator on behalf of Glenmark hereunder are not in conflict with any other obligations the Institution and Investigator may have.

11.7. Save for those express warranties set out herein, the Parties neither make nor give any other express or implied (whether by statute, custom or otherwise) warranties in relation to its obligations, duties or activities owed or performed under this Agreement and hereby excludes any other such express or implied warranty in respect of that subject matter.

12. DEFAULT AND TERMINATION

12.1. For the purpose of this Section 12 each of the following constitutes an event of default ("Default"):

12.1.1. If any Party breaches any of its obligations under this Agreement and fails to remedy the breach within 30 days of written notice being given by the other Party identifying and requiring that breach to be remedied;

12.1.2. if a Party becomes insolvent, is dissolved or makes a general assignment for the benefit of its creditors, has a receiver appointed for a substantial part of its assets or makes the requisites filings as a sick company before the relevant authorities;

12.1.3. if conducting the Services becomes prohibited by law, rule, regulation or any amendment thereof.

12.2. Either Party may immediately terminate this Agreement by notice in writing to the other Party if a default by that other Party occurs.

12.3. Without prejudice to any other rights Glenmark may have, Glenmark may terminate this Agreement immediately by written notice if, in the reasonable opinion of Glenmark, any of the following events occurs:

12.3.1. there is unsatisfactory progress of the Services and/or Trial;
12.3.2. if patient recruitment is not initiated within 60 days of Site initiation;

12.3.3. Any Co-Investigator ceases to be employed by or engaged in the performance of a Trial at any Site;

12.3.4. there is breach of Section 10 or 13 of this Agreement by the Institution and/or Investigator or any employee, director, agent, contractor, sub-agent, sub-contractor, the Co-Investigator or any other person appointed by or under control of or claiming through the Investigator;

12.3.5. there is an inability to recruit an adequate number of Subjects within the prescribed period as advised at the time of commencement;

12.3.6. there occur Adverse Events with the conduct of the Trial which in necessitate the discontinuance of the Trial;

12.4. Glenmark may terminate this Agreement upon 30 days prior written notice without cause.

12.5. On termination or expiry of this Agreement for any reason whatsoever Institution and the Investigator:

12.5.1. will deliver to Glenmark all Investigational Product, Trial Materials within 14 days of the date of termination or expiry;

12.5.2. will return any sums paid for Services which have not been performed before the date of termination or expiry;

12.5.3. will co-operate with Glenmark and do everything necessary to bring about the orderly termination of all Services;

12.6. On termination or expiry of this Agreement for any reason , Glenmark will pay for all Services performed by the Institution and the Investigator to the satisfaction of Glenmark in compliance with this Agreement ;

12.7. Each Party will be regarded as discharged from any further obligations under this Agreement except for those expressed to survive termination or expiry.

12.8. The termination of this Agreement pursuant to this Section 12 will not affect the rights of either Party in respect of any antecedent breach of this Agreement. Further, in the event of any termination of this Agreement on account of a Default under Section 12.2, the non-breaching Party shall have the right to recourse to such remedies that may be available to them at law or in equity.

13. **INTELLECTUAL PROPERTY**

13.1. Institution and the Investigator acknowledge and agree that Glenmark is the sole owner of all the Intellectual Property Rights as defined herein above and this Agreement does not grant, transfer or assign to the Institution and the Investigator any legal right or beneficial ownership in any Intellectual Property Rights of Glenmark.

13.2. Institution and the Investigator further acknowledge and agree that all rights to any discovery or invention conceived or reduced to practice in the direct performance of the Study conducted under this Agreement in accordance with the Protocol will belong to Glenmark. Institution and the Investigator agree to assign to Glenmark, at the request of Glenmark, the sole and exclusive ownership thereto, upon the payment of costs by Glenmark, if any, incurred by Institution and the Investigator in the filing, prosecution, or maintenance of any patent application or patent issuing thereon. Such application, if any, will be filed and prosecuted by Glenmark. Institution and the Investigator will promptly disclose to Glenmark any invention or discovery arising under this Agreement

13.3. All Intellectual Property and other data of Glenmark which the Institution and the Investigator may gain or have access to pursuant to this Agreement shall remain the property of Glenmark.

13.4. The Institution and the Investigator will not use Glenmark's name, trademark or brand in any publicity, advertising or news release without the prior written consent of Glenmark. For the avoidance of doubt, this restriction does not apply to the inclusion in documents of or use of Glenmark's name for the proper performance of the Services under this Agreement.

13.5. [illegible]

13.6. [illegible]

13.7. The Institution and the Investigator agree to co-operate regarding a reasonable request of Glenmark or to procure the assistance from another person or entity involved in the Services as may be required in any patent filings Glenmark deems necessary.

13.8. The Institution and the Investigator will not infringe the intellectual property rights of a third party or misappropriate any know-how or intellectual property rights of a third party in performing the Services.

13.9. Upon expiry or termination of this Agreement, the Institution and the Investigator shall stop using, return forthwith all the Intellectual Property Rights to Glenmark and restrain from using any Intellectual Property Rights.

14. PUBLICATION RIGHTS

Glenmark has the exclusive right to authorize any and all publications and/or communications relevant to the Trial/Study and Investigator undertakes to make no presentations or publications of the results of the Trial/Study without the prior written approval of the Glenmark with regard to the content and the timing of said presentations or publications. When permission for presentation or for publication is granted, Institution and Investigator agrees that, prior to submission of a manuscript or abstract to the publisher, Institution and or the Investigator shall forward a copy of said manuscript or abstract to the Glenmark for its written approval

15. RELATIONSHIP OF PARTIES

15.1. Glenmark, Institution and the Investigator have entered into this Agreement as independent contractors and nothing in this Agreement creates a relationship of employer and employee, principal and agent, joint venture or partnership between the Parties.

15.2. The Institution and the Investigator acknowledge and agree that the Institution and the Investigator are responsible for all the employees and all other personnel deputed by the Institution and the Investigator to conduct Services covered by this Agreement and a breach by any such person of the terms of this Agreement shall constitute a breach by the Institution and the Investigator of the same terms of this Agreement.

16. FORCE MAJEURE

16.1. A Party shall be excused from performing its obligations under this Agreement if its performance is delayed or prevented by any cause beyond such Party's reasonable control, including but not limited to, acts of God, fire, explosion, war, insurrection, civil strife, riots and government action which materially affects a Party's ability to perform its obligations under this Agreement. Performance shall be excused only to the extent of and during the reasonable continuance of such disability. Any deadline or time for performance specified in this Agreement which falls due during or subsequent to the occurrence of a Force Majeure occurrence, shall be automatically extended for a period of time equal to the period of such disability. The Service Provider shall immediately notify Glenmark if, by reason of any of the disabilities referred to herein, the Institution and the Investigator is unable to meet any specified deadline or time for performance.

16.2. In the event that any part of the Services is rendered invalid as a result of such disability, the Institution and the Investigator shall, upon written request from Glenmark, repeat that part of the Services affected by the disability. Provided, however, that if a Force Majeure Event continues for more than 2 months, a Party may terminate this Agreement by giving at least 15 days notice to the other Parties.

17. GOVERNING LAW / ARBITRATION

17.1. This Agreement is entered into and will be deemed for all purposes to be governed and construed in accordance with the laws of India.

17.2. All disputes arising out or in connection with the present Agreement, which cannot be settled amicably, shall be finally settled under the Indian Arbitration and Conciliation Act, 1996 by a sole arbitrator to be appointed in accordance with the said Act. The place of the arbitration shall be Mumbai. The language of the arbitration proceedings shall be English. Except as otherwise required by law, for the purposes of enforcement or any applicable stock exchange rules and regulations, the arbitral proceedings and the award shall not be made public without the joint consent of the Parties hereto and each such Party shall maintain the confidentiality of such proceedings or the award and such shall be deemed to be Confidential Information.

18. **NO WAIVER**

18.1. Any waiver by any Party of any breach of, or failure to comply with or failure to enforce at any time, any of the provisions of this Agreement shall not be construed as or constitute a continuing waiver of such provision, or a waiver of any other breach of or failure to comply with, any other provision of this Agreement, nor shall it in any way affect the validity of this Agreement or any part thereof or the right of any party thereafter to enforce each and every provision of this Agreement.

19. **SEVERABILITY**

19.1. Should one or more provisions of this Agreement be or become invalid or unenforceable, the parties shall substitute such invalid provisions by valid provisions as close in meaning and effect as the original provisions. Should such substitution not be possible the invalidity or unenforceability of such provision shall not affect the validity of the Agreement as a whole.

20. **ASSIGNMENT**

20.1. Neither Party shall assign or sub-contract this Agreement or part or all of its obligations herein without the prior written consent of the other Parties. Any Party, which does sub-contract, as permitted with the other Parties consent will remain responsible for the acts and omissions of its sub-contractors as though they were its own.

21. **AGREEMENT AND AMENDMENT**

21.1. Any change in the terms of this Agreement shall be valid only if the change is made in writing, agreed and signed by the Parties.

21.2. This Agreement including its Annexures contains the entire understanding between the Parties and supersedes all other negotiations representations and undertakings whether written or oral of prior date between the Parties relating to the Services that are the subject of this Agreement.

22. This Agreement is made in English in more than one copy each of which shall be deemed to be an original and may have been translated to another language. All such copies are valid and in case of any discrepancy, English text will prevail over other languages.

23. **THIRD PARTY RIGHTS**

23.1. Nothing in this Agreement is intended to confer on any third party any right to enforce any term of this Agreement.

24. **SURVIVAL OF OBLIGATIONS**

24.1. The agreements, covenants and obligations set forth in Sections 6, 7, 8, 9, 10, 11, 12, 13, 14, 17 and 24 shall continue to be binding upon the Parties hereto and shall survive any termination or expiry of this Agreement. Any other terms of this Agreement which are either expressed so as to survive (or are capable of surviving) expiry, or termination of this Agreement or from their nature or context it is contemplated that they are to survive expiry or termination, shall remain in full force and effect notwithstanding any expiry or earlier termination of this Agreement.

MUMBAI 400099.

25. NOTICES

25.1. All notices required or permitted under this Agreement shall be in writing and shall be deemed delivered when delivered in person or by fax or five (5) days after the date postmarked if sent by registered or certified mail or courier, return receipt requested, postage prepaid, addressed as follows:

If for Glenmark Pharmaceuticals Limited:

B/2 Mahalaxmi Chambers, 22, Bhulabhai Desai Road, Mumbai – 400026, India and its corporate office at Glenmark House, B D Sawant Marg, Chakala, Andheri (E), Mumbai – 400099, India

If for the Institution: MGM Medical College and Hospital, N-6, CIDCO, Aurangabad-431003, Maharashtra, India

If for the Investigator: Dr. Deepak Sadashiv Bhosle, Flat No 201, regency Royal, Surana Nagar, Aurangabad-431003, Maharashtra, India.

If for the SMO: Grapecity research Solution LLP, Prakash housing society, Block No 2, Thergaon, Pune, Maharashtra, India

25.2. A Party may change its address from time to time by providing written notice to the other Parties in the manner set forth above.

(Signature Page to follow)

MUMBAI 400099. GLENMARK LTD.

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed.

For Glenmark Pharmaceuticals Limited

Name: Suyog Shetty
Title: General Manager - Legal

GLENMARK PHARMACEUTICALS LTD. MUMBAI 400099.

For the Institution

DEAN
MGM'S MEDICAL COLLEGE
AURANGABAD

Name: Dr Rajendra Bohra
Title: Dean,

Investigator

Name: Dr Deepak sadashiv Bhosle
Title: Principal Investigator

For SMO

Name: Dr Sushil Chaudhary
Title: Director

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

ANNEXURE 1

PROTOCOL

The Protocol title and protocol number are as follows:

Protocol Title: Ref: "A 24-week, randomised, double-blind, double-dummy parallel-group, multi- centre, active-controlled study to evaluate efficacy and safety of remogliflozin etabonate in subjects with type-2 diabetes mellitus.

Sub: Clinical Trial Agreement

Protocol Number: **GPL/CT/2016/009/III**

Clinical Trial Phase: III

Protocol has already been provided to the Investigator separately and will form an integral part of this Agreement.

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

ANNEXURE 2

Description of Responsibilities

1. OBLIGATIONS OF THE INSTITUTION AND THE INVESTIGATOR

The Institution and Investigator hereby represent and warrant that it has the expertise, facilities and all appropriate registrations, licenses, permits and authorisations necessary to provide the Services and more particularly to conduct Trial to the highest of the professional standards and in accordance with this Agreement, the Protocol, ICH GCP and all applicable standard operating procedures.

1.1 Throughout the Term the Investigator shall:

1.1.1 appoint appropriately and professionally trained, experienced and qualified personnel to perform the Services under this Agreement;

1.1.2 appoint the Co-investigators who meet the conditions stipulated in **Annexure 6**, time to time review eligibility of such Co-investigators and discontinue/remove those Co-investigators from further conducting the Trial who no longer meet those conditions;

1.1.3 use all reasonable endeavours to ensure the smooth running of the Trial at all times as per the Protocol and time lines mentioned in **Annexure 4** and will ensure that the Co-investigator performs the Trial in accordance with the terms of this Agreement, the Protocol and as per the provisions of all laws and practices applicable;

1.1.4 act professionally and responsibly as the necessary interface between the Co-investigator, Institution, Site and Glenmark;

1.1.5 collect all information and data required by Glenmark pursuant to and in furtherance of the Trial;

1.1.6 immediate reporting to Glenmark in accordance with the SAE reporting plan on becoming aware of any SAEs at the Sites;

1.1.7 fully co-operate with Glenmark throughout the Term and even thereafter in respect of the performance of the Services and compilation and use of information and data generated from the Trial and follow all directions and instructions relating to the Trial provided by Glenmark;

1.1.8 use all reasonable endeavours to ensure that the Trial is planned, performed and concluded within the estimated Trial timeline as per the projection.

1.1.9 Where required as explicitly informed by Glenmark, nominate for Glenmark's approval an appropriate number of Co-Investigators for the Trial and keep Glenmark and Institution and its personnel at the Site notified of the contact details of the respective Co-Investigator (including an emergency number) allocated responsibility for overseeing the Trial at such Site;

1.1.10 ensure that the Investigational Product supplied pursuant to Glenmark's obligations hereunder is not used for any purpose other than the Trial;

1.2 Prior to the commencement of the Trial, the Investigator shall:

1.2.1 having regard to the scope of the Trial, eligibility criteria for Subjects, the Protocol and such relevant investigate, select and prepare a list of suitable Sites and the Co-Investigators (subject to section 1.1.9 above) for the Trial based upon the Investigator's assessment made at such time, evaluation of the patient database at such Site as well as ensuring that such Site has the necessary manpower, facilities and infrastructure to conduct the Trial pursuant to ICH-GCP guidelines and Glenmark's requirements and to collect and retain all essential documents including Consent Forms and the Trial Materials for each Site;

Page 17 of 25

1.2.2 compile and prepare all documentation necessary for seeking Ethics Committee's approvals for conducting such Trial;

1.2.3 obtain all appropriate approvals and authorisations and make all necessary arrangements for:

1.2.3.1 initiation, continuation and performance of the Trial in all selected Sites;

1.2.3.2 storage and administration of the Investigational Products at every Site for use in the Trial and of any other Trial Materials as well as storage, processing of laboratory samples and data taken from Subjects in the Trial;

1.2.3.3 obtain the necessary approvals from the Ethics Committee at each Site for the conduct of the Trial and storage and use of the Investigational Product;

1.2.3.4 prepare all necessary documentation for the performance of the Trial including language translations of Consent Forms and patient diaries into local languages;

1.2.4 educate and train all Site personnel involved, directly or indirectly, in the conduct of the Trial at each Site regarding ICH GCP guidelines and in relation to creating and maintaining the necessary documentation required during conducting the Trial including the management and compilation of the Site File;

1.3 In preparation for and during the conduct and performance of the Trial, the Investigator shall:

1.3.1 at each Site ensure that the Trial is performed specifically in accordance with the Protocol and the obligations hereunder;

1.3.2 at each Site ensure that the Co-Investigator is monitoring the conduct of the Trial at the Site and has completed all CRFs throughout the performance of the Trial;

1.3.3 ensure that Site has adequate and appropriate processes established and operating to ensure:

1.3.3.1 patient randomisation in pursuance with the Protocol;

1.3.3.2 maintenance of all study related logs regarding screening of the Subjects and their enrolment including proper collection and storage of all Consent Forms;

1.3.3.3 proper accounting and storage of Investigational Product and Trial Materials whilst on Site;

1.3.3.4 all other relevant and applicable communications and information regarding the Subjects and the Trial are recorded and logged, including telephone logs of clinical questions, CRFs and questions relating to CRFs;

1.3.3.5 ensure the expiry date, shelf life or use by date (or equivalent) of any Trial Materials or Investigational Product are monitored to ensure efficient rotation of stocks and safe destruction (pursuant to Glenmark's instructions) or return to supplier of any such materials that have expired;

[redacted]

1.3.3.7.2 ensuring any Ineligible Subject is not enrolled or participate in the Trial;

1.3.3.8 ensure randomisation of Subjects in the agreed timeframe and ensure adequate process for scheduling Subject visits as specified in the Protocol to ensure the Trial is in compliance with the Protocol;

1.3.3.9 conduct a close out visit at the Site on termination or expiry of the Trial or this Agreement as the case may be, during which any Trial Material, unused Investigational Product or any other material exclusively procured for the Trial purposes shall be collected and submitted to Glenmark or to the Central Storage Facility or by the Co-Investigators at the Sites pursuant to the written guidelines of Glenmark;

1.3.4 The Institution and the Investigator will provide all necessary support to Glenmark in fulfilling its obligations relating to the Trial including all support and expertise required for Adverse Event and SAE follow-up, tracking and reporting to applicable Agencies, Institutions and Sites, and providing status reports to the applicable Agencies.

1.3.5 The Institution and the Investigator will at all times permit Glenmark and/or its nominees to conduct an audit at such intervals as required by Glenmark of all Services provided by the Investigator under this Agreement including all records and documents relating to the Protocol, Services and Trial, and any equipment or materials supplied and/or maintained by the Institution and the Investigator in connection therewith and will provide such assistance as reasonably requested by Glenmark in connection therewith and shall ensure that Glenmark can audit the Site and the records of the Institution of such Site (including the Investigator's records) applicable to the Trial and Services.

1.3.6 The Institution and the Investigator will promptly notify Glenmark if the Co-Investigator ceases to be employed or engaged in the performance of the Trial at a Site together with the reasons why such the Co-Investigator is no longer involved and the Investigator will use best efforts to find a replacement acceptable to Glenmark as soon as possible.

1.4 The Institution and the Investigator warrant and represent that in entering into this Agreement it has not committed, any of the following acts:

1.4.1 providing or offering to provide to any person in the employment of the Institution and/or Site any gift or consideration other than that which is a reasonable financial arrangement either under this Agreement or by any other arrangement;

1.4.2 making payment or agreeing to make payment of any commission to any person in the employment of the Institution;

1.5 Institution and the Investigator will comply with all applicable laws and regulations in its/his/her performance of activities under this Agreement. Institution and Investigator will provide reasonable assistance to Glenmark so that Glenmark may comply with any applicable law or regulation in the performance of the activities under this Agreement.

1.6 Without limiting the generality of Section 1.5, Investigator will:

1.6.1 Take appropriate actions so that he/she will properly disclose protected or sensitive health information created or received by Investigator to Glenmark pursuant to any applicable Privacy Rule. Glenmark agrees to take appropriate measures to protect the privacy and confidentiality of the protected health information received in connection with the Trial.

1.6.2 Obtain a Glenmark approved written informed Consent Form from each Trial subject and will maintain a signed original of the written informed Consent Form in the Study subject's records.

2. <u>Glenmark Responsibilities:</u>

2.1 Glenmark agrees and acknowledges that it will ensure that the Investigational Product supplied for the Trial is manufactured and supplied to the Sites as per the Protocol and that it complies with the obligations of a clinical Trial sponsor as delegated under this Agreement in accordance with section 5 of ICH GCP.

2.1.1 Prior to commencement of the Trial, Glenmark shall:

2.1.1.1 prepare and finalize the Protocol, patient information sheet and Consent Form in English, Investigator brochure and provide the Trial Material to the Investigator for compiling the submissions for Ethics Committee approvals;

2.1.1.2 develop and finalise the monitoring and source data verification plan ("Monitoring and SDV Plan");

2.1.2 During the course of the Trials, Glenmark shall:

2.1.2.1 appoint a physician to act as a medical monitor to respond to Site questions regarding Subjects, their eligibility, dose modifications of the Investigational Product and to develop, authorise and maintain Protocol exceptions and/or deviations;

2.1.2.2 review Adverse Events and SAE reports as received from the Sites, along with the drug safety contact of the Investigator who will be primarily responsible for Adverse Event and SAE management;

2.1.2.3 establish and maintain the safety database for each Site;

2.1.2.4 notify all Sites, the Co-Investigators and Agencies of reported Adverse Events and SAEs as required by statutory bodies;

2.1.2.5 prepare periodic status reports for the study for the Agencies;

2.2 Glenmark shall assist the Institution and the Investigator in the performance of Services relating to seeking and obtaining approvals from the Ethics Committee, providing and maintaining on-site specific training/support to the Investigator to enable it to provide appropriate training and support to each Site and archiving of Trial related documents.

RESPONBILITIES OF ALL PARTIES:

1. All Parties further understand, acknowledge and agree that prior to or at any time during the course of the Agreement, Glenmark may amend or vary the Services and/or the Protocol. In such an event:

1.1. the Institution and the Investigator will co-operate with Glenmark to promptly incorporate and act upon such amendments in its performance of the Services going forward including undertaking further Site audits, training of personnel at each Site, seeking approvals to the amendments as appropriate from the Ethics Committees;

1.2. All Parties will negotiate in good faith any amendments to modifications in price and payment in **Annexure 5**, if applicable and required having regard to the impact of the changes in light of the previous scope of Services and the Protocol.

ANNEXURE 3
Standards

The following Standards are applicable to the provision of the Services by the Service Provider and Glenmark under this Agreement:-

- The Protocol annexed hereto as **Annexure 1** and any subsequent amendments
- ICH GCP
- Schedule Y (If an Indian study only)
- Other local laws and regulations

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

GLENMARK PHARMACEUTICALS LTD. * MUMBAI 400099.

ANNEXURE 4

FPI and CRF completion timelines

First Patient in (FPI)	Jul 2017
FPI to last Patient in (LPI)	Jul 2017 – Jan 2018
LPI to Last Patient Out (LPO)	Jan 2018 – Jul 2018

- CRF to be completed within 3 days of patient visit.
- All DCFs should be resolved within 2 days of issuance.
- All SAEs reporting to Glenmark, Ethics Committee and Regulatory Authorities to be done as per local regulatory requirements.
- All safety reports/updates from other sites provided by Glenmark to the Site shall be submitted by the Investigator to the Ethics Committee within 7 days of the receipt of the same or within such period as may be statutorily laid down.
- In case of no recruitment within 30 days of Site Initiation a joint decision would be taken by Sponsor and Investigators for continuation in the study

Dr. Rajesh B. Goel
Registrar
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KAMOTHE, NAVI MUMBAI

[illegible]

[illegible]

[illegible]

Site Budget	
Visit Details	Cost
Visit 1 (Screening & Lead-In)	5800
Visit 2 (Baseline-Day 1)	5500
Visit 3 (Day 8)	3900
Visit 4 (Day 29)	4200
Visit 5 (Day 57)	4200
Visit 6 (Day 85)	4400
Visit 7 (Day 112)	4200
Visit 8 (Day 141)	4200
Visit 9 (Day 169)	4600
Visit 10 (Day 183)	4000
Total Per Patient	**INR 45000**
Intitutional Overhead (20%)	**INR 9000**
Travel Reimbursements per patient all visit (1000/per visit x 10 visits	**INR 10000**

Description of Payments	**Cost(INR)**	**No. of patients projected at site**	**Total**
Total Per Patient	45000	30	13,50,000
Institutional Overhead Charges(20%)	9,000	30	27,0000
Travel Reimbursements per patient all visits	10,000	30	300,000
Site Facility Charges:- ECG(300x5)	1,500	30	45,000
Serum bicarbonate test 500X10	5,000	30	150,000
Serum Lactic acid test 1500X10	15,000	30	450,000
			INR 2,565,000

1. Patient travel reimbursement is upto maximum INR 1,000/- per visit and as per actuals. The amount for patient travel reimbursement mentioned above would be paid on actuals based on invoice received.
2. Local Laboratory and local test charges would be paid as per actual on case to case basis after confirmation from Sponsor.
3. Serum bicarbonate and Serum lactic acid test will be performed at local laboratory.
4. Payment for the recommended rescue medications (after confirmation from sponsor) would be paid on actuals, based on invoice received.
5. A maximum of 30% screen failed patients would be paid of the total randomized subjects an amount of Rs. 3000 as screening expenses only if screening procedures are conducted as per protocol at the end of the recruitment period.
6. As it is a competitive trial, the budget would be based on total number of patient enrolled on pro-rata basis for the grant mentioned above; for each completed patient.
7. For all patient visits, Investigator and Institute payments TDS will be deducted at source as per the existing rates.
8. Request for payment would be made by letter stating the amount on Investigator's

letter head/Institute letterhead and signed by Investigator/Hospital Authority after verified by the monitor per the completed visits and source data verified CRFs

9. The final payment would be released at the time of close out.
10. All payments made hereunder will be made in Indian Rupees.
11. Glenmark shall be entitled to deduct from any sums due hereunder any withholding taxes and other statutory duties which is mandatory to be deducted according to the applicable laws in force on the date of payment or invoice booking whichever is earlier.
12. GST (Goods and Service Tax) at the prevailing rate shall be payable by Glenmark in addition to the above Consideration.
13. All invoices shall mention the GST (Goods and Service Tax) number along with HSN code as mandated by law. If Grapecity Research solution LLP is exempted from GST, necessary certificates and declaration shall be provided by Grapecity Research solution LLP to Glenmark. If Grapecity Research solution LLP fails to comply with the above, then the invoice will not be payable by Glenmark.
14. Grapecity Research solution LLP shall pay all its GST liability & file its return on time to enable Glenmark to claim credit of the GST. If Grapecity Research solution LLP fails to comply with the same, then Sponsor will raise a debit note on Grapecity Research solution LLP for the default amount which Grapecity Research solution LLP will be liable to refund to Glenmark.
15. Any interest so charged by the authorities on Glenmark for default of Grapecity Research solution LLP, will also be recovered by Glenmark from Grapecity Research solution LLP by way of raising a debit note on Grapecity Research solution LLP.
16. If your site is given a laptop and/or dongle by Glenmark, then the same will be retrieved from your site before/during the Close Out Visit of your site.

Payee name	Grapecity Research solution LLP
PAN No.	AAPFG8186L
Name of the Bank and its Mailing address	ICICI Bank, plot No 1A , Gulmohar Road, aundh, Pune
Branch	Aundh
Bank Account No.	007305009846
IFSC code	ICIC0000073

Dr. Rajesh B. Goel
Registrar
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NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

ANNEXURE 6

Conditions Applicable to each the Co-Investigator

Each Co-Investigator:

1. must be free to participate in the clinical Trial and there are no rights which may be exercised by or obligations owed to any third party which might prevent or restrict his performance of the obligations detailed in this Agreement.

2. must not be involved in any regulatory or misconduct litigation or investigation by the Food and Drug Administration, the Medicines Control Agency, the European Medicines Evaluation Agency, the General Medical Council or other regulatory Agencies. No data produced by the Co-Investigator in any previous clinical study has been rejected because of concerns as to its accuracy or because it was generated by fraud.

3. must have considered, and is satisfied that, facilities appropriate to the Trial are available to him at the Site and that he/she is supported, and will continue to be supported, by medical and other staff of sufficient number and experience to enable the performance of the Trial efficiently and in accordance with the obligations under the Agreement and Protocol.

4. must during the Trial, not serve as the Co-Investigator or other significant participant in any clinical Trial for another sponsor if such activity might adversely affect his/her ability to perform his/her obligations under this Agreement.

5. has not nor have his spouse nor any dependent children, entered into and will not enter into any financial arrangements with Glenmark or the Investigator to hold financial interests in Glenmark or the Investigator that are required to be disclosed pursuant to the US Code of Federal Regulations Title 21, Part 54, namely (i) any financial arrangement whereby the value of the compensation paid in respect of the performance of the Trial could be influenced by the outcome of the Trial (as defined in 21 CFR 54.2(a)), (ii) any proprietary interest in the product being tested (as defined in 21 CFR 54.2(c)), (iii) any significant equity interest in Glenmark or the Investigator (as defined in 21 CFR 54.2(b)) and (iv) any significant payments from Glenmark or the Investigator such as grants to fund ongoing research, compensation in the form of equipment, retainers for ongoing consultation or honoraria (as defined in 21 CFR 54.2(f)). In the case of subparagraphs (iii) and (iv) the Co-Investigator understands that such prohibitions relate to the period that the Co-Investigator is carrying out the Trial and for 1 year following completion of the Trial.

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

Mahatma Gandhi Mission
Medical College & Hospital
N-6 CIDCO, Aurangabad-431003 (Maharashtra)
Phone : +91-0240-6601100, Fax: 0240-2487727, web:www.mgmmcha.org

Date: - 01 Mar 2019

To,
Member Secretary,
MGM-ECRHS,
MGM Campus, N-6 Cidco, Aurangabad. 431003.
India

Protocol Number: Protocol no: GPL/CT/2016/009/III

Protocol Title: A 24-week, randomized, double-blind, double-dummy parallel-group, multi-centre, active-controlled study to evaluate efficacy and safety of remogliflozin etabonate in subjects with type-2 diabetes mellitus.

Subject: Submission of Ethics committee fees for protocol amendment.

Dear Madam,

With Reference to above Subject, Here by I am submitting cheque towards EC Fees for protocol amendment.

Payment Details:

Sr.No	Payment	Cheque No	Amount Rs.	Date
01	EC Payment	028514	20,000	21 Feb 2019

Kindly acknowledge the receipt of the same by signing the box below and attesting the stamp of the Ethics Committee.

Dr. Deepak Bhosle
Principal Investigator
MGM Medical College
N-6 Cidco. Aurangabad. -431003.
Maharashtra.

A/c to accept
4/3/19

Dean/Medical Director
MGM Medical College,
Aurangabad.

4/3/19

Acknowledgement

Name	Designation	Signature & date
Dr Deepali Jaybhaye	Member Secretary	01/03/2019

Member Secretary
MGM-ECRHS
MGM's Medical College,Aurangabad

Rec'd 04/03/19

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

MGM-ECRHS AURANGABAD

Glenmark
Glenmark Pharmaceuticals Limited
Glenmark House, B D Sawant Marg, Andheri (E),
Mumbai 400099. Tel No. 4018 9999, Fax No. 4018 9986.

Glenmark

PAYMENT ADVICE

To

MGM Medical College, Aurangabad
MGM Medical college, N-6 CIDCO,

431003,Aurangabad,Maharashtra

VOUCHER NO. 1003070760

DATE 21.02.2019

SUPPLIER CODE : 10025168

DOC NO.	BILL DATE	BILL NO.	AMOUNT DEBIT	CREDIT / TDS	REMARK
1001407132	22.01.2019	02/2019	22,222.00	2,222.00	

TOTAL 2,222.00

RUPEES IN WORDS : TWENTY THOUSAND & PAISE ZERO ONLY

PARTICULARS 028514 :

CHQ NO. 028514

Bank : BANK OF INDIA. KOPARKHAIRNE BRANCH

Prepared by Checked by Approved by Receiver's Signature

A/C Payee Not Negotiable

बैंक ऑफ इंडिया
कोपरखैरणे ब्रान्च
नवी मुंबई
IFSC : BKID0000171

BANK OF INDIA
Koparkhairne Branch,
Navi Mumbai -400709

VALID FOR THREE MONTHS FROM THE DATE OF ISSUE

2	1	0	2	2	0	1	9
D	D	M	M	Y	Y	Y	Y

Not Over Rs. 20,000.00

Pay MGM Medical College, Aurangabad

या उनके आदेश पर Or Order

रुपये Rupees TWENTY THOUSAND & PAISE ZERO ONLY

अदा करें ₹ 20,000.00

खा.सं A/c No. 017130110000041

For Glenmark Pharmaceuticals Limited

Authorised Signatories

Please sign above

PAYABLE AT ALL OUR BRANCHES IN CLEARING

Seshasai (M) CTS - 2010/10.2018

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

⑈028514⑈ 400013163⑈ 004518⑈ 30

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

Glenmark

Glenmark Pharmaceuticals Limited
~~Glenmark House, B D Sawant Marg, Andheri (E),~~
Mumbai 400099, Tel No. 4018 9999, Fax No. 4018 9986.

Glenmark

To

MGM Medical College, Aurangabad
MGM Medical college, N-6 CIDCO,

431003,Aurangabad,Maharashtra

PAYMENT ADVICE

VOUCHER NO.	1003070760
DATE	21.02.2019
SUPPLIER CODE :	10025168

DOC NO.	BILL DATE	BILL NO.	AMOUNT DEBIT	AMOUNT CREDIT / TDS	REMARK
1001407132	22.01.2019	02/2019	22,222.00	2,222.00	
		TOTAL	22,222.00	2,222.00	

RUPEES IN WORDS : TWENTY THOUSAND & PAISE ZERO ONLY

PARTICULARS 028514 :
~~028512~~

CHQ NO. 028514

Bank : BANK OF INDIA, KOPARKHAIRNE BRANCH

Prepared by | Checked by | Approved by | Receiver's Signature

A/c Payee Only Not Negotiable

बैंक ऑफ इंडिया Bank of India BOI

बैंक ऑफ इंडिया BANK OF INDIA
कोपरखैरणे शाखा Koparkhairne Branch,
नवी मुंबई–४०० ७०९ Navi Mumbai -400709
IFSC : BKID0000171

जारी की गई तारीख से तीन माह के लिए वैध
VALID FOR THREE MONTHS FROM THE DATE OF ISSUE

2	1	0	2	2	0	1	9
D	D	M	M	Y	Y	Y	Y

Not Over Rs. 20,000.00

Pay MGM Medical College, Aurangabad या उनके आदेश पर Or Order

रुपये Rupees TWENTY THOUSAND & PAISE ZERO ONLY

अदा करें ₹ 20,000.00

खा.सं A/c No. 017130110000041

For Glenmark Pharmaceuticals Limited

Authorised Signatories

Please sign above

PAYABLE AT ALL OUR BRANCHES IN CLEARING

Sectasaal (M) OTS : 2010/10.2018

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

⑈028514⑈ 400013163⑈ 004518⑈ 30

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

MAHATMA GANDHI MISSION
MEDICAL COLLEGE
N-6 CIDCO, Aurangabad-431003 (Maharashtra)
Phone : +91-0240-6601100-Ext.174/329, E-mail : mgmpharmacologydept@gmail.com

Date: 28.09.2017

To
Member Secretary
Dr. Deepali Jaybhaye
MGM-ECRHS
MGM Medical College.N-6 Cidco. Aurangabd.-431003.

Protocol Number: GPL/CT/2016/009/III

Protocol Title: A 24-week, randomised, double-blind, double-dummy parallel-group,multi-centre, active-controlled study to evaluate efficacy and safety of remogliflozin etabonate in subjects with type-2 diabetes mellitus. **Version 2.0 (Amendment 1.0)**

Subject: Submission of Ethics Committee Fees.

Dear Dr. Deepali Jaybhaye,

With Reference to above Subject, here by I am submitting cheque towards EC review Fees
Payment Details:

Sr.No	Payment	Cheque No	Amount Rs.	Tax Deducted Rs	Net Amount Rs	Date
01	EC Payment	016588	44,445.00	4,445.00	40,000.00	20 Sep 2017

Kindly acknowledge the receipt of the same by signing the box below and attesting the stamp of the Ethics Committee.

With best regards,

Professor & H.O.D.
Department of Pharmacology
MGM's Medical College
Aurangabad.

Dr. Deepak Bhosle
Principal Investigator
Mahtama Gandhi Mission's Medical College and Hospital.
N-6 , Cidco .Aurangabad-431003.

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

Dr.Shashank D. Deshmukh
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

MAHATMA GANDHI MISSION
MEDICAL COLLEGE
N-6 CIDCO, Aurangabad-431003 (Maharashtra)
Phone : +91-0240-6601100-Ext.174/329, E-mail : mgmpharmacologydept@gmail.com

I acknowledge the receipt of EC Review fee cheque on behalf of the Ethics Committee

28 SEP 2017		Dr. Deepali Jaybhaye
Date received	Signature	Name of the Personnel

Seal of the Ethics Committee

MGM-ECRHS AURANGABAD

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
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(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

(6)

2019-20

MAHATMA GANDHI MISSION

Mahatma Gandhi Mission's Medical College & Hospital

N-6 CIDCO, Aurangabad - 431003

DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS

(CLINICAL RESEARCH UNIT)

Office: Dr. Deepak Bhosle, Prof & Head, Dept. of Clinical Pharmacology & Therapeutics, MGM Medical College & Hospital
N-6,CIDCO,Aurangabad – 431003. Ph. No: 0240-6601423, 0240-6601174, Email: pharmacolgy@mgmmcha.org

Date: 28 Jun 2019

To,
The Dean,
MGM Medical College and Hospital.
N-6 Cidco, Aurangabad -431003.

Protocol No.: GPL/CT/2016/009/III

Protocol Title: A 24-week randomized, double blind, double-dummy parallel-group, multi-centre, active-controlled study to evaluate efficacy and safety of remogliflozin etabonate in subjects with type-2 diabetes mellitus.

Subject: Submission of Study Payment including Institutional Overhead Charges.

Respected Sir,

With Reference to above Subject, Here by I am submitting cheque towards study payment including Institutional overhead charges.

Payment Details:

Sr.No	Payment	Cheque No	Amount Rs.	TDS Rs.	Payable Amount Rs.
01	Study Payment + Institutional Overhead Charges	000673	72046.00	7204.00	64842.00

Kindly acknowledge the receipt of the same by signing in the below box.

With best regards,

Dr. Deepak Bhosle
Principal Investigator
Mahtama Gandhi Mission's Medical College and Hospital.
N-6, Cidco .Aurangabad-431003.

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

29/6

We accept cheque

29/6/19

MGM Medical College, Aurangabad.

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

MAHATMA GANDHI MISSION
Mahatma Gandhi Mission's Medical College & Hospital
N-6 CIDCO, Aurangabad - 431003
DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS
(CLINICAL RESEARCH UNIT)
Office: Dr. Deepak Bhosle, Prof & Head, Dept. of Clinical Pharmacology & Therapeutics, MGM Medical College & Hospital
N-6,CIDCO,Aurangabad – 431003. Ph. No: 0240-6601423, 0240-6601174, Email: pharmacolgy@mgmmcha.org

Acknowledgement of Receipt	
Received By: **(Authorized Person- Signature & Stamp)**	 **Date:**

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
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Dr.Shashank D.Dalvi
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ICICI Bank
Aundh Branch
Gulmohar Park, Plot 1 A, III Road, Aundh, Pune - 411 007.
RTGS / NEFT IFS Code : ICIC0000073

VALID FOR THREE MONTHS ONLY

26 06 2019
D D M M Y Y Y Y

Pay M G M Medical College OR ORDER

Rupees Sixty four Thousand Eight Hundred
fourty Two Rupees Only. ₹ 64842/-

A/c No. 007305009846

CABUS CBS

BUSINESS BANKING - CURRENT ACCOUNT
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Payable at par at all branches of ICICI Bank Limited in India

26/10/18

FOR GRAPECITY RESEARCH SOLUTIONS LLP

AUTHORISED SIGNATORIES
Please sign above

⑈000673⑈ ⑆122900⑆ 009846⑈ 29

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हरियाणा HARYANA

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OUS Templates
OUS LOA
Revised: 07 2017

17-May-2018

Dr. Hemangi Jerajani
Professor and Head, Department of Dermatology
MGM Institute of Health Sciences
3rd Floor, Sector-1, Kamothe
Navi Mumbai - 410209

Dear Jerajani:

This agreement ("Agreement") is by and between Eli Lilly and Company (India) Pvt. Ltd.("Lilly"), **AND Dr. Hemangi Jerajani,** Professor and Head, Department of Dermatology, as the principal investigator ("Investigator"), **of MGM Institute of Health Sciences, 3rd Floor, Sector 1, Kamothe, Navi Mumbai - 410209** ("Institution") for the performance of the study ("Study) entitled "A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Baricitinib in Adult Patients with Moderate to Severe Atopic Dermatitis," protocol **I4V-MC-JAHL** ("Protocol"), which Protocol is incorporated herein by reference. Investigator is an independent contractor of Institution with privileges to use Institution's facilities and resources. This agreement ("Agreement") sets forth the obligations of Lilly, the Investigator and Institution.

I. YOUR OBLIGATIONS

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

A. Conduct of the Study

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

In carrying out Investigator and Institution's responsibilities under this Agreement, Investigator and Institution agree to comply with all applicable anti-bribery laws in the countries where Investigator and Institution have Institution's principal place of business and where Investigator and Institution conduct activities under this Agreement. Additionally, Investigator and Institution understand and agree to comply with the U.S. Foreign Corrupt Practices Act, as revised, which generally prohibits the offer, promise, payment or giving of anything of value either directly or indirectly to any government official for the purpose of obtaining or retaining business or any improper advantage. For purposes of this section, "government official" means any official, officer, representative, or employee of, including any doctor employed by, any non-U.S. government department, agency or instrumentality (including any government-owned or controlled commercial enterprise), or any official of a public international organization or political party or candidate for political office. Additionally, if Investigator and Institution or any of Institution's owners, directors, employees, agents, and consultants are government officials, Investigator and Institution agree that Lilly's payment of Investigator and Institution in connection with this Agreement is not intended to influence any decision that any individual may make in their capacity as a government official. Investigator and Institution further represent that neither Investigator and Institution nor any of Institution's owners, directors, employees, agents, or consultants will directly or indirectly offer to pay, promise to pay or give anything of value to any government official for purposes of (i) influencing any act or decision of such government official in his official capacity; (ii) inducing such government official to do or omit to do any act in violation of the lawful duty of such official; (iii) securing any improper advantage; or (iv) inducing such government official to use his influence with the government or instrumentality thereof to affect or influence any act or decision of the government or such instrumentality with respect to any activities undertaken relating to this Agreement. Additionally, Investigator and Institution will make reasonable efforts to comply with requests for information, including answering questionnaires and narrowly tailored audit inquiries, to enable Lilly to ensure compliance with applicable anti-bribery laws. Investigator and Institution agree that Lilly's payment to Investigator and Institution in connection with the services to be provided under this Agreement is not intended to influence any decision Investigator and Institution may make regarding the prescription of Lilly medicines or to otherwise influence any pending or future Lilly business.

Investigator and Institution shall also ensure that each investigator and sub-investigator at Institution'sStudy Site (s) provides Lilly with the appropriate financial information for compliance with all applicable laws and regulations and Lilly policy, and Investigator and Institution understand and shall ensure that each investigator and sub-investigator understands that laws, regulations and Lilly policy may require certain financial information to be submitted to regulatory authorities.

If Investigator is not a licensed physician, Investigator and/or Institution shall ensure that a licensed physician is an investigator or sub-investigator at Study Site (s) and will be responsible for patient care and other appropriate aspects of this Study.

Investigator acknowledges that Investigator has read and understands all information in the investigator's brochure provided to Investigator by Lilly, including the potential risks and side effects of the Study drug.

Investigator and Institution agree not to pay fees to another physician for the referral of patients.

Investigator and Institution agree to only use an informed consent document which has been reviewed and approved by Lilly.

Investigator and Institution agree that Lilly, Lilly-designated representatives and domestic or foreign regulatory agencies may inspect procedures, facilities and Study records (including portions of other pertinent records for all patients in the Study) and those procedures, facilities or Study records of any contractor, agent Study Site (s) used in conducting the Study. Investigator and Institution shall provide Lilly with immediate notice of any governmental or regulatory review, audit or inspection of the facility or processes related to the StudyLilly shall be given the opportunity to provide assistance to Investigator and Institution in responding to any such review, audit or inspection.Investigator and Institution shall provide Lilly with the results of any such review, audit or inspection. When data are reviewed by an on-site scheduled visit of a Lilly-designated representative, Investigator and/or Institution will have all reasonably available data obtained through the preceding day complete and ready for evaluation. Information obtained from such inspections may be shared with Lilly and Lilly-designated representatives. In the event that there is a lack of compliance with this Agreement, Lilly is entitled to secure compliance or discontinue shipments of Study drug and end Investigator and/or Institution's participation in the Study.

B. Clinical Trial Materials and Record Retention

Drugs furnished for the Study will be used solely under the Protocol and may not be used for any other purposes. Investigator and Institution shall follow Lilly's instructions related to disposition of clinical trial materials. Investigator and Institution shall be responsible for compliance with all laws and regulations applicable to any destruction or disposition of clinical trial materials at Study Site(s). All Study records must be retained for fifteen (15) years after completion or termination of the Study, provided, however, that in the unlikely event that ICH or FDA record retention requirements, (i.e., two (2) years after the date of marketing application approval by FDA for the Study drug(s) indication investigated, or if an application is not approved, two (2) years after the FDA is notified by Lilly of discontinuation of the IND) are longer than fifteen (15) years, Lilly will notify Investigator and Institution regarding any additional length of time that records must be

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retained to meet such requirements. The Investigator and/or Institution agree to take the appropriate measures to prevent premature destruction of essential documents.

C. Confidentiality and Non-Use

All information provided to Investigator and/or Institution by Lilly or Lilly-designated representatives, or generated by Investigator and/or Institution in connection with the Study, will be kept in confidence and not used for any purpose not expressly provided for in this Agreement for at least five (5) years after the termination or conclusion of the Study, except to the extent that Lilly gives Investigator and/or Institution written permission or particular information is required by laws or regulations to be disclosed to the ERB, the patient or local regulatory agencies. To the extent disclosure is requested by any other person or entity, Investigator and/or Institution shall promptly notify Lilly and shall not disclose any information without Lilly's prior written consent. If such disclosure is sought by a third party under a claim of legal right, Investigator and/or Institution will reasonably cooperate with Lilly in the event Lilly wishes to take legal action to challenge such claim or the disclosure; provided, however, in no event shall Investigator and/or Institution be obligated to defy any law, regulation or judicial or governmental order.Investigator and Institution shall be responsible for ensuring that their employees, sub investigators, contractors and agents are obligated to these same terms of confidentiality and non-use. The terms of confidentiality and non-use set forth herein shall supersede any prior terms of confidentiality and non-use agreed to by the parties in connection with this Study. The terms of this Agreement shall also be considered confidential information and may be disclosed only to the extent required by law or necessary for approval of this Study.Additionally, in the event Investigator is invited to be an author of a Lilly publication or presentation during the course of or after the conclusion of the Study covered by this Agreement, Investigator and Institution agree that they will hold all new information (including data from other investigator sites for multi-site studies) provided to Investigator or Institution by Lilly or Lilly-designated representatives, or generated by Investigator or Institution in connection with such authorship, in confidence for five (5) years from the date of such disclosure or the generation of information, as applicable. This obligation survives the expiration, cancellation or termination of this Agreement.

The foregoing obligations of confidentiality and non-use will not apply to information that:

(1) is or later becomes part of the public domain other than through Investigator or Institution's act or omission;

(2) was known by Investigator and/or Institution prior to disclosure by Lilly or becomes known from an independent source or third party under no obligation to Lilly or any other third party to keep such information confidential, as can be shown by prior written documentation; or

(3) is independently developed, as shown by written documentation, by Investigator or Institution or their personnel who have not had access to confidential information provided by Lilly.

D. Data

Data generated in connection with the Study, excluding patient medical records not recorded as case report forms, shall be the sole property of Lilly and shall be subject to the obligations of Confidentiality and Non-Use set forth above.

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E. Publications

Notwithstanding the obligations of Confidentiality and Non-Use set forth above, Investigator and Institution will be free to publish and present the results of the Study subject to the following conditions: Lilly will be furnished with a copy of any proposed publication or presentation for review and comment thirty (30) days prior to such presentation or submission for publication. Such thirty (30) day period does not begin until receipt of the proposed publication or presentation at Lilly in Indianapolis, Indiana. At the expiration of such thirty (30) day period, Investigator and/or Institution may proceed with the presentation or submission for publication; provided, however, that in the event Lilly has notified Investigator or Institution in writing that Lilly reasonably believes that prior to such publication or presentation it must take action to protect its intellectual property interests, such as the filing of a patent application claiming an invention or a trademark registration application, Investigator and/or Institution shall either (1) delay such publication or presentation for an additional sixty (60) days or until the foregoing action(s) have been taken, whichever shall first occur; or (2) if Investigator and/or Institution are unwilling to delay the publication or presentation, Investigator and/or Institution will remove from the publication or presentation the information which Lilly has specified it reasonably believes would jeopardize its intellectual property interests. Under certain circumstances, a shorter review period may be granted in writing by Lilly. Investigator and/or Institution will assist Lilly in obtaining reprints of Investigator or Institution's publication(s) resulting from the Study.

F. Inventions

If during the course of the Study or within one (1) year after termination of this Agreement, Investigator and/or Institution conceive or actually reduce to practice what Investigator and/or Institution believe to be a new invention (including, without limitation, new uses, processes, formulations, therapeutic combinations or methods) occurring as a result of the performance of the Study covered by this Agreement or involving the Study drug(s), device(s), or simple derivatives of the Study drug(s) (e.g. but not limited to, antibody fragments, analogs, salts, solvates, conformers, stereoisomers, racemic mixtures, amorphous forms, crystal forms, crystal habits, metabolites, prodrugs, free acids, chelates, complexes, synthetic intermediates, isotopic or radiolabeled equivalents or mixtures thereof), Investigator and/or Institution shall promptly notify Lilly. The new invention or use shall be the sole property of and shall be assigned to Lilly.

G. Publicity

Consistent with the obligations of Confidentiality and Non-Use set forth above Investigator and/or Institution agree to the following:

(1) Solicitation of patients. Lilly and the ERB must approve, in writing, the text of any communication soliciting patients for the Study before placement, including, but not limited to, newspaper and radio advertisements, direct mail pieces, internet advertisements or communications and newsletters. Such communications must comply with applicable laws and guidelines.

(2) Press releases. Lilly must approve, in writing, press statements by Investigator and/or Institution regarding the Study or the Study drug(s) before the statements are released.

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(3) Inquiries from media and financial analysts. During and after the Study Investigator and Institution may receive inquiries from reporters or financial analysts. Investigator and Institution agree to confer with Lilly's Research Physician or Medical Director at +91-124-4753000 or Lilly's Corporate Communications Department in the United States at (001-317-276-3402) to discuss such inquiries before responding to them.

(4) Use of name. Neither Lilly nor Investigator and Institution will use the name or names of the other party or their employees in any advertising or sales promotional material or in any publication without prior written permission; provided, however, Investigator and Institution agree to the use of their names in Study publications and communications, including clinical trial web sites and Study newsletters and Lilly may disclose Investigator and Institution's name and the names of any sub-investigators, the type of services performed by Investigator and Institution and and/or any sub-investigator for Lilly under this Agreement, the existence and terms of this Agreement, and the amount of compensation Lilly paid in exchange for Investigator and Institution's services or the services of any sub-investigator, in order to comply with applicable laws and regulations.Investigator and Institution shall be responsible for ensuring that all sub-investigators have consented to these same terms of disclosure.

H. Debarment Certification (Generic Drug Enforcement Act of 1992)

Investigator and Institution agree that they are not and have not been debarred or disqualified from participating in clinical research by any United States regulatory authority or by any other regulatory authority, and that they will not use or involve any person or organization in connection with this Study that is or has been debarred or disqualified by any regulatory authority from participating in clinical research. In the event that Investigator and/or Institution or any person or organization they use or involve in connection with the Study should become debarred or disqualified during the course of the Study, Investigator and/or Institution agree to promptly notify Lilly in writing.

I. Contract Research Organization Involvement

Lilly shall be entitled to authorize a contract research organization to perform certain sponsor obligations for this Study. Investigator and Institution agree to cooperate with any Lilly-authorized contract research organization in performing this Study.

J. Equipment

Lilly is providing Investigator and/or Institution with equipment ("Equipment") for use in the Study. Investigator and Institutionagree to comply with all manuals and instructions from Lilly regarding the use and care of the Equipment. Investigator and Institution agree that the Equipment shall remain in the same condition, ordinary wear and tear excepted, and that Investigator and Institution shall be responsible for the Equipment including the maintenance or any risk of loss in connection with the Equipment during the term of the Study. Investigator and Institution will follow Lilly's instructions for disposition of the Equipment at the completion or termination of the Study.

K. Site Personnel Data

Lilly may collect personal information from Investigator and Institution personnel including but not limited to names, titles and business contact information ("Site Personnel Data") and may provide that information to Lilly's business partners and vendors working with Lilly on matters related to the Study to fulfill Lilly's business purposes, including:

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(1) Compliance with laws and regulations regarding possible financial conflicts of interest;
(2) Assessment of personnel qualifications to conduct the Study;
(3) Quality control and Study management; and
(4) Disclosures to ERBs, Ethics Committeesor national or foreign regulatory authorities in connection with their performance of review or oversight responsibilities for the Study.

Site Personnel Data may also be aggregated with data from other Lilly sources and evaluated for business decisions including those involving future research. Lilly may store or process such Site Personnel Data in the U.S. or other countries at Lilly or Lilly-associated facilities, as long as a business need or legal obligation exists.

Investigator and Institution personnel may have access to Site Personnel Data about themselves that Lilly has collected and may have corrections made to Site Personnel Data about themselves that is inaccurate. Investigator and Institution agree to obtain the permission of their personnel for the transfer and use of Site Personnel Data for the purposes described in this section

Investigator and Institution may contact Lilly with inquiries regarding Lilly's collection or use of Site Personnel Data. Lilly agrees to comply with all applicable laws and regulations regarding Lilly's use of Site Personnel Data.

II. LILLY SUPPORT

Lilly will provide Investigator and/or Institution with Study drug(s) and/or device(s) as applicable to the Study. In addition, Lilly will provide financial support for the Study as follows:

A. Payee
Payment in connection with the Study will be made to the name and address listed below:

Payee: MGM Institute of Health Sciences

Address:MGM Institute of Health Sciences

3rd Floor, College Building, Sector 1, Kamothe, Navi Mumbai - 410209

PAN: AACTM0014C
(Identification Number for Tax Purposes)

B. Payment Schedule
In connection with the Study, Institution will be paid in accordance with the terms set forth in the budget ("Budget"), attached hereto as Exhibit A. For those amounts designated for patient services, Institutionwill receive payment only for data received based on the actual number of visits and procedures performed in accordance with agreed upon procedure fees outlined in the Budget. Such compensation is limited to payment for the number of patients designated in the Budget who are enrolled in the Study by **30-Dec-2018**, unless Lilly givesInvestigator or Institution written approval to enroll additional patients or extend the enrollment period. In the event that such approval is granted, Institution will be paid in accordance with the fees set forth in the Budget for the additional

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patients.Other than the final payment, Lilly shall not issue any payment for a total amount less than INR 1,000 (Rupees One Thousand Only). In the event the amount due in any given period is less than INR 1,000 (Rupees One Thousand Only), such amount shall carry over without payment to the next payment period. In addition to the payments set forth above, Lilly will also reimburse Payee for reimbursable expenses as set forth in the Budget.

To be eligible for payment, all procedures must be performed in full compliance with the Protocol and this Agreement, and the data submitted must be complete and correct. For data to be complete and correct, each patient must have signed an ERB-approved consent document, and all procedures designated in the Protocol must be carried out on a "best efforts" basis; omissions must be satisfactorily explained. Final payment will be made by Lilly to the Payee when all patients at the Site have completed the Study and upon final acceptance by Lilly of all CRFs pages, all data clarifications issued, the receipt and approval of any outstanding regulatory documents as required by Lilly, the return of all unused supplies to Lilly, and upon satisfaction of all other applicable conditions set forth in this Agreement.It is expected that for all items required under the Protocol for which Lilly has agreed to provide compensation, Lilly will be the sole source of compensation. Institution will not seek payment from any third party payor, whether public or private, for any costs covered by payments made by Lilly under this Agreement. Matters in dispute shall be payable upon mutual resolution of such dispute.

When Investigator and/or Institution data are reviewed by an on-site scheduled visit of a Lilly-designated representative, Investigator and/or Institution will have all reasonably available data obtained through the preceding day complete and ready for evaluation. Lilly reserves the right to refuse payment for data not received by Lilly within ten (10) days after the representative's review.

In addition, if Lilly requests Investigator and/ or Institution attendance at a Study startup meeting or other meeting necessary to provide Investigator and/or Institution information regarding the Study or Study drug, Lilly shall reimburse Institution for reasonable and necessary travel and lodging expenses (including meals) that are incurred to attend such meeting(s) that have been specifically approved in advance by Lilly. Lilly shall make such reimbursements within thirty (30) days of receiving acceptable detailed documentation of such expenses, provided that Lilly receives such documentation within sixty (60) days of the date that the expenses were incurred.

C. Subject Injury Reimbursement

Lilly agrees to reimburse Institution for the following additional costs:

(1) All reasonable and customary costs incurred and associated with the diagnosis of an adverse event involving the Study drug or a Protocol procedure; and

(2) All reasonable and customary costs incurred for treatment of physical injury to the subject if Lilly determines after consulting with Investigatorthat the adverse event was reasonably related to administration of the Study drug or Protocol; provided, however, that:

(a) such costs are not covered by the subject's medical or hospital insurance or other governmental program providing such coverage;

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(b) the adverse event is not attributable to Investigator and/or Institution or any of their agents' or employees' negligence or misconduct;

(c) the adverse event is not attributable to any underlying illness, whether previously diagnosed or not; and

(d) Investigator and Institution have adhered to and complied with the specifications of the Protocol and all recommendations furnished by Lilly for the use and administration of any drug or device used in the Study.

Lilly shall have the option of paying the additional costs directly to the provider of the service or to Institution.

D. Limit of Patient Entry or Enrollment and Study Termination

Lilly reserves the right to limit entry or enrollment of additional patients at any time. This may occur in a competitive-enrollment Study because sufficient patients have been entered by other investigators to complete the needs of the Study. Lilly also reserves the right to terminate Investigator, Institution or any patient's participation in the Study or the Study itself at any time for any reason. Investigator and/or Institution may terminate the Study upon thirty (30) days written notice in the event (1) there is a breach of a material provision of this Agreement by Lilly, which breach is not cured by Lilly within ninety (90) days following receipt from Investigator and/or Institution of written notice thereof; (2) if the Investigator becomes unavailable due to death or disability and Institution and Lilly are unable to agree upon an acceptable replacement; or (3) if the authorization and approval to perform the Study is withdrawn by any local regulatory authority, any United States regulatory authority or by the ERB. In the event Investigator and/or Institution's participation in the Study or the Study itself is terminated, Investigator and/or Institutionagree to return, retain or dispose of all Study drug(s) in accordance with instructions to be provided by Lilly and regulatory requirements.

In the event of termination, payments will be made for all work that has been performed up to the date of termination and shall be limited to reasonable non-cancelable costs which were incurred by Investigator and/or Institution in connection with the Study as required under the Protocol and contemplated in the Budget. If any paymentsexceed the amount owed for work performed under the Protocol, Investigator and/or Institution agree to return the excess balance to Lilly.

III. INDEMNIFICATION

In consideration of the performance by Investigator, Institution and their staff, officers, agents and employees ("Indemnitees") of the Study, Lilly agrees to indemnify, defend and hold harmless the Indemnitees from and against loss, damage, cost and expense of claims and suits (including reasonable legal fees) resulting from an injury to a patient seeking damages alleged to have been directly caused or contributed to by any substance or procedure administered in accordance with the Protocol, including the cost and expense of handling such claims and defending such suits; provided, however, (1) that Indemnitees have adhered to and complied with all applicable federal, state and local regulations (including, without limitation, obtaining informed consents and IRB approvals), the specifications of the Protocol and all recommendations furnished by Lilly for the use and administration of any drug or device described in the Protocol; (2) that Lilly is promptly notified of any such claim or suit; (3) that the Indemnitees cooperate fully in the investigation and defense of any such claim or suit; (4) that Lilly retains the right to defend the lawsuit in any manner it deems appropriate, including the right to retain

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counsel of its choice; and (5) that Lilly shall have the sole right to settle the claim or suit; provided, however, that Lilly shall not admit fault on Indemnitees' behalf without Indemnitees' advance written permission. In addition, Lilly's obligation of indemnification shall not extend to any loss, damage or expense arising from the negligence, willful malfeasance or unlawful act or malpractice by the Indemnitees, it being understood that the administration of any substance in accordance with the Protocol shall not constitute negligence, willful malfeasance or unlawful act or malpractice for purposes of this Agreement.

IV. SURVIVORSHIP CLAUSE

The obligations under the sections INVESTIGATOR AND INSTITUTION OBLIGATIONS, SUBJECT INJURY REIMBURSEMENT and INDEMNIFICATION shall survive the expiration, termination or cancellation of this Agreement.

V. INDEPENDENT CONTRACTOR

Institution and Lilly will be acting as independent contractors and not as an agent, partner or employee of the other party. Neither Institution nor Lilly will have any authority to make agreements with third parties that are binding on the other party.

By signing this Agreement, Investigator and Institution represent and warrant thatthey have the authority and ability to or will otherwise contractually bind any individual or entity who performs services for Investigator and Institutionin connection with the Study hereunder to the terms and conditions of this Agreement. This Agreement is legally binding when, but not until, each party has received from the other a counterpart of the Agreement signed by the authorized representative. The parties' representatives may sign separate, identical counterparts of this document; taken together, they constitute one agreement. A signed counterpart may be delivered by any reasonable means, including facsimile or other electronic transmission. Additionally, the parties agree that facsimile or email copies of this Agreement are considered to be a legal original and signatures thereon shall be legal and binding agreement.

This Agreement represents the entire understanding between the parties and supersedes all other agreements, express or implied, between the parties concerning the subject matter hereof. This Agreement has been thoughtfully considered by the parties and, consequently, shall not be strictly construed against either party. This Agreement shall be interpreted in accordance with the laws of India (Haryana Jurisdiction).

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Exhibit A:JAHL

S. No.	Investigations	No of Visits	Cost/frequency INR (Y)	Total Amount (X*Y*Z)
1.	**Principle Investigator Fee:** @Rs. 4000/- per patient clinic visit x 9 visits for 10 enrolled patients **(Z)**	Total-9 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8/ED, 801)	4000	360,000
2.	**Co-Investigator Fee:** @ Rs. 2500/- patient clinic visit x 9 visits for 10 enrolled patients	Total-9 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8/ED, 801)	2500	225,000
3.	**Study Coordinator Fee:** @ Rs. 1500/- per patient clinic visit x 9 visits for 10 enrolled patients	Total 9 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8/ED, 801)	1500	135,000
4.	**Phlebotomist Fee** @ Rs. 700/- per patient clinic visit x 7 visits for 10 enrolled patients	Total 7 Visits (Visits-1, 2, 5, 6, 7, 8/ED, 801)	700	49,000
5.	**Patient Inconvenience** including TDS @ Rs. 1111/- per patient x 9 clinic visits x10 enrolled patients	Total-9 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8/ED, 801)	1111	99,990
6.	**Institutional Grant** 20% of PI+ Co-I + SC fees	Total-9 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8/ED, 801)	1600	144,000
7.	**Admin grant** @ Rs. 444 per visit x 9 clinic visits x 10 enrolled patients	Total-9 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8/ED, 801)	444	39,960
8.	**Chest X-Ray** @ Rs.300/- x 1 visit for 10 enrolled patients	Visit 1	300	3,000
9.	**12-lead ECG** (performed and read locally) @ INR 300/-per patient on visit 1 for 10 enrolled patients	Visit 1	300	3,000
10.	Initial Admin Grant paid after Site initiation visit		30,000	30,000
11.	Final Admin Grant paid after data base lock		30,000	30,000
			Total Grant for 10 Patients	**11,18,950**
12.	Screen Failure Cost (Assume 10 pts)	Visit 1	12,455	1,24,550
13.	Pre-Screening Reimbursement @ INR 1000 per identified patient in pre-screening log for upto 30 patients		1000	30,000

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Exhibit B: Payment Schedule

The payments will be made per patient visit entered into the data management system (based on the investigation schedule and cost outlined in the table number 1, unless indicated otherwise, as per the following table:

S. No.	Particulars	Cost INR
	Total Payment for each visit inclusive of 20% institutional Grant on PI, Co-I, CRC fees	
1.	Visit 1 & Screen Failures	12,455
2.	Visit 2	11,855
3.	Visit 3	11,155
4.	Visit 4	11,155
5.	Visit 5	11,855
6.	Visit 6	11,855
7.	Visit 7	11,855
8.	Visit 8	11,855
9.	Visit 801	11,855
10.	Early discontinuation Visit	11,855

Exhibit C: Procedural Payments

S. No.	Procedure at Local Lab	Visit	Cost of Procedure	Total Amount for 10 pts
1.	**Urine Pregnancy test** @ Rs.300/- x 7 visit for 10 enrolled patients	Total-7 visits (Visit 2, 4, 5,6,7,8,801)	300	21,000
2.	Herpes Zoster Vaccine, provided & administered locally by Site, if required. Up to one vaccine administration per patient			On Actuals
3.	Reimbursement of locally-sourced over-the-counter emollients (up to 500g). Price is per bottle/Tube and requires third-party receipts to be provided.			On Actuals
4.	**Purified PPD TB test** @ Rs.300/- x 1 visit for 10 enrolled patients	Total-1 Visit (Visit 1)	300	3,000
5.	**QuantiFERON®-TB Gold test** @ Rs.4000/- x 1 visit for 10 enrolled patients	Total-1 Visit (Visit 1)	4000	40,000

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Descriptions:

- Per Patient budget excluding GST: **INR 1,11,895**
- Site enrollment target (Z): **10 patients**
- Total Budget including Pre-screened patients, Screen failure patients& Procedural Payments:**INR13,37,500**
- Total Budget, including GST: **INR 15,78,250**

Payment Cycle and Procedure:

- Payments will be made on a monthly basis, based on invoices received on or before 5th of every month
- All the visits and procedures included in the invoice must be entered into CRF (Case Report Form) for the payment to be processed
- Payments for Pre-screening will be processed based on the pre-screening logs received from site on weekly basis.

Procedural Payment:

- Procedural payments will be processed and reimbursed on request from the site.
- The procedures performed at site's internal laboratory will be reimbursed based on amount specified in this agreement. A copy of invoice for the procedure is needed in this case.
- The procedures performed at External laboratory will be reimbursed based on amount claimed in invoice. A copy of invoice for the procedure is mandatory in this case.

GST:

- The above mentioned calculation of visit payment does not include GST. GST will be paid as applicable based on the invoices received
- **Eli Lilly India PAN number: AAACE8901F**

Screen Failure Patients:

- The Payment of screen failure patients would be paid on the basis of patients who have signed the ICF and the eCRF data entry for the same has been completed in Electronic Data Management System (INFORM) and as per amount specified for screen failure in Exhibit A (Visit 1).

Patient Reimbursement

- Patient reimbursement amount is inclusive of the TDS amount.

Screen Failure & Early Discontinuation Patients:

- This LOA is valid for a maximum of 30 pre-screened, 10 screen failures & 10 Randomized patients.
- Early Discontinuation fee will be paid if all required procedures as per schedule of events in study protocol have been carried out at a clinic visit by the patient.

Pre-Screening Reimbursement:

- To commence after site has received Ethics Committee approval and this Letter of agreement is fully signed & executed.
- Payable upon weekly receipt of completed Pre-screening Log, for identified subjects based on I/E criteria.
- Frequency of payment will be Monthly.

Kindly note that if final number of patient visits/ lab tests is more or less, addition or deduction respectively would be made to the above grant heads at the rates given against each.

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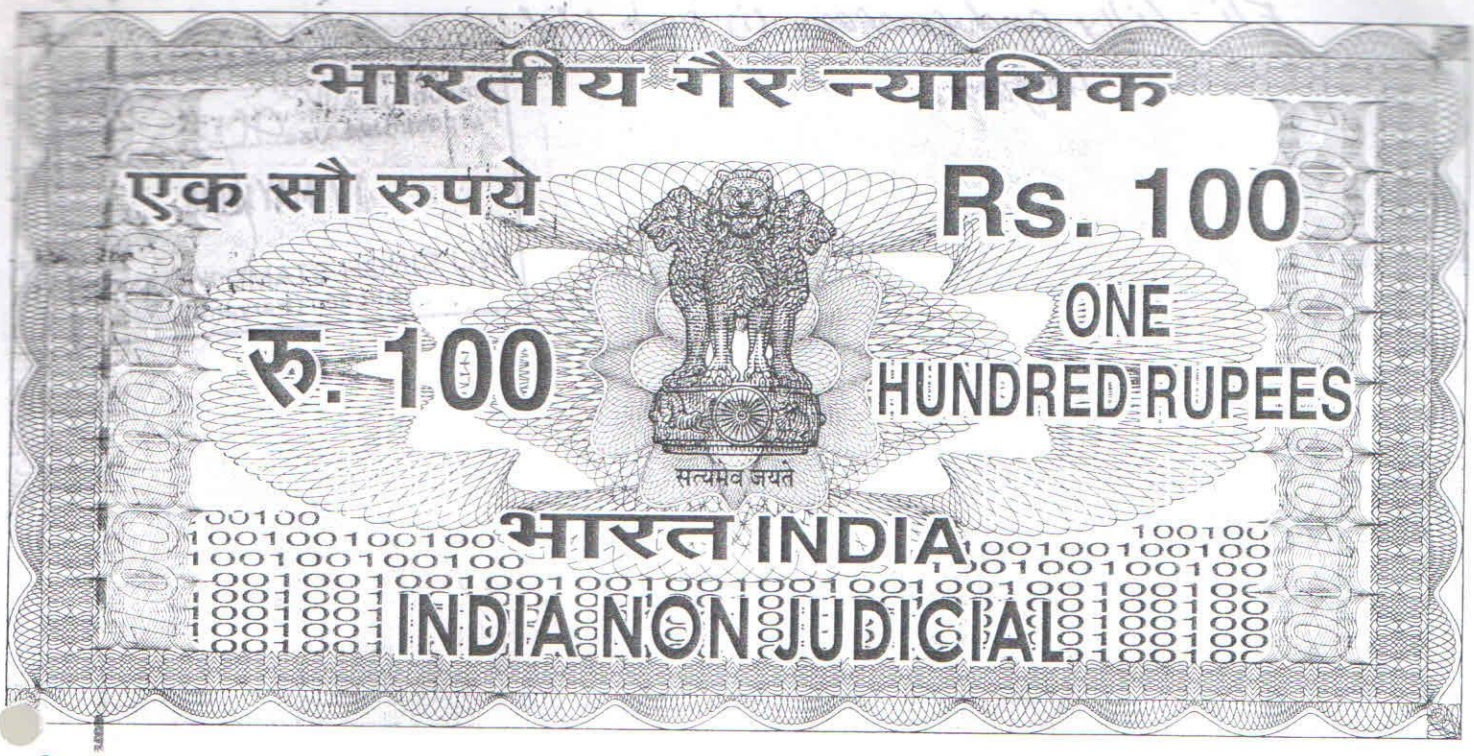

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OUS Templates
OUS LOA
Revised: 07 2017

17-May-2018

Dr. Hemangi Jerajani
Professor and Head, Department of Dermatology
MGM Institute of Health Sciences
3rd Floor, Sector-1, Kamothe
Navi Mumbai - 410209

Dear Jerajani:

This agreement ("Agreement") is by and between Eli Lilly and Company (India) Pvt. Ltd.("Lilly"), **AND Dr. Hemangi Jerajani,** Professor and Head of Department of Dermatology, as the principal investigator ("Investigator"), of **MGM Institute of Health Sciences, 3rd Floor, Sector 1, Kamothe, Navi Mumbai - 410209** ("Institution") for the performance of the study ("Study) entitled "Phase 3 Multicenter, Double-Blind Study to Evaluate theLong-Term Safety and Efficacy of Baricitinib in Adult Patients with Atopic Dermatitis" protocol **I4V-MC-JAHN** ("Protocol"), which Protocol is incorporated herein by reference. Investigator is an independent contractor of Institution with privileges to use Institution's facilities and resources. This agreement ("Agreement") sets forth the obligations of Lilly, the Investigator and Institution.

I. YOUR OBLIGATIONS

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

A. Conduct of the Study
Investigator and Institution agree that Investigator will personally conduct or supervise the Study at Institution and any Lilly-approved Investigator satellite sites (collectively "Study Sites"), if

Eli Lilly and company (i) Pvt Ltd
Gurgaon

2615

Sr No.....
Amount.....
Purpose/Use.....

17 MAY 2018

RAJ SINGH STAMP VENDOR
Gurgaon (Haryana)

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

In carrying out Investigator and Institution's responsibilities under this Agreement, Investigator and Institution agree to comply with all applicable anti-bribery laws in the countries where Investigator and Institution have Institution's principal place of business and where Investigator and Institution conduct activities under this Agreement. Additionally, Investigator and Institution understand and agree to comply with the U.S. Foreign Corrupt Practices Act, as revised, which generally prohibits the offer, promise, payment or giving of anything of value either directly or indirectly to any government official for the purpose of obtaining or retaining business or any improper advantage. For purposes of this section, "government official" means any official, officer, representative, or employee of, including any doctor employed by, any non-U.S. government department, agency or instrumentality (including any government-owned or controlled commercial enterprise), or any official of a public international organization or political party or candidate for political office. Additionally, if Investigator and Institution or any of Institution's owners, directors, employees, agents, and consultants are government officials, Investigator and Institution agree that Lilly's payment of Investigator and Institution in connection with this Agreement is not intended to influence any decision that any individual may make in their capacity as a government official. Investigator and Institution further represent that neither Investigator and Institution nor any of Institution's owners, directors, employees, agents, or consultants will directly or indirectly offer to pay, promise to pay or give anything of value to any government official for purposes of (i) influencing any act or decision of such government official in his official capacity; (ii) inducing such government official to do or omit to do any act in violation of the lawful duty of such official; (iii) securing any improper advantage; or (iv) inducing such government official to use his influence with the government or instrumentality thereof to affect or influence any act or decision of the government or such instrumentality with respect to any activities undertaken relating to this Agreement. Additionally, Investigator and Institution will make reasonable efforts to comply with requests for information, including answering questionnaires and narrowly tailored audit inquiries, to enable Lilly to ensure compliance with applicable anti-bribery laws. Investigator and Institution agree that Lilly's payment to Investigator and Institution in connection with the services to be provided under this Agreement is not intended to influence any decision Investigator and Institution may make regarding the prescription of Lilly medicines or to otherwise influence any pending or future Lilly business.

Investigator and Institution shall also ensure that each investigator and sub-investigator at Institution'sStudy Site (s) provides Lilly with the appropriate financial information for compliance with all applicable laws and regulations and Lilly policy, and Investigator and Institution understand and shall ensure that each investigator and sub-investigator understands that laws,

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regulations and Lilly policy may require certain financial information to be submitted to regulatory authorities.

If Investigator is not a licensed physician, Investigator and/or Institution shall ensure that a licensed physician is an investigator or sub-investigator at Study Site (s) and will be responsible for patient care and other appropriate aspects of this Study.

Investigator acknowledges that Investigator has read and understands all information in the investigator's brochure provided to Investigator by Lilly, including the potential risks and side effects of the Study drug.

Investigator and Institution agree not to pay fees to another physician for the referral of patients.

Investigator and Institution agree to only use an informed consent document which has been reviewed and approved by Lilly.

Investigator and Institution agree that Lilly, Lilly-designated representatives and domestic or foreign regulatory agencies may inspect procedures, facilities and Study records (including portions of other pertinent records for all patients in the Study) and those procedures, facilities or Study records of any contractor, agent Study Site (s) used in conducting the Study. Investigator and Institution shall provide Lilly with immediate notice of any governmental or regulatory review, audit or inspection of the facility or processes related to the StudyLilly shall be given the opportunity to provide assistance to Investigator and Institution in responding to any such review, audit or inspection.Investigator and Institution shall provide Lilly with the results of any such review, audit or inspection. When data are reviewed by an on-site scheduled visit of a Lilly-designated representative, Investigator and/or Institution will have all reasonably available data obtained through the preceding day complete and ready for evaluation. Information obtained from such inspections may be shared with Lilly and Lilly-designated representatives. In the event that there is a lack of compliance with this Agreement, Lilly is entitled to secure compliance or discontinue shipments of Study drug and end Investigator and/or Institution's participation in the Study.

B. Clinical Trial Materials and Record Retention

Drugs furnished for the Study will be used solely under the Protocol and may not be used for any other purposes. Investigator and Institution shall follow Lilly's instructions related to disposition of clinical trial materials. Investigator and Institution shall be responsible for compliance with all laws and regulations applicable to any destruction or disposition of clinical trial materials at Study Site(s). All Study records must be retained for fifteen (15) years after completion or termination of the Study, provided, however, that in the unlikely event that ICH or FDA record retention requirements, (i.e., two (2) years after the date of marketing application approval by FDA for the Study drug(s) indication investigated, or if an application is not approved, two (2) years after the FDA is notified by Lilly of discontinuation of the IND) are longer than fifteen (15) years, Lilly will notify Investigator and Institution regarding any additional length of time that records must be retained to meet such requirements. The Investigator and/or Institution agree to take the appropriate measures to prevent premature destruction of essential documents.

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C. Confidentiality and Non-Use

All information provided to Investigator and/or Institution by Lilly or Lilly-designated representatives, or generated by Investigator and/or Institution in connection with the Study, will be kept in confidence and not used for any purpose not expressly provided for in this Agreement for at least five (5) years after the termination or conclusion of the Study, except to the extent that Lilly gives Investigator and/or Institution written permission or particular information is required by laws or regulations to be disclosed to the ERB, the patient or local regulatory agencies. To the extent disclosure is requested by any other person or entity, Investigator and/or Institution shall promptly notify Lilly and shall not disclose any information without Lilly's prior written consent. If such disclosure is sought by a third party under a claim of legal right, Investigator and/or Institution will reasonably cooperate with Lilly in the event Lilly wishes to take legal action to challenge such claim or the disclosure; provided, however, in no event shall Investigator and/or Institution be obligated to defy any law, regulation or judicial or governmental order. Investigator and Institution shall be responsible for ensuring that their employees, sub investigators, contractors and agents are obligated to these same terms of confidentiality and non-use. The terms of confidentiality and non-use set forth herein shall supersede any prior terms of confidentiality and non-use agreed to by the parties in connection with this Study. The terms of this Agreement shall also be considered confidential information and may be disclosed only to the extent required by law or necessary for approval of this Study. Additionally, in the event Investigator is invited to be an author of a Lilly publication or presentation during the course of or after the conclusion of the Study covered by this Agreement, Investigator and Institution agree that they will hold all new information (including data from other investigator sites for multi-site studies) provided to Investigator or Institution by Lilly or Lilly-designated representatives, or generated by Investigator or Institution in connection with such authorship, in confidence for five (5) years from the date of such disclosure or the generation of information, as applicable. This obligation survives the expiration, cancellation or termination of this Agreement.

The foregoing obligations of confidentiality and non-use will not apply to information that:

(1) is or later becomes part of the public domain other than through Investigator or Institution's act or omission;

(2) was known by Investigator and/or Institution prior to disclosure by Lilly or becomes known from an independent source or third party under no obligation to Lilly or any other third party to keep such information confidential, as can be shown by prior written documentation; or

(3) is independently developed, as shown by written documentation, by Investigator or Institution or their personnel who have not had access to confidential information provided by Lilly.

D. Data

Data generated in connection with the Study, excluding patient medical records not recorded as case report forms, shall be the sole property of Lilly and shall be subject to the obligations of Confidentiality and Non-Use set forth above.

E. Publications

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Notwithstanding the obligations of Confidentiality and Non-Use set forth above, Investigator and Institution will be free to publish and present the results of the Study subject to the following conditions: Lilly will be furnished with a copy of any proposed publication or presentation for review and comment thirty (30) days prior to such presentation or submission for publication. Such thirty (30) day period does not begin until receipt of the proposed publication or presentation at Lilly in Indianapolis, Indiana. At the expiration of such thirty (30) day period, Investigator and/or Institution may proceed with the presentation or submission for publication; provided, however, that in the event Lilly has notified Investigator or Institution in writing that Lilly reasonably believes that prior to such publication or presentation it must take action to protect its intellectual property interests, such as the filing of a patent application claiming an invention or a trademark registration application, Investigator and/or Institution shall either (1) delay such publication or presentation for an additional sixty (60) days or until the foregoing action(s) have been taken, whichever shall first occur; or (2) if Investigator and/or Institution are unwilling to delay the publication or presentation, Investigator and/or Institution will remove from the publication or presentation the information which Lilly has specified it reasonably believes would jeopardize its intellectual property interests. Under certain circumstances, a shorter review period may be granted in writing by Lilly. Investigator and/or Institution will assist Lilly in obtaining reprints of Investigator or Institution's publication(s) resulting from the Study.

F. Inventions

If during the course of the Study or within one (1) year after termination of this Agreement, Investigator and/or Institution conceive or actually reduce to practice what Investigator and/or Institution believe to be a new invention (including, without limitation, new uses, processes, formulations, therapeutic combinations or methods) occurring as a result of the performance of the Study covered by this Agreement or involving the Study drug(s), device(s), or simple derivatives of the Study drug(s) (e.g. but not limited to, antibody fragments, analogs, salts, solvates, conformers, stereoisomers, racemic mixtures, amorphous forms, crystal forms, crystal habits, metabolites, prodrugs, free acids, chelates, complexes, synthetic intermediates, isotopic or radiolabeled equivalents or mixtures thereof), Investigator and/or Institution shall promptly notify Lilly. The new invention or use shall be the sole property of and shall be assigned to Lilly.

G. Publicity

Consistent with the obligations of Confidentiality and Non-Use set forth above Investigator and/or Institution agree to the following:

(1) Solicitation of patients. Lilly and the ERB must approve, in writing, the text of any communication soliciting patients for the Study before placement, including, but not limited to, newspaper and radio advertisements, direct mail pieces, internet advertisements or communications and newsletters. Such communications must comply with applicable laws and guidelines.

(2) Press releases. Lilly must approve, in writing, press statements by Investigator and/or Institution regarding the Study or the Study drug(s) before the statements are released.

(3) Inquiries from media and financial analysts. During and after the Study Investigator and Institution may receive inquiries from reporters or financial analysts. Investigator and Institution agree to confer with Lilly's Research Physician or Medical Director at +91-124-

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4753000 or Lilly's Corporate Communications Department in the United States at (001-317-276-3402) to discuss such inquiries before responding to them.

(4) Use of name. Neither Lilly nor Investigator and Institution will use the name or names of the other party or their employees in any advertising or sales promotional material or in any publication without prior written permission; provided, however, Investigator and Institution agree to the use of their names in Study publications and communications, including clinical trial web sites and Study newsletters and Lilly may disclose Investigator and Institution's name and the names of any sub-investigators, the type of services performed by Investigator and Institution and and/or any sub-investigator for Lilly under this Agreement, the existence and terms of this Agreement, and the amount of compensation Lilly paid in exchange for Investigator and Institution's services or the services of any sub-investigator, in order to comply with applicable laws and regulations. Investigator and Institution shall be responsible for ensuring that all sub-investigators have consented to these same terms of disclosure.

H. Debarment Certification (Generic Drug Enforcement Act of 1992)

Investigator and Institution agree that they are not and have not been debarred or disqualified from participating in clinical research by any United States regulatory authority or by any other regulatory authority, and that they will not use or involve any person or organization in connection with this Study that is or has been debarred or disqualified by any regulatory authority from participating in clinical research. In the event that Investigator and/or Institution or any person or organization they use or involve in connection with the Study should become debarred or disqualified during the course of the Study, Investigator and/or Institution agree to promptly notify Lilly in writing.

I. Contract Research Organization Involvement

Lilly shall be entitled to authorize a contract research organization to perform certain sponsor obligations for this Study. Investigator and Institution agree to cooperate with any Lilly-authorized contract research organization in performing this Study.

J. Equipment

Lilly is providing Investigator and/or Institution with equipment ("Equipment") for use in the Study. Investigator and Institutionagree to comply with all manuals and instructions from Lilly regarding the use and care of the Equipment. Investigator and Institution agree that the Equipment shall remain in the same condition, ordinary wear and tear excepted, and that Investigator and Institution shall be responsible for the Equipment including the maintenance or any risk of loss in connection with the Equipment during the term of the Study. Investigator and Institution will follow Lilly's instructions for disposition of the Equipment at the completion or termination of the Study.

K. Site Personnel Data

Lilly may collect personal information from Investigator and Institution personnel including but not limited to names, titles and business contact information ("Site Personnel Data") and may provide that information to Lilly's business partners and vendors working with Lilly on matters related to the Study to fulfill Lilly's business purposes, including:

(1) Compliance with laws and regulations regarding possible financial conflicts of interest;
(2) Assessment of personnel qualifications to conduct the Study;

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(3) Quality control and Study management; and
(4) Disclosures to ERBs, Ethics Committeesor national or foreign regulatory authorities in connection with their performance of review or oversight responsibilities for the Study.

Site Personnel Data may also be aggregated with data from other Lilly sources and evaluated for business decisions including those involving future research. Lilly may store or process such Site Personnel Data in the U.S. or other countries at Lilly or Lilly-associated facilities, as long as a business need or legal obligation exists.

Investigator and Institution personnel may have access to Site Personnel Data about themselves that Lilly has collected and may have corrections made to Site Personnel Data about themselves that is inaccurate. Investigator and Institution agree to obtain the permission of their personnel for the transfer and use of Site Personnel Data for the purposes described in this section

Investigator and Institution may contact Lilly with inquiries regarding Lilly's collection or use of Site Personnel Data. Lilly agrees to comply with all applicable laws and regulations regarding Lilly's use of Site Personnel Data.

II. LILLY SUPPORT

Lilly will provide Investigator and/or Institution with Study drug(s) and/or device(s) as applicable to the Study. In addition, Lilly will provide financial support for the Study as follows:

A. Payee

Payment in connection with the Study will be made to the name and address listed below:

Payee: MGM Institute of Health Sciences

Address:MGM Institute of Health Sciences

3rd Floor, College Building, Sector 1, Kamothe, Navi Mumbai - 410209

PAN: AACTM0014C
(Identification Number for Tax Purposes)

B. Payment Schedule

In connection with the Study, Institution will be paid in accordance with the terms set forth in the budget ("Budget"), attached hereto as Exhibit A. For those amounts designated for patient services, Institutionwill receive payment only for data received based on the actual number of visits and procedures performed in accordance with agreed upon procedure fees outlined in the Budget. Such compensation is limited to payment for the number of patients designated in the Budget who are enrolled in the Study by **30-Dec-2020**, unless Lilly givesInvestigator or Institution written approval to enroll additional patients or extend the enrollment period. In the event that such approval is granted, Institution will be paid in accordance with the fees set forth in the Budget for the additional patients.Other than the final payment, Lilly shall not issue any payment for a total amount less than INR 1,000 (Rupees One Thousand Only). In the event the amount due in any given period is less than INR 1,000 (Rupees One Thousand Only), such amount shall carry over without payment to

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the next payment period. In addition to the payments set forth above, Lilly will also reimburse Payee for reimbursable expenses as set forth in the Budget.

To be eligible for payment, all procedures must be performed in full compliance with the Protocol and this Agreement, and the data submitted must be complete and correct. For data to be complete and correct, each patient must have signed an ERB-approved consent document, and all procedures designated in the Protocol must be carried out on a "best efforts" basis; omissions must be satisfactorily explained. Final payment will be made by Lilly to the Payee when all patients at the Site have completed the Study and upon final acceptance by Lilly of all CRFs pages, all data clarifications issued, the receipt and approval of any outstanding regulatory documents as required by Lilly, the return of all unused supplies to Lilly, and upon satisfaction of all other applicable conditions set forth in this Agreement. It is expected that for all items required under the Protocol for which Lilly has agreed to provide compensation, Lilly will be the sole source of compensation. Institution will not seek payment from any third party payor, whether public or private, for any costs covered by payments made by Lilly under this Agreement. Matters in dispute shall be payable upon mutual resolution of such dispute.

When Investigator and/or Institution data are reviewed by an on-site scheduled visit of a Lilly-designated representative, Investigator and/or Institution will have all reasonably available data obtained through the preceding day complete and ready for evaluation. Lilly reserves the right to refuse payment for data not received by Lilly within ten (10) days after the representative's review.

In addition, if Lilly requests Investigator and/ or Institution attendance at a Study startup meeting or other meeting necessary to provide Investigator and/or Institution information regarding the Study or Study drug, Lilly shall reimburse Institution for reasonable and necessary travel and lodging expenses (including meals) that are incurred to attend such meeting(s) that have been specifically approved in advance by Lilly. Lilly shall make such reimbursements within thirty (30) days of receiving acceptable detailed documentation of such expenses, provided that Lilly receives such documentation within sixty (60) days of the date that the expenses were incurred.

C. Subject Injury Reimbursement

Lilly agrees to reimburse Institution for the following additional costs:

(1) All reasonable and customary costs incurred and associated with the diagnosis of an adverse event involving the Study drug or a Protocol procedure; and

(2) All reasonable and customary costs incurred for treatment of physical injury to the subject if Lilly determines after consulting with Investigatorthat the adverse event was reasonably related to administration of the Study drug or Protocol; provided, however, that:

(a) such costs are not covered by the subject's medical or hospital insurance or other governmental program providing such coverage;

(b) the adverse event is not attributable to Investigator and/or Institution or any of their agents' or employees' negligence or misconduct;

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(c) the adverse event is not attributable to any underlying illness, whether previously diagnosed or not; and

(d) Investigator and Institution have adhered to and complied with the specifications of the Protocol and all recommendations furnished by Lilly for the use and administration of any drug or device used in the Study.

Lilly shall have the option of paying the additional costs directly to the provider of the service or to Institution.

D. Limit of Patient Entry or Enrollment and Study Termination

Lilly reserves the right to limit entry or enrollment of additional patients at any time. This may occur in a competitive-enrollment Study because sufficient patients have been entered by other investigators to complete the needs of the Study. Lilly also reserves the right to terminate Investigator, Institution or any patient's participation in the Study or the Study itself at any time for any reason. Investigator and/or Institution may terminate the Study upon thirty (30) days written notice in the event (1) there is a breach of a material provision of this Agreement by Lilly, which breach is not cured by Lilly within ninety (90) days following receipt from Investigator and/or Institution of written notice thereof; (2) if the Investigator becomes unavailable due to death or disability and Institution and Lilly are unable to agree upon an acceptable replacement; or (3) if the authorization and approval to perform the Study is withdrawn by any local regulatory authority, any United States regulatory authority or by the ERB. In the event Investigator and/or Institution's participation in the Study or the Study itself is terminated, Investigator and/or Institutionagree to return, retain or dispose of all Study drug(s) in accordance with instructions to be provided by Lilly and regulatory requirements.

In the event of termination, payments will be made for all work that has been performed up to the date of termination and shall be limited to reasonable non-cancelable costs which were incurred by Investigator and/or Institution in connection with the Study as required under the Protocol and contemplated in the Budget. If any paymentsexceed the amount owed for work performed under the Protocol, Investigator and/or Institution agree to return the excess balance to Lilly.

III. INDEMNIFICATION

In consideration of the performance by Investigator, Institution and their staff, officers, agents and employees ("Indemnitees") of the Study, Lilly agrees to indemnify, defend and hold harmless the Indemnitees from and against loss, damage, cost and expense of claims and suits (including reasonable legal fees) resulting from an injury to a patient seeking damages alleged to have been directly caused or contributed to by any substance or procedure administered in accordance with the Protocol, including the cost and expense of handling such claims and defending such suits; provided, however, (1) that Indemnitees have adhered to and complied with all applicable federal, state and local regulations (including, without limitation, obtaining informed consents and IRB approvals), the specifications of the Protocol and all recommendations furnished by Lilly for the use and administration of any drug or device described in the Protocol; (2) that Lilly is promptly notified of any such claim or suit; (3) that the Indemnitees cooperate fully in the investigation and defense of any such claim or suit; (4) that Lilly retains the right to defend the lawsuit in any manner it deems appropriate, including the right to retain counsel of its choice; and (5) that Lilly shall have the sole right to settle the claim or suit; provided, however, that Lilly shall not admit fault on Indemnitees' behalf without Indemnitees' advance written permission. In addition, Lilly's obligation of indemnification shall not extend to any loss, damage or

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expense arising from the negligence, willful malfeasance or unlawful act or malpractice by the Indemnitees, it being understood that the administration of any substance in accordance with the Protocol shall not constitute negligence, willful malfeasance or unlawful act or malpractice for purposes of this Agreement.

IV. SURVIVORSHIP CLAUSE

The obligations under the sections INVESTIGATOR AND INSTITUTION OBLIGATIONS, SUBJECT INJURY REIMBURSEMENT and INDEMNIFICATION shall survive the expiration, termination or cancellation of this Agreement.

V. INDEPENDENT CONTRACTOR

Institution and Lilly will be acting as independent contractors and not as an agent, partner or employee of the other party. Neither Institution nor Lilly will have any authority to make agreements with third parties that are binding on the other party.

By signing this Agreement, Investigator and Institution represent and warrant thatthey have the authority and ability to or will otherwise contractually bind any individual or entity who performs services for Investigator and Institutionin connection with the Study hereunder to the terms and conditions of this Agreement. This Agreement is legally binding when, but not until, each party has received from the other a counterpart of the Agreement signed by the authorized representative. The parties' representatives may sign separate, identical counterparts of this document; taken together, they constitute one agreement. A signed counterpart may be delivered by any reasonable means, including facsimile or other electronic transmission. Additionally, the parties agree that facsimile or email copies of this Agreement are considered to be a legal original and signatures thereon shall be legal and binding agreement.

This Agreement represents the entire understanding between the parties and supersedes all other agreements, express or implied, between the parties concerning the subject matter hereof. This Agreement has been thoughtfully considered by the parties and, consequently, shall not be strictly construed against either party. This Agreement shall be interpreted in accordance with the laws of India (Haryana Jurisdiction).

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If the foregoing is acceptable, please sign the enclosed Agreement and return it to Lilly by courier service to **Saurabh Sharma, Eli Lilly and Company, Plot No. 92, Sector – 32, Gurgaon, Haryana - 122001**, If You have any questions, please call **Saurabh Sharma** at **+91-9891614224.**

Sincerely,

ELI LILLY AND COMPANY (INDIA) PVT. LTD.

(Signature of Authorized Official)

Dr. Rajeev SharanShrivastava
Associate Director –Regulatory Affairs and Pharmacovigilance

(Typed or Printed Name and Title)

17 MAY- 2018

(Date)

AGREED AND ACCEPTED:
Investigator

H. R. Jerajani

Dr. Hemangi Jerajani

Professor & Head, Department of Dermatology
MGM Medical College, Navi Mumbai
(PI on behalf of MGMIHS.

(Date) 22-05-2018

AGREED AND ACCEPTED:
Registrar
MGM Institute of Health Sciences
Sector-1, Kamothe, Navi Mumbai

(Signature of Authorized Official)

Dr. Rajesh B Goel, Registrar
(Typed or Printed Name and Title)

22.05.2018

(Date)

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Exhibit A:JAHN

S. No.	Investigations	No of Visits	Cost/frequency INR (Y)	Total Amount (X*Y*Z)
1.	**Principle Investigator Fee:** @Rs. 4000/- per patient clinic visit x 17 visits for 10 enrolled patients **(Z)**	Total-17 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16/ED, 801)	4000	680,000
2.	**Co-Investigator Fee:** @ Rs. 2500/- patient clinic visit x 17 visits for 10 enrolled patients	Total-17 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16/ED, 801)	2500	425,000
3.	**Study Coordinator Fee:** @ Rs. 1500/- per patient clinic visit x 17 visits for 10 enrolled patients	Total-17 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16/ED, 801)	1500	255,000
4.	**Phlebotomist Fee** @ Rs. 700/- per patient clinic visit x 12 visits for 10 enrolled patients	Total-12 visits (Visits-1, 2, 3, 4, 5, 6, 8, 11, 13, 15, 16/ED, 801)	700	84,000
5.	**Patient Inconvenience** including TDS @ Rs. 1111/- per patient x 17 clinic visits x 10 enrolled patients	Total-17 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16/ED, 801)	1111	188,870
6.	**Institutional Grant** 20% of PI+ Co-I + SC fees	Total-17 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16/ED, 801)	1600	272,000
7.	**Admin grant** @ Rs. 235 per visitx 9 clinic visits x 10 enrolled patients	Total-17 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16/ED, 801)	235	39,950
8.	Initial Admin Grant paid after Site initiation visit		30,000	30,000
9.	Final Admin Grant paid after data base lock		30,000	30,000
			Total Grant for 10 Patients	**20,04,820**

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Exhibit B: Payment Schedule

The payments will be made per patient visit entered into the data management system (based on the investigation schedule and cost outlined in the table number 1, unless indicated otherwise, as per the following table:

S. No.	Particulars	Cost INR
Total Payment for each visit inclusive of 20% institutional Grant on PI, Co-I, CRC fees		
1.	Visit 1*	11,646
2.	Visit 2	11,646
3.	Visit 3	11,646
4.	Visit 4	11,646
5.	Visit 5	11,646
6.	Visit 6	11,646
7.	Visit 7	10,946
8.	Visit 8	11,646
9.	Visit 9	10,946
10.	Visit 10	10,946
11.	Visit 11	11,646
12.	Visit 12	10,946
13.	Visit 13	11,646
14.	Visit 14	10,946
15.	Visit 15	11,646
16.	Visit 16 or Early Discontinuation	11,646
17.	Visit 801	11,646

*Visit 1 can occur 0 to 56 days from last visit of JAHL study and will be paid if V1 occurs separate from V8 in JAHL study. For the majority of patients, Visit 1 will also be the last visit of JAHL study; thus any assessments/procedures conducted during the final visit in JAHL study should not be repeated during first visit for Study JAHN.

Exhibit C: Procedural Payments

S. No	Procedure at Local Lab	Visit	Cost of Procedure	Total Amount for 10 pts
1.	**Urine Pregnancy test** @ Rs.300/- x 17 visit for 10 enrolled patients	Total-17 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16/ED, 801)	300	51,000
2.	Reimbursement of locally-sourced over-the-counter emollients (up to 500g). Price is per bottle/Tube and requires third-party receipts to be provided.			On Actuals

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Descriptions:

- Per Patient budget excluding GST: **INR 2,00,482**
- Site enrollment target (Z): **10 patients**
- Total Budget for 10 patients including procedural payments:**INR20,55,820**
- Total Budget, including GST: **INR 24,25,868**

Payment Cycle and Procedure:

- Payments will be made on a monthly basis, based on invoices received on or before 5th of every month
- All the visits and procedures included in the invoice must be entered into CRF (Case Report Form) for the payment to be processed

Procedural Payment:

- Procedural payments will be processed and reimbursed on request from the site.
- The procedures performed at site's internal laboratory will be reimbursed based on amount specified in this agreement. A copy of invoice for the procedure is needed in this case.
- The procedures performed at External laboratory will be reimbursed based on amount claimed in invoice. A copy of invoice for the procedure is mandatory in this case.

GST:

- The above mentioned calculation of visit payment does not include GST. GST will be paid as applicable based on the invoices received
- **Eli Lilly India PAN number: AAACE8901F**

Patient Reimbursement

- Patient reimbursement amount is inclusive of the TDS amount.

Screen Failure & Early Discontinuation Patients:

- This LOA is valid for a maximum of 10 Randomized patients.
- Early Discontinuation fee will be paid if all required procedures as per schedule of events in study protocol have been carried out at a clinic visit by the patient.

Kindly note that if final number of patient visits/ lab tests is more or less, addition or deduction respectively would be made to the above grant heads at the rates given against each.

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INVESTIGATOR CLINICAL STUDY AGREEMENT

This Clinical Study Agreement (the "Agreement"), effective as of the later of the dates appearing on the signature page, is entered into by and among, Dr. Pole Shivaji Marotrao, Assistant Professor and Interventional Radiologist ("Principal Investigator") Mahatma Gandhi Missions Medical College and Hospital, N-6 CIDCO, Aurangabad 431003, Maharashtra, India.

("INSTITUTION"), **SIRO Clinpharm Pvt Ltd.,** a company incorporated under the laws of India whose principal place of business is located at Kalpataru Prime, 1st Floor, Unit nos 3 and 4, Plot no D-3, Road no 16, Wagle Industrial Estate, Thane (West) – 400604, Maharashtra,, INDIA (hereinafter referred to as "SIRO")

WHEREAS, the Principal Investigator is engaged in the treatment of subjects with potential exposure to vascular anomalies is Assistant Professor and Interventional Radiologist at Mahatma Gandhi Missions Medical College and Hospital, N-6 CIDCO, Aurangabad 431003, Maharashtra, India.

WHEREAS, the SMO is engaged in site management Ardent Clinical Research Services, at 318, Level-3, Cannaught place building, Next to Franklin, Bund garden road, Opposite Wadia College, Pune-411001, Maharashtra, India; and providing CRC support throughout the study.

WHEREAS, the INSTITUTION is a Private Multispecialty Hospital

WHEREAS, SPONSOR is engaged in the research and development of human pharmaceutical products.

WHEREAS, SPONSOR is the Sponsor of the clinical study of "Safety and Efficacy of Lipiodol ultra fluid in association with surgical glues during vascular embolization. A phase IV study." (the "Clinical Study")

WHEREAS, SIRO is the Clinical Research Organization acting on behalf of SPONSOR to administer the clinical study;

WHEREAS, the Principal Investigator is engaged in the treatment of subjects with potential exposure to vascular anomalies and

WHEREAS, the Principal Investigator wishes to participate in the Clinical Study and SPONSOR wishes to have the participation of the Principal Investigator..

NOW THEREFORE, the parties agree as follows:

1. Protocol

1.1 Title. The Clinical Research protocol LUF-44-001, titled a "Safety and Efficacy of Lipiodol ultra fluid in association with surgical glues during vascular embolization. A phase IV study" which will guide the performance of the Clinical Study, has been prepared by SPONSOR and accepted by the Principal Investigator (the protocol, together with any of its subsequent amendments, shall be referred to in this Agreement as the "Protocol").

1.2 **Conflicts.** In the event of a conflict between the terms and conditions set forth in this Agreement and the Protocol, this Agreement will govern.

1.3 **GCP.** If generally accepted standards of Good Clinical Practice ("GCP") relating to the safety of subjects participating in the Clinical Study require a deviation from the Protocol, these standards will be followed. Any party who becomes aware of the deviation from the Protocol will immediately inform the other parties to this Agreement of the facts causing the deviation as soon as the facts are known to the

Authorised Signatory
For Thane Bharat Sahakari Bank Ltd.
Thane Main Branch

Thane Bharat Sahakari Bank Ltd.
Main Branch, Naupada, Thane.
D-5/STP/VVC.R.1005/1004/2006

Special Addressing DEC 13 2018 12:29

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MGM Medical College,
Aurangabad

party. In addition, the Principal Investigator will promptly inform the Institution's institutional review board ("IRB") of the deviation.

1.4 **Amendments.** SIRO, on behalf of SPONSOR, may also, from time to time, make changes to the Protocol. Changes in the Protocol must take the form of written amendments and shall be approved by all signatories of the final version of the Protocol. Any amendments to the Protocol which affect the patient (e.g. changes in procedures/assessments or matters relating to patient safety) require approval of the relevant ethics committee as well as further informed consent from each concerned patient prior to implementation. The Principal Investigator shall obtain such approval. Changes of purely administrative nature shall be notified to the committee by the Principal Investigator, but do not require formal approval.

2. Principal Investigator

2.1 The Principal Investigator shall carry out the Clinical Study in a professional, competent manner in accordance with the Protocol and the terms of this Agreement. The Principal Investigator will also be responsible for the direction of the Clinical Study in accordance with any applicable Institution policies. The Principal Investigator shall ensure that all staff of site and SMO are bound by and comply with the terms of the Protocol and this Agreement. The Principal Investigator or the INSTITUTION or SMO should inform SIRO and SPONSOR in the event of a discrepancy between the terms of the Protocol, this Agreement and its own INSTITUTION policies within twenty-one (21) days of the Effective Date of this Agreement. In the absence of any such intimation by the Principal Investigator or the INSTITUTION, the terms of the Protocol and this Agreement shall prevail The Principal Investigator shall ensure that all staff are bound by and comply with the terms of the Protocol and this Agreement.

3. Study Initiation and Subjects

3.1 It is anticipated that the Clinical Study will commence upon execution of this Agreement, that subject enrollment will be completed on or 31 December 2019 and that the Clinical Study will be completed on or about July 2020 unless otherwise terminated in accordance with the provisions of Para 17 of this Agreement.

3.2 If however, the Clinical Study obligations have not been completed by December 2019, the Principal Investigator shall continue with, and complete all obligations under this Agreement. All payments shall correspond with the appropriate milestone, as listed in Schedule A.

3.3 The Clinical Study will involve the competitive enrollment of a maximum of 125 subjects (provided there may be an increase in enrollment upon SIRO or SPONSOR request) meeting all Protocol eligibility requirements ("Subjects"). SIRO shall not be obligated to pay any sums for tests performed on subjects who do not meet all Protocol eligibility criteria or for additional subjects who are enrolled in the Clinical Study without SIRO's prior written approval.

4. Patient Information and Consent

4.1 It is the Principal Investigator's responsibility to explain the Study to each potential patient and obtain written informed consent before any Study procedures are performed. This is an unconditional prerequisite for participation of a patient in the Study. The Investigator shall inform the subject or his/her nominee(s) for their rights to contact the sponsor or SIRO (whosoever has obtained permission from the licensing authority for the conduct of clinical trial) for the purpose of lodging claims in case of any trial related injury/death. The explanation shall at least include all points listed in the Guideline for Good Clinical Practice, section 4.8.10 including but not limited to applicable regulations, and it must be given both verbally and in writing in compliance with Indian GCP, ethical principles based on the Declaration of Helsinki in its current version and national requirements. Patients shall be given sufficient time to consider their participation in the Study. Consent must be documented by the patient's dated signature on the trial informed consent form. A copy of the signed and dated information and consent form must be provided to the patient. In the event the Patient is not able to give informed consent, the same may be obtained from a legally acceptable representative. For the purpose of this section, a legally acceptable representative is a person who is able to give consent for or authorize an intervention in the Patient as provided by the

applicable law(s) of India. In the event the Patient and where required his/her legally acceptable representative is unable to read/write, an impartial witness will remain present during the entire informed consent process and who must append his/her signatures to the trial informed consent form. The Principal Investigator will obtain prior approval from the relevant ethics committee in the event of any amendments to the trial informed consent form.

4.2 Provision of consent will be confirmed in the CRF as well as by the Principal Investigator's signature on the consent form. The signed and dated declaration of informed consent will remain at the INSTITUTION and must be safely archived by the Principal Investigator, so that the forms can be retrieved at any time for monitoring, auditing and inspection purposes.

5. Insurance Coverage

5.1 SPONSOR shall adequately insure each and every participating patient covering any injury or illness suffered as a direct result of their participation in this Clinical Study. Provided that the SPONSOR shall not be responsible to provide for insurance coverage with respect to any injury (including death) or illness arising as a result of (i) negligent acts of Principal Investigator, and/or INSTITUTION and/or SMO with respect to activities or services undertaken pursuant to this Agreement; (ii) improper or negligent administration or use of the Clinical Study Drug during the course of the Clinical Study by the Principal Investigator,; or (iii) in violation of any and all applicable Central, State or Local laws rules and regulations in India and in France by Principal Investigator, INSTITUTION, SMO and SIRO. All participating patients will be informed by the Principal Investigator about the existence of the insurance policy and the extent of the coverage.

5.2 Both, the INSTITUTION and the Principal Investigator, shall have adequate insurance coverage for any claims arising from their negligence, willful misconduct and other actions or omissions. The Institution and the Investigator will provide a copy of their insurance certificate to SIRO and the SPONSOR upon signature of this Agreement.

6. Ethics Committee Approval

6.1 The Study will only be started, when full written approval of/ favorable opinion on the Protocol has been obtained from the concerned Investigational Review Board (IRB). It is the Principal Investigator's responsibility to obtain EC/IRB approval/opinion for the Protocol and all subsequent amendments, in compliance with the national regulatory requirements and laws.

7. Study Management

7.1 **Case Report Form Handling.** The Principal Investigator shall be responsible for providing correct Case Report Forms ("CRF") according to the following:

7.1.1 The main objective of the CRF is to obtain those data required by the Protocol in a complete, accurate, legible and timely fashion. The data in the CRF must be consistent with the relevant source documents, and they must be suitable for submission to authorities.

7.1.2 The data recorded in the course of the Study shall be documented in the CRFs and, as necessary, on the SAE report. They will then be forwarded to SIRO/SPONSOR for data management and biometric analysis.

7.1.3 The data in the CRF shall be recorded, evaluated, and stored in anonymous form in accordance with data-protection regulations. The Principal Investigator shall ensure that patient names are not mentioned on any document, neither CRFs nor other documents that will be forwarded to SIRO/SPONSOR.

7.1.4 Wherever possible, all data obtained in the course of the Study must be recorded in the original patient files. Data to be recorded directly on the CRFs and considered as source data will be identified as such. All data in the CRFs must correspond exactly with data recorded in the source documents.

7.1.5 If CRFs are not complete the Principal Investigator shall be obliged to complete them on request of SIRO/SPONSOR.

7.2 **Source Data.** The Principal Investigator shall be responsible for providing the Source Data according to the following regulations.

Source data are the original patient records of all variables collected for the trial as well as the patient's medical history. Specifically they comprise:

- Signed informed consent form.
- Patient hospital file and individual clinical notes.
- Laboratory reports.
- Pharmacy records.
- Study specific source documents (e.g. angiograms).
- Appropriate sections of the CRF, where data are recorded directly onto specific forms.
- Other reports and records of any procedure performed in accordance with the Protocol.

The Principal Investigator shall safely maintain the original Study documentation together with all source data for the maximum period of time permitted by the hospital, research institute or practice in question, but not less than 15 years after the clinical part of the trial has been completed. If archiving can no longer be maintained at site, the Principal Investigator will notify SIRO/SPONSOR. If the duration of archival by the Institution is less than 15 years, SIRO will transfer the records at Guerbet cost to a different archival center at the time of termination of the INSTITUTION archival period.

7.3 **Investigator Study File and Archiving.** The INVESTIGATOR shall prepare and maintain complete and accurate study documentation in compliance with Indian GCP standards and local regulations. Therefore, an investigator study file shall be prepared which contains all relevant documents necessary for the conduct of the study, including without limitation:

- Signed protocol and amendments.
- Investigator's Brochure and updates.
- EC composition, approval(s)/opinion correspondence/reporting.
- Notifications of regulatory authorities.
- CVs and signature sheet for key study personnel (e.g. investigators, study nurses).
- Signed study agreements including financial agreement.
- Trial initiation report.
- Approved and signed informed consent forms.
- Study insurance certificate.
- CRFs (investigator's copy).
- SAE documentation and related correspondence/reporting.
- Shipping/accountability/destruction records for investigational product and material.
- Certificate of analysis.
- Instructions for handling of investigational product and material.
- Laboratory accreditation/certification and up-to-date reference ranges of normal values.
- Screening, enrollment, and monitoring logs and subject identification code list.
- Appointment diaries.
- Study related correspondence with SPONSOR or SIRO.

7.4. **Documentation and Material (Supplies).** All supplies provided to the Principal Investigator for the purpose of carrying out the Study are supplied only for the purpose of the Study and must not be used for any other purpose whatsoever. The Principal Investigator, or a person(s) delegated by him, are responsible for the security and accountability of all supplies.

The inventory must be available for monitoring, auditing and inspection. When the study is completed, or if it is prematurely terminated, any supplies of Investigational Product and any other material for the Study, supplied by SIRO/SPONSOR (except documentation required to be retained by the Principal Investigator), must be returned to SIRO/SPONSOR or destroyed at site, alternatively. In the latter case

the identification and quantity of each unit of study medication, the method of destruction, and the person in charge must be documented.

7.5. **Monitoring, Quality Assurance, and Inspection by Authorities.** The Study will be monitored by SIRO. Its representatives (alone or together with representatives from SPONSOR) will be allowed access to all information resulting from this Study and SPONSOR will have an unrestricted right to use such information.

SIRO (alone or together with representatives from SPONSOR) will perform regular on-site monitoring visits throughout the Study. The tasks of the monitor comprise the following, included without limitation:

- to ensure protocol adherence,
- to verify the data in the CRFs against source documents (SDV),
- to check progress of the study and to motivate, if necessary,
- to review the CRFs for complete and accurate capture of data, including laboratory test reports and other patient records
- to check all data for possible SAEs and AEs,
- to review signed informed consent forms for signatures and date of consent,
- to ensure accurate record of drug accountability,
- to ensure adequate storage of study supplies,
- to collect completed CRFs,
- to discuss and help resolve any problems,
- to verify adequate insurance coverage undertaken by PI,
- to verify the ICF(s) as per the applicable regulatory guidelines.

Source Data Verification (SDV) shall be performed on 100% of key data such as informed consent, demographics, inclusion/exclusion criteria, parameters for the evaluation of the main endpoints, safety evaluation, and drug accountability.

The visits shall involve the Principal Investigator or his appointed representative(s) and any other staff, as required. The Principal Investigator shall ensure that sufficient time will be allowed for monitoring visits. Follow-up correspondence between the site and SIRO relating to apparent inconsistencies or clarification of CRF entries will be kept on file at both SIRO and the site.

This Study shall be audited on behalf of SPONSOR to assure GCP compliance as well as validity of the study data according to a study specific audit plan. The audits will be conducted in accordance with the SOPs of the SIRO.

For monitoring visits and in case of audits and inspections by authorities the Principal Investigator must provide direct access to the complete study records including CRFs, original source data, study documentation, and, if necessary, any additionally required background data. Furthermore, access to Study related facilities must be ensured.

7.6 **Confidentiality of Patient Records.** The INSTITUTION, Principal Investigator and SMO must assure that study patients' anonymity will be maintained, and that their identities are protected from unauthorized parties. Documents stating patients' names must be kept in strict confidence by the Principal Investigator. On CRFs or other documents removed from the INSTITUTION patients must not be identified by their names, but by initials and patient identification number. The Principal Investigator is obliged to maintain a subject identification code list showing the patients' full names and dates of birth together with the corresponding patient identification numbers to allow revealing identity of any subject.

The Principal Investigator agrees that representatives of SPONSOR, SIRO, of the responsible EC/IRB and of national or international regulatory authorities may inspect the patient records at the site for source data verification. SPONSOR and SIRO guarantee for their representatives that patient data will be treated confidentially. Monitors and auditors are bound to secrecy.

8. Budget

Cost and payment terms are set forth in Schedule "A" attached to this Agreement and incorporated by reference. All the payment obligations of the Sponsor shall be routed through SIRO. All the payment obligations of the Site shall be routed through SMO.

9. Data and Information

9.1 **Confidential Information.** During the term of this Agreement, and for a period of ten (10) years after termination of this Agreement, the Principal Investigator and Institution shall not disclose or use for any purpose other than performance of the Clinical Study, information including but not limited to any and all trade secrets, know-how, privileged records or other confidential or proprietary information and data, both technical and non-technical, disclosed to the Principal Investigator and Institution by SIRO or SPONSOR ("Information"). The obligation of non-disclosure shall not apply to the following:

9.1.1 Information at or after such time that it is or becomes publicly available through no fault of the Principal Investigator/Institution;

9.1.2 Information that is already independently known to the Principal Investigator/Institution as evidenced by their prior written records;

9.1.3 Information at or after such time that it is disclosed to the Principal Investigator/Institution on a non-confidential basis by a third party with the legal right to do so;

9.1.4 Information developed by the Principal Investigator/Institution without the use of SIRO's or SPONSOR's Information as evidenced by their written records; or

9.1.5 Information required to be disclosed by law.

9.2 **Medical Records.** In the event that either SIRO or SPONSOR come into contact with Subjects' medical records, such party shall hold in confidence the identity of the Subject and shall comply with the Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011 made under the Information Technology Act, 2000 (and all other applicable law(s) with respect to the confidentiality of such records.

9.3 **Trading in Securities.** Securities and Exchange Board of India (SEBI) interalia, prohibits any person either on his own behalf or on behalf of any other person, deal in securities of a company listed on any stock exchange when in possession of or is likely to have access to or has received any unpublished price sensitive information. The Principal Investigator, by virtue of their participation in the Clinical Study, has access to data and information arising out of the conduct of the Clinical Study, which is material non-public information that belongs to SPONSOR. The Principal Investigator agrees not to use, or cause any other person to use, the data and information arising out of the Clinical Study to purchase or sell securities in SPONSOR Company.

9.4 **Proprietary Rights.** All information resulting from the Clinical Study conducted under this Agreement, including all data, results, conclusions, observations, discoveries, inventions, ideas, know-how, procedures, advancements and the like, whether patentable or not ("Data") shall be fully disclosed by the Principal Investigator to SPONSOR. All Data shall be the sole property of SPONSOR and SPONSOR shall have the unrestricted right to freely utilize all such Data in whatever manner it desires.
Principal Investigator and/or the INSTITUTION agree to undertake such actions reasonably requested by SPONSOR to give effect to such ownership and agrees to sign, execute, affirm all documents, including, without limitation, all applications, forms, instruments of assignment and supporting documentation and perform all other acts as may be required for this purpose.
INSTITUTION and Principal Investigator hereby assigns to SPONSOR all inventions and any and all related patents, copyrights, trademarks, trade names, and other industrial and intellectual property rights and applications therefore, and appoints any officer of SIRO as his duly authorized agent to execute, file, prosecute and protect the same before any government agency, court or authority

9.5 **Resignation etc. of the Principal Investigator:** The INSTITUTION shall inform SIRO in case the Principal Investigator ceases to be associated with the INSTITUTION for any reason during the course of the Study. They shall also replace the Principal Investigator in case SIRO so desires and render all assistance to safeguard patient safety and Study data.

9.6 **Change of SMO**: The INSTITUTION and/or Principal Investigator shall inform SIRO in case the SMO ceases to be associated with the INSTITUTION for any reason during the course of the Study. They shall also replace the SMO in case SIRO so desires and render all assistance to safeguard patient safety and Study data.

10. Drug Safety

10.1 The recording of adverse events (AEs) is an important aspect of study documentation. It is the Principal Investigator's responsibility to document all AEs according to the detailed guidelines of the Protocol. The Principal Investigator agrees to answer any questions of SPONSOR/SIRO's medical monitor concerning any AEs.

10.2 According to the Protocol, the Principal Investigator will assess whether any adverse event (AE) including abnormal laboratory values or worsening of pre-existing diseases has occurred during the course of the study. The details of all AEs, whether reported by the patient or observed by the Principal Investigator /Study personnel during the entire Study, will be recorded onto the appropriate source document. Each adverse event must be recorded in the AE section of the case report form (CRF), regardless of the causal relationship. All AEs must be followed until complete resolution or sequelae stabilization.

10.3 The Principal Investigator must immediately report all Serious Adverse Events (SAE) (as defined in protocol) and **within at most 24 hours of occurrence of SAE**, which occur during the course of the Study and up to the date of the patient´s last visit, to the sponsor (Guerbet HQ Pharmacovigilance), to the Health Authority and to the Ethics Committees (addressee given below). The study specific SAE Report form will be used for documentation and reporting.
In addition, a due analysis report has to be submitted to the following addressee within 14 calendar days of occurrence to the DCGI (Licensing Authority), Ethics Committee Chairman and Head of the Institution for all the Initial and Follow-up information until stabilization/ resolution of the event.

The SAEs must be reported within 24 hours to:

- Licensing authority: all Initial SAE forms only are to be e-mailed and faxed at :
  - Email ID: dci@nb.nic.in
  - Fax no.: 011-23236973

- Guerbet HQ Pharmacovigilance: all Initial and follow up SAE reports are to be sent on the following:
  - Email ID: pharmacovigilance.headquarters@guerbet.com
  - or faxed to the number: 0033 1 45916770.

- Ethics Committee: all Initial and follow up SAE reports are to be sent via e-mail mgmecrhs@gmail.com to Ethics committee.

The SAE must be reported within 14 Days to:

- Licensing authority: For all SAEs as hard copy via courier at DCGI address by Guerbet or its representative

The Drugs Controller General (India)
FDA Bhavan, CHEB Campus *Kotla Road,* *(Adjacent to Mata Sundari Girls College)* *New Delhi – 110 002.* *Fax: 011-23236973*

- Chairman of Ethics Committee by the principal investigator: For all SAEs as hard copy via courier at MGM Ethics Committee for Research on Human Subject, harmacology Department, 3rd Floor, MGM Medical college and Hospital, N-6 Cidco, Aurangabad 431003, Maharashtra, India.
- Head of the Institution by the principal investigator: For all SAEs as hard copy via courier at, Mahatma Gandhi Missions Medical college and Hospital, N-6 CIDCO, Aurangabad 431003, Maharashtra, India.

10.4 The Principal Investigator will inform the local Ethics Committee of any findings that could adversely affect the patients' safety, could have an impact on the conduct of the study, or could alter the ECs / IRBs approval to continue the study.

10.5 Guerbet and/or its representative will be responsible to notify on time the DCGI any findings that could adversely affect the patients' safety, could have an impact on the conduct of the study, or could alter the ECs / IRBs approval to continue the study.

11. Study Drug and Study Materials

11.1 **Study Drug.** SIRO, on behalf of SPONSOR, will provide Clinical Study Drug for the Clinical Study. The use of the Clinical Study Drug for any purpose outside of the Clinical Study is prohibited by this Agreement. While SIRO in no way condones the use of the Clinical Study Drug for any purpose outside of the Clinical Study, if such work is performed, all data, results, conclusions, observations, discoveries, inventions, ideas, know-how, procedures, advancements and the like, whether patentable or not, shall be treated in all respects as Data in accordance with this Agreement. INSTITUTION and Principal Investigator shall assure that the Clinical Study Drug will be dispensed or administered to Subjects only under the supervision of authorized investigator/personnel responsible for this activity,

11.2 **Materials.** Access to Study Materials shall be limited to only those persons who under the Principal Investigator's direct control will be using Study Materials for the Clinical Study. The term "Study Materials" shall include the Clinical Study Drug, reagents and materials derived from Subjects enrolled in the Clinical Study, including, but not limited to, blood, bone marrow, sera, and other biological materials. At no time shall any Study Materials be used for any purpose other than as described in the Protocol or transferred to any third party without SPONSOR's prior written consent. Upon termination or completion of the Clinical Study, all unused Study Materials shall be returned to SPONSOR or at SPONSOR's sole option, destroyed.

12. Publications

12.1 The Principal Investigator /INSTITUTION/SMO shall not publish any article or paper nor make any presentations, nor assist any other person in publishing any articles or papers or in making any presentations, relating or referring to:

(a) the Study or any results, data or insights therefrom;
(b) the Services performed hereunder; or
(c) any data, information or materials obtained or generated in the performance of its obligations hereunder, in whole or in part, without the prior written consent of SIRO and SPONSOR , which consent may be granted or withheld depending on the Study Sponsor's sole discretion.

13. Use of Name and Advertising

13.1 **Use of Name.** The INSTITUTION / Principal Investigator / SMO and SIRO, on behalf of SPONSOR, shall each obtain prior written consent from the other before using the name, symbols or marks of the other in any form of publicity in connection with the Clinical Study. If the INSTITUTION or SIRO is legally required to make any disclosure that identifies the existence or terms of this Agreement, then either may do so with prior written consent from the other,

13.2 **Advertising.** In the event that the Principal Investigator elects to advertise to recruit Subjects for enrollment in the Clinical Study, Principal Investigator will provide a copy of any such advertisement to

SIRO / SPONSOR for prior approval. In addition, Principal Investigator will obtain Institutional Review Board and Ethics Committee approval of all advertisement prior to use. Any promotional representation or suggestion that an investigational drug is safe or effective for the purposes for which it is under investigation is not permissible / a violation of the United States Code of Federal Regulation 21 CFR 312.7(a).(Strike out if not applicable depending upon the country of the sponsor)

14. Compliance with Law; Financial

14.1 The Principal Investigator, the INSTITUTION and the SMO shall perform the Clinical Study in compliance with generally accepted standards of Indian Good Clinical Practice as defined by Central Drugs Standard Control Organisation (CDSCO), the Protocol, instructions provided by SIRO and SPONSOR and all applicable local, state and federal laws and regulations governing the performance of clinical investigations including but not limited to the Indian Drugs and Cosmetics Act, 1940 and the Rules thereunder, World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects, June 1964, and amended in October 2013 (Fortaleza), DCGI Order F. No. GCT/20/SC/Clin./2013 of November 19, 2013, Appendix XII of Schedule Y- "Compensation in case of injury or death during Clinical Trial" of Drugs and Cosmetics (Amendment) January 30th 2013, Drugs and Cosmetics (Sixth Amendment) Rules, December 12th 2014, Guideline on good pharmacovigilance practices (GVP), Module VIII – Post-authorization safety studies, Directive 2010/84/EU from 15 December 2010 amending, as regards pharmacovigilance. The Principal Investigator shall retain any records mutually agreed to by SIRO, resulting from the Clinical Study for the time required by applicable local and federal regulations, and to allow for inspection of all such records including the Subjects' medical records. The informed consent form signed by the Subjects shall provide for access to the Subjects' medical records by SIRO, SPONSOR and by regulatory agencies.

15. Debarment

15.1 The Principal Investigator certifies that neither the Principal Investigator nor any person employed by the Principal Investigator or SMO or any other subcontractor to perform any services in connection with the Agreement has been subject to any legal or regulatory discipline, nor ever been suspended, debarred, or is under any medical license limitation or condition, or otherwise disqualified from providing medical services by any governmental, regulatory or administrative body or organization within their jurisdiction.

16. Indemnification

16.1 SPONSOR warrants that they shall defend, indemnify and hold harmless SIRO, PRINCIPAL INVESTIGATOR, INSTITUTION and any of their agents and employees ("indemnitees of Sponsor") from any and all liabilities, claims, actions or suits for personal injury or death directly arising out of the administration or use of the Clinical Study Drug during the course of the Clinical Study in accordance with the Study Protocol.

16.2 The indemnity granted in this Article 16 shall NOT apply in the event such liability, damage, loss, or expense is caused by the failure of an Indemnitee to:

16.2.1 adhere materially to the terms of the Protocol;

16.2.2 comply with government regulations or requirements; or

16.2.3 conduct the Clinical Trial in accordance with generally accepted medical standards including avoidance of negligence and willful misconduct.

16.3 SIRO warrants that it shall indemnify, defend and hold harmless SPONSOR, INSTITUTION and Principal Investigator, including their agents and employees (the "Indemnitees of SIRO") from any and all liabilities, claims, actions or suits for personal injury or death directly arising out of negligent or deliberate wrongful acts of SIRO or its employees during the term of this Agreement; except to the extent that the same is caused as a result of the Project Materials provided by the Sponsor or adhering to the

instructions of the Sponsor or Applicable Laws while rendering the Services or due to reasons attributable to the SPONSOR, INSTITUTION or Principal Investigator and their agents and employees.

16.4 The indemnity granted in Article 16 shall apply separately to each Indemnitee in such manner and to the same extent as though a separate indemnity had been given to each. Said indemnity shall survive the completion or early termination of this Agreement.

16.5 Each party warrants that it shall provide a diligent defense against and/or settlement of, any claims brought or actions filed for the loss which is the subject of the indemnity, whether such claims or actions are rightfully or wrongfully brought or filed. The indemnifying Party shall have the right to settle claims at its sole expense.

16.6 The Principal Investigator/ INSTITUTION/SMO shall promptly notify SIRO and SPONSOR of any claim for which indemnity may be sought. The Principal Investigator / INSTITUTION/SMO shall fully cooperate with SPONSOR / SIRO and its legal representatives in the investigation and defense of any claim or suit covered under this Agreement. If the claim or action is asserted, the Principal Investigator shall have the right to select and obtain representation by separate legal counsel, as long as the Principal Investigator pays for all costs and expenses incurred by it for the separate counsel.

16.7 SPONSOR warrants that it maintains policies or programs of insurance or self insurance at levels sufficient or have SIRO to maintain such programs of insurance at the cost of SPONSOR to support the indemnification obligations assumed under this Agreement. Upon request, SPONSOR will provide evidence of their insurance or self-insurance.

16.8 The SMO,Principal Investigator and INSTITUTION each shall indemnify, defend and hold harmless the Sponsor, including its agents and employees, and SIRO, including its agents and employees, against any losses suffered and from all liabilities, claims, actions or suits for personal injury or death, directly arising out of the negligence, willful misconduct or any other act or omission by the Principal Investigator or the INSTITUTION, or by their agents and employees, during the course of the Clinical Study.

16.9 The SMO, Principal Investigator and the INSTITUTION each shall also indemnify, defend, and hold harmless the Sponsor and SIRO against:

(i) any and all loss, costs, claims, actions, liability and/or suits (including without limitation, interest, penalties and reasonable attorneys' fees) on the Sponsor or SIRO due to negligence, gross negligence or intentional misconduct of Principal Investigator and/or SMO and/or INSTITUTION in connection with its performance of the services, obligations, responsibilities and undertakings under this Agreement;

(ii) SMO, Principal Investigator's and/or INSTITUTION's violation of any and all applicable Central, State or Local laws rules and regulations of India;

(iii) Principal Investigator's and/or INSTITUTION's and/or SMO's breach or default in performance of its obligations in connection with a Study;

(iv) Principal Investigator's and/or INSTITUTION's and/or SMO's material deviation from the Protocol or other written recommendation or instructions furnished by SPONSOR through SIRO to Principal Investigator and the INSTITUTION for the Study;

(v) Principal Investigator's and/or INSTITUTION's and/or SMO's failure to complete the Study and any such delay attributable solely to Principal Investigator's and/ or INSTITUTION's willful misconduct, negligence or mistakes and/or or failure to comply with its obligations under this Agreement.

Without prejudice to any other Section, the reference to SMO, Principal Investigator and INSTIUTION above includes reference to its agents and employees.

17. Independent Contractor

17.1 The parties to this Agreement hereby agree that the Principal Investigator, SMO and Institution are independent contractors hereunder and are not employees or agents of the SPONSOR or SIRO. The Principal Investigator, SMO and INSTITUTION further agree that neither they nor their employees or agents shall make any claim against the SPONSOR or SIRO for compensation, vacation pay, sick leave, retirement benefits, social security benefits, workers' compensation, disability or unemployment benefits or employee benefits of any kind. Further, their agents and employee shall not be considered to be employees of the Sponsor or SIRO under any circumstance.

18. Termination

18.1 This Agreement may be terminated:

18.1.1 by the Principal Investigator upon thirty (30) days' prior written notice;

18.1.2 by SIRO on behalf of SPONSOR immediately upon thirty (30) days written notice;

18.1.3 by SIRO immediately if the Principal Investigator is unable to continue to serve and his/her successor as acceptable to SIRO is not available; or

18.1.4 upon the occurrence of an event qualifying as a termination event as described in the Protocol

18.1.5 upon thirty (30) days prior written notice to the other party if the authorization and approval to perform the Clinical Study is withdrawn by the applicable regulatory agency having jurisdiction over the Clinical Study. However, the Principal Investigator shall immediately upon receipt of such notice, cease entering new subjects onto the Clinical Study, cease conducting procedures to the extent medically permissible on the existing subjects already entered into the Protocol and shall initiate the process of their safe withdrawal from the Clinical Study as per the prevailing medical standard and Principal Investigator's medical judgment.

18.2 Upon the effective date of termination, the Principal investigator shall conduct an accounting review, which is subject to verification by SIRO. If SIRO objects to any charges, the parties shall use reasonable efforts to resolve expeditiously any disagreement. Within thirty (30) days upon receipt of adequate documentation therefor, SIRO will make payment to the Institution for:

18.2.1 all services properly rendered and monies properly expended by the Principal Investigator prior to the date of termination and not yet paid for; and

18.2.2 reasonable non-cancelable obligations properly incurred for the Clinical Study by the Principal Investigator prior to the effective date of termination.

18.3 The Principal Investigator will credit or return to SIRO any funds not expended or obligated by the Principal Investigator in connection with the Clinical Study prior to the effective termination date.

18.4 Immediately upon receipt of a notice of termination, the Principal Investigator shall stop enrolling Subjects into the Clinical Study and shall cease conducting procedures on Subjects already enrolled in the Protocol as directed by SIRO to the extent medically permissible and appropriate.

18.5 Termination of this Agreement by either party shall not affect the rights and obligations of the parties accrued prior to the effective date of the termination. The rights and duties under Sections 4.2, 7.2, 8, 9, 11.2 and 16 survive the termination or expiration of this Agreement.

19. Miscellaneous

19.1 **Applicable Law And Arbitration.** This Agreement is entered into and will be deemed for all purposes to have been made in Mumbai, India and shall be governed and construed in accordance with the laws of India applicable to contracts and agreements. Notwithstanding the foregoing, SPONSOR may

seek injunctive or equitable relief, in addition to damages, for a breach of any of the confidentiality provisions contained herein in any court of competent jurisdiction.

19.2 All disputes arising out or in connection with the present Agreement, which cannot be settled amicably, shall be referred to and settled by sole arbitrator. The proceedings will be governed by the Indian (Arbitration & Conciliation) Act, 1996. The place of the arbitration shall be Mumbai and the language of the arbitration proceedings shall be English. Any judgment, decision or award of the arbitrators shall be final and binding on both the Parties, and shall be enforceable in any court of competent jurisdiction.

19.3 Subject to 19.2 above the courts of Mumbai will have exclusive jurisdiction to try and entertain any dispute arising out of this Agreement.

19.4 The parties shall share equally the costs of the Board of Arbitration unless the Board determines otherwise.

19.5 **Amendments.** This Agreement may only be amended by the mutual written consent of the parties hereto.

19.6 **Entire Agreement.** This Agreement represents the entire understanding of the parties with respect to the subject matter of this Agreement and supercedes all prior agreements, undertakings, negotiations and discussions, whether oral or written between the parties and there are no warranties, condition, representations or other Agreements between the parties in connection with the subject matter of this Agreement. In the event of any inconsistency between this Agreement and the Protocol, the terms of this Agreement shall govern. This Agreement may be executed in any number of counterparts, each of which shall be an original and all of which together shall be one document binding on all the parties even though each of the parties may have signed different counterparts. This Agreement shall also be considered executed by the parties upon receipt by SIRO by facsimile transmission of the counterparts signed by all the parties.

19.7 **Severability.** Should one or more provisions in this Agreement be or become invalid or unenforceable, the Parties shall substitute such invalid provisions by valid provisions as close in meaning and effect as the original provisions. Should such substitution not be possible the invalidity or unenforceability of such provision shall not affect the validity of the Agreement as a whole.

19.8 **Assignment.** The Principal Investigator may not assign or transfer any of their rights or obligations under this Agreement without the prior written consent of SIRO. SIRO may assign this Agreement and all its rights and obligations hereunder to a successor or assignee of the business to which this Agreement relates.

19.9 **Waiver.** Any waiver by any Party of any breach of, or failure to comply with or failure to enforce at any time, any of the provisions of this Agreement shall not be construed as or constitute a continuing waiver of such provision, or a waiver of any other breach of or failure to comply with, any other provision of this Agreement, nor shall it in any way affect the validity of this Agreement or any part thereof or the right of any Party thereafter to enforce each and every provision of this Agreement.

19.10 **Notice.** Any notice required or permitted hereunder shall be in writing and shall be deemed given as of the date it is (A) delivered by hand or (B) received by Registered or Certified Mail, postage prepaid, return receipt requested, or received by facsimile and addressed to the party to receive such notice at the address set forth below, or such other address as is subsequently specified in writing:

If to Principal Investigator:

Dr. Pole Shivaji Marotrao,
Assisstant Professor and Interventional Radiologist.
Mahatma Gandhi Missions Medical college and Hospital,
N-6 CIDCO, Aurangabad 431003,
Maharashtra, India.

If to INSTITUTION:

Dr Rajendra Bohra
Dean
Mahatma Gandhi Missions Medical college and Hospital, N-6 CIDCO, Aurangabad 431003,

Maharashtra, India.

If to SIRO:

Partha Chatterjee
Head Clinical Research and CTSM.
SIRO Clinpharm Pvt. Ltd
Kalpataru Prime, 1st Floor, Unit nos 3 and 4, Plot no D-3, Road no 16, Wagle Industrial Estate, Thane (West) – 400604, Maharashtra, India

If to SMO

Mr. Chandu Devanpally
Managing Director
318, Level-3, Cannaught place building, Next to Franklin, Bund garden road, Opposite Wadia College, Pune-411001, Maharashtra, India.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement Triplicate by proper persons thereunto duly authorized.

SIRO Clinpharm Pvt. Ltd

Signature:_____

Name: Partha Chatterjee

Designation: Head Clinical Research and CTSM

Date: 16 DEC 2018

INSTITUTION

Signature:_____

Dean
MGM Medical College,
Aurangabad.

Name: Dr Rajendra Bohra

Designation: Dean

Date: 26 DEC 2018

INVESTIGATOR

Signature:_____

Name: Dr. Pole Shivaji Marotrao

Designation: Principal Investigator

Date: 26 DEC 2018

Dr. Shivaji Pole
MBBS,MD,FVIR(KEM Mum)
Asso. Prof. & International Radiologist
MGM MCH and MCRI
Reg. No. 2006/03/1698

SMO

Signature:_____

Name: Mr. Chandu Devanpally

Designation: Managing Director

Date: 27/Dec/2018

Ardent Clinical Research Service
Pune

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

SCHEDULE A
BUDGET AND PAYMENT SCHEDULE

Type of visit	Professional fees	Procedural fees	Patient Travel Reimbursement
	(INR)	(INR)	(INR)
Screening	3000.00	2,000.00	500.00
First Study Procedure	33,000.00	16000.00	500.00
Second study procedure (Optional as per PI discretion)	10000.00	5,000.00	500.00
Final Follow Up Visit	5,000.00	2,000.00	500.00
Total (A)	51,000.00	25000.00	2000.00
Institutional Overhead (B=25% of A)	12750.00	NA	NA
Total (A+B=C)	63,750.00	25000.00	2000.00
GST (D=18%)	11475.00	4500.00	360.00
Total	**75225.00**	**29500.00**	**2360.00**
Total per subject	**₹ 1,07,085.00**		

1. **PAYMENT TERMS**

1.1 Payments by CRO to Payee will be made in accordance with the Budget and the following principles:

(a) Payments of professional fees are made on a quarterly basis

(b) Payments are made only for every completed visit for the properly enrolled subject according to the Protocol

(c) Payments shall be based on prior quarter enrollment data confirmed by subject Case Report Forms ("CRFs").

1.1 Actual payments shall be limited to ninety percent (90%) of each payment due.

1.2 Payee Details (for all study related payments) :

- Cheque in favor of : **Ardent Clinical Research Services**
- Bank Name : HDFC
- Account Number : 50200007013912
- IFSC : HDFC0003708
- Category : the Research And Experimental Development Services In Medical Sciences And Pharmacy
- HSN/SAC Code : 998113
- PAN Number : APQPD7081M, (Ghorpadi, Pune Branch)
- GSTIN No. : 27APQPD7081M1Z9

All the payment obligations of the Site shall be routed through SMO; the Principal Investigator and the Institution have no objections for this arrangement.

1.3 Ten percent (10%) of the compensation earned by Site in accordance with the Budget will be reserved by CRO, and will be paid by CRO to the Payee upon completion of the following ("Final Deliverables"):

(a) final acceptance by Sponsor of all CRFs pages;

(b) final acceptance by Sponsor of all data clarifications issued;

(c) receipt and approval by Sponsor of any outstanding regulatory documents as required by CRO and/or Sponsor;

(d) return of all unused supplies of the Investigational Product and comparator product to CRO and/or Sponsor; and

(e) approval by Sponsor of Site's satisfaction of all other applicable conditions set forth in the Agreement.

1.4 Material violations of the Protocol constituting disqualifications shall not be payable under the Agreement.

1.5 Any expense or cost incurred by Site in performing the Study under this Agreement not specifically designated as reimbursable by Sponsor shall not be payable. Such expense or cost shall be Site's sole responsibility.

2. SCREENING FAILURE PAYMENTS.

Procedure costs of Screening failures will be reimbursed in accordance with the following principles:

2.1 Only visit which a subject has undergone for the study with properly obtained informed consent will be reimbursed upon receipt of invoice.

2.2 Payments require submission of completed screening CRF pages to CRO and any additional information requested by CRO for proper documentation of subject screening procedures.

3. **DISCONTINUED OR EARLY TERMINATION PAYMENTS.** Discontinued or early termination subject will be reimbursed based on the number of confirmed completed visits.

4. ORIGINAL INVOICES AND RECEIPTS.

4.1 Original Invoices preferably in English and/or receipts pertaining to the Study shall be submitted to CRO for reimbursement at the following address:

CRO Name	SIRO Clinpharm Pvt. Ltd
Attention	Project Manager
Address	SIRO Clinpharm Pvt Ltd Kalpataru Prime, 1st Floor, Unit Nos. 3 and 4, Plot No. D-3, Road No. 16, Wagle Industrial Estate, Thane (West) – 400604
Telephone	+91 (022) 6108 8000

4.2 To properly process invoices, (a) Sponsor name, (b) Protocol number,(c) invoice number, (d) Investigator name, (e) Site number, (f) invoice date, (g) date and description of services provided, (h) CRO project number, (i) total amount payable, (k) exchange rate used where applicable, and (l) CRO Address listed above must be specified in the invoice. After receipt and verification, reimbursement for invoices will be included in the next regularly scheduled payment for subject activity.

4.3 Payment Instructions: For professional fees, the Payee shall send invoice to CRO, via e-mail transmission followed by couriering the original. Payments shall be made by CRO on behalf of Sponsor and shall be paid within Forty Five (45) days of receipt of original invoice, review and approval of an original invoice submitted to the CRO's address.

For subject procedural reimbursement, payments shall be made by CRO on behalf of Sponsor and shall be paid within Thirty (30) days of receipt, review and approval of original invoice and bills, submitted to the CRO's address.

5. Additional Expenses

5.1 Any additional expenses connected to the Study and specified in this Section shall be reimbursed to Payee only if such expenses were previously approved by CRO and Sponsor and actually incurred. Such expenses shall be reimbursed to Payee on the pass-through basis upon acceptance by CRO of invoices and/or receipts or other documentations. CRO shall not reimburse any additional expenses which were incurred by Site or Site Personnel without prior written approval by CRO or Sponsor.

(a) Institutional Review Boards ("IRBs") or Independent Ethics Committees ("IECs") Payments

- IRB/IEC costs shall be reimbursed upon receipt of original invoices and shall not be included in the Budget, and
- Any costs for subsequent re-submissions or renewals of IRB/IEC shall be reimbursed upon receipt of appropriate documentation subject to approval by CRO and Sponsor.

(b) Archiving Fee: a one time, non-refundable payment will be paid on actual basis as per hospital policy;

- Payment shall be used for archiving and storage of Study files by Site for a period of fifteen (15) years,
- In accordance with Sponsor's Protocol requirements, Institution shall maintain all Study records in a safe and secure location to allow easy and timely retrieval, when needed.
- Payment shall be used for archiving and storage of Study files by Institution for a period of fifteen years,
- Payment shall be made upon completion and receipt by CRO of all original contractual and regulatory documentation, and receipt by CRO of original invoice.

(c) Subject Expenses: A maximum of 500 INR per visit exclusive of overhead fee will be paid for the Subject travel expenses reimbursement only for the 4 visits of the study. This amount needs to be reflected in the informed consent form as it will be provided to the subject. The Subject travel expenses will be paid upon receipt of the corresponding support documentation.

(d) Start Up fees: A non-refundable payment of 25000 INR for start-up related activities will be made upon execution of the Agreement, and IRB/EC approval, and prior to site initiation.

(e) Equipment: The Site will be provided with the following Study-dedicated infrastructure:

- External Hard disk
- Set of CD's
- Thermo hygrometer

All equipment needed for the conduct of the Study (and Sub-Study, if applicable) will be supplied to the Site by CRO for its strict and sole use in performing the Study. Sponsor retains ownership of such equipment at all times. Site must use reasonable efforts to protect the equipment from damage or loss. Such equipment must be returned to CRO following the closure of the Study at the Site and CRO shall coordinate its return with the Site, to ensure that all equipment is returned within 30 calendar days after site closure at Site.

(f) NO OTHER ADDITIONAL FUNDING REQUESTS WILL BE CONSIDERED

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

MAHATMA GANDHI MISSION

Mahatma Gandhi Mission's Medical College & Hospital

N-6 CIDCO, Aurangabad - 431003

DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS
(CLINICAL RESEARCH UNIT)

Office: Dr. Deepak Bhosle, Prof & Head, Dept. of Clinical Pharmacology & Therapeutics, MGM Medical College & Hospital
N-6,CIDCO,Aurangabad – 431003. Ph. No: 0240-6601423, 0240-6601174, Email: pharmacolgy@mgmmcha.org

Date: 25 Jun 2019

To,
Dean,
MGM Medical College and Hospital.
N-6 Cidco, Aurangabad -431003,
Maharashtra, India.

Protocol Number: LUF-44-001

Protocol Title: Safety and Efficacy of Lipiodol ® Ultra Fluid in Association with Surgical Glues during Vascular Embolization, a phase IV study.

Subject: Submission of Procedural fees (Sub no.012003 & Sub no.012004)

Respected Sir,
With Reference to above Subject Here by I am submitting cheque towards procedural fees of protocol LUF-44-001.
Details:

Sr.No	Payment	Cheque No	Amount Rs.	10 % TDS	Payable Amount
01	Procedural Fees of Sub no 01203 & Sub no.012004)	035322	18,114	NA	18,114

Kindly acknowledge the receipt of the same by signing the box below.

With best regards,

25/6/19

Principal Investigator
Dr. Shivaji Pole,
Interventional Radiologist
N-6, Cidco, Aurangabad-431003.

Ale accept cheque
25/6/2019

Dean/Medical Director
MGM Medical College,
Aurangabad.

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

MAHATMA GANDHI MISSION

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N-6 CIDCO, Aurangabad - 431003

DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS

(CLINICAL RESEARCH UNIT)

Office: Dr. Deepak Bhosle, Prof & Head, Dept. of Clinical Pharmacology & Therapeutics, MGM Medical College & Hospital
N-6,CIDCO,Aurangabad – 431003. Ph. No: 0240-6601423, 0240-6601174, Email: pharmacolgy@mgmmcha.org

Acknowledgement of receipt	
Received By: (Authorized person-signature & stamp	Date:

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

यूनियन बैंक Union Bank of India

बी.टी. कवाडे रोड शाखा, पुणे - 411 001
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दिनांक DATE 11 06 2019

1GP20

PAY MGM Medical College या धारक को OR BEARER

रुपये RUPEES Eighteen thousand One hundred and fourteen rupees only — अदा करें। ₹ 18,114/-

खाता सं. A/c No. 438901010036758

चेक क्र. Cheque No. 12035322

For ARDENT CLINICAL RESEARCH SERVICES

Proprietor

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VOID

भारत की हमारी सभी शाखाओं में सममूल्य पर देय
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SESHVASAI \ CTS-2010 09/08/18

CA 3971619M

⑈035322⑈ 411026040⑆ 606712⑈ 29

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

MAHATMA GANDHI MISSION

Mahatma Gandhi Mission's Medical College & Hospital

N-6 CIDCO, Aurangabad - 431003

DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS
(CLINICAL RESEARCH UNIT)

Office: Dr. Deepak Bhosle, Prof & Head, Dept. of Clinical Pharmacology & Therapeutics, MGM Medical College & Hospital
N-6,CIDCO,Aurangabad – 431003. Ph. No: 0240-6601423, 0240-6601174, Email: pharmacolgy@mgmmcha.org

Date: 18 Jun 2019

To,
Dean,
MGM Medical College and Hospital.
N-6 Cidco, Aurangabad -431003,
Maharashtra, India.

Protocol Number: LUF-44-001

Protocol Title: Safety and Efficacy of Lipiodol ® Ultra Fluid in Association with Surgical Glues during Vascular Embolization, a phase IV study.

Subject: Submission of Procedural fees (Sub no.012001 & Sub no.012002)

Respected Sir,
With Reference to above Subject Here by I am submitting cheque towards procedural fees of protocol LUF-44-001.
Details:

Sr.No	Payment	Cheque No	Amount Rs.	10 % TDS	Payable Amount
01	Procedural Fees of Sub no 012001 & Sub no.012002)	035317	22,358	NA	22,358

Kindly acknowledge the receipt of the same by signing the box below.

With best regards,

18/6/19

Principal Investigator
Dr. Shivaji Pole,
Interventional Radiologist
N-6, Cidco, Aurangabad-431003.

Accepted Cheque
18/6/2019

Dr. Shivaji Pole
MBBS,MD,FVIR(KEM Mum),Fellow (S.Korea)
Asso. Prof. & Interventional Radiologist
MGM MCH, MCRI Hospital A'bad.
Reg. No. 2005/03/1699

Dean/Medical Director
MGM Medical College,
Aurangabad.

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

MAHATMA GANDHI MISSION
Mahatma Gandhi Mission's Medical College & Hospital
N-6 CIDCO, Aurangabad - 431003
DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS
(CLINICAL RESEARCH UNIT)
Office: Dr. Deepak Bhosle, Prof & Head, Dept. of Clinical Pharmacology & Therapeutics, MGM Medical College & Hospital
N-6,CIDCO,Aurangabad – 431003. Ph. No: 0240-6601423, 0240-6601174, Email: pharmacolgy@mgmmcha.org

Acknowledgement of Receipt	
Received By:	
(Authorized Person- Signature & Stamp)	**Date:**

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
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Dr. Rajesh B. Goel
Registrar
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Page 155

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B.T.Kawade Road Branch, Pun - 411 001
IFS Code : UBIN0560677

VALID FOR 3 MONTHS FROM THE DATE OF ISSUE

दिनांक DATE 30 05 2019
D D M M Y Y Y Y

1SX46

PAY MGM Medical College. या धारक को OR BEARER

रुपये RUPEES Twenty two thousand three hundred and fifty Eight. अदा करें ₹ 22,358/-

SESHASAI \ CTS-2010 09/08/18

27.05.19

खाता सं. A/c No. 438901010036758

चेक क्र. Cheque No. 12035317

For ARDENT CLINICAL RESEARCH SERVICES

CA 397161 9M

VOID

भारत की हमारी सभी शाखाओं में सममूल्य पर देय
PAYABLE AT PAR AT ALL OUR BRANCHES IN INDIA

Proprietor

PLEASE SIGN ABOVE THIS LINE

⑈035317⑈ ⑆110260401⑆ 606712⑈ 29

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

(9)

2019-20

MAHATMA GANDHI MISSION

Mahatma Gandhi Mission's Medical College & Hospital

N-6 CIDCO, Aurangabad - 431003

DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS
(CLINICAL RESEARCH UNIT)

Office: Dr. Deepak Bhosle, Prof & Head, Dept. of Clinical Pharmacology & Therapeutics, MGM Medical College & Hospital
N-6,CIDCO,Aurangabad – 431003. Ph. No: 0240-6601423, 0240-6601174, Email: pharmacolgy@mgmmcha.org

Date: 08 Aug 2019

To,
Dean,
MGM Medical College and Hospital.
N-6 Cidco, Aurangabad -431003.

Protocol Number: LUF-44-001

Protocol Title: Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization, a phase IV study.

Subject: Submission of study procedural fees of sub no.012005 to sub no01210, Professional fees of sub no.012001 to sub no.012007 and Institutional overhead charges for protocol LUF-44-001

Respected Sir,

With Reference to above Subject Here by I am submitting 03 cheques towards procedural fees, professional fees and Institutional overhead charges.
Payment Details:

Sr.No	Payment	Cheque No	Amount Rs.	10%TDS deducted	Payable Amount
01	**Procedural** fees of sub no. 012005 to sub no.012010	035336	59,120	5, 912	53,208

Sr.No	Payment	Cheque No	Amount Rs.	10%TDS deducted	Payable Amount
02	**Professional** fees of sub no. 012001 to sub no.012007	035337	1,71,600	17,160	1,54,440

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
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Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

2019-20

MAHATMA GANDHI MISSION

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N-6 CIDCO, Aurangabad - 431003

DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS
(CLINICAL RESEARCH UNIT)

Office: Dr. Deepak Bhosle, Prof & Head, Dept. of Clinical Pharmacology & Therapeutics, MGM Medical College & Hospital
N-6,CIDCO,Aurangabad – 431003. Ph. No: 0240-6601423, 0240-6601174, Email: pharmacolgy@mgmmcha.org

Sr.No	Payment	Cheque No	Amount Rs.	10%TDS deducted	Payable Amount
03	**Institutional Overhead Charges**	035335	71,500	7,150	64,350

Kindly acknowledge the receipt of the same by signing the box below and attesting the stamp of the Ethics Committee.

With best regards,

Dr. Shivaji Pole
Principal Investigator
Mahtama Gandhi Mission's Medical College and Hospital.
N-6, Cidco .Aurangabad-431003.

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

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बी.टी. कवाडे रोड शाखा, पुणे - 411 001
B.T.Kawade Road Branch, Pun - 411 001
IFS Code : UBIN0560677

दिनांक DATE 02 08 2019 (D D M M Y Y Y Y)

1RF42

PAY M.G.M Medical College या धारक को OR BEARER

रुपये RUPEES Sixty Four Thousand Three Hundred and Fifty Only

अदा करें ₹ 64,350/-

खाता सं. A/c No. 438901010036758

चेक क्र. Cheque No. 12035335

For ARDENT CLINICAL RESEARCH SERVICES

Proprietor

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⑈035335⑈ 411026040⑆ 606712⑈ 29

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B.T.Kawade Road Branch, Pun - 411 001
IFS Code : UBIN0560677

VALID FOR 3 MONTHS FROM THE DATE OF ISSUE

दिनांक DATE 02 08 2019 (D D M M Y Y Y Y)

1WX54

PAY M.G.M Medical College या धारक को OR BEARER

रुपये RUPEES Fifty Three Thousand Two Hundred and Eight

अदा करें ₹ 53,208/-

खाता सं. A/c No. 438901010036758

चेक क्र. Cheque No. 12035336

For ARDENT CLINICAL RESEARCH SERVICES

Proprietor

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⑈035336⑈ 411026040⑆ 606712⑈ 29

यूनियन बैंक ऑफ इंडिया Union Bank of India

बी.टी. कवाडे रोड शाखा, पुणे - 411 001
B.T.Kawade Road Branch, Pun - 411 001
IFS Code : UBIN0560677

VALID FOR 3 MONTHS FROM THE DATE OF ISSUE

दिनांक DATE 02 08 2019 (D D M M Y Y Y Y)

1ZR60

PAY M.G.M. Medical College या धारक को OR BEARER

रुपये RUPEES One lakh Fifty four thousand four hundred and forty

अदा करें ₹ 1,54,440/-

खाता सं. A/c No. 438901010036758

चेक क्र. Cheque No. 12035337

For ARDENT CLINICAL RESEARCH SERVICES

Proprietor

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PAYABLE AT PAR AT ALL OUR BRANCHES IN INDIA

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

⑈035337⑈ 411026040⑆ 606712⑈ 29

(9)
EC
2019-20

MAHATMA GANDHI MISSION

Mahatma Gandhi Mission's Medical College & Hospital
N-6 CIDCO, Aurangabad - 431003
DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS
(CLINICAL RESEARCH UNIT)

Office: Dr. Deepak Bhosle, Prof & Head, Dept. of Clinical Pharmacology & Therapeutics, MGM Medical College & Hospital, N-6,CIDCO,Aurangabad – 431003. Ph. No: 0240-6601423, 0240-6601174, Email: pharmacolgy@mgmmcha.org

Date:- 27 Dec 2019

To,
Dean,
MGM Medical College and Hospital
N-6 Cidco, Aurangabad -431003,
Maharashtra India.

Protocol Number: LUF-44-001

Protocol Title: Safety and Efficacy of Lipiodol ® Ultra Fluid in Association with Surgical Glues During Vascular Embolization, a phase IV study.

Subject: Submission of Procedural fees (Sub No:- 012011 & Sub No:- 012012)

Respected Sir,

With Reference to the above Subject Here by I am submitting cheque towards procedural fees of Protocol LUF-44-001.

Details:-

Sr No.	Payment	Cheque No	Amount Rs	10 % TDS	Payable Amount
01	Procedural Fees of Sub No:- 012011 & Sub No:- 012012)	185939	18550	NA	18550

Kindly acknowledge the receipt of the same by signing the box below.

With best regards,

27/12/19

Principal Investigator

Dr. Shivaji Pole

Interventional Radiologist

N-6, CIDCO, Aurangabad-431003

27/12/19

Page 01

Received
6/1/2020

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

MAHATMA GANDHI MISSION
Mahatma Gandhi Mission's Medical College & Hospital
N-6 CIDCO, Aurangabad - 431003
DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS
(CLINICAL RESEARCH UNIT)

Office: Dr. Deepak Bhosle, Prof & Head, Dept. of Clinical Pharmacology & Therapeutics, MGM Medical College & Hospital N-6,CIDCO,Aurangabad – 431003. Ph. No: 0240-6601423, 0240-6601174, Email: pharmacolgy@mgmmcha.org

Acknowledgement of Receipt	
Received By Authorized Person Signature and Stamp	 Date:-

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
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Current Account - Indus Silver
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₹ 18,550/-

ARDENT CLINICAL RESEARCH SERVICES

Please sign above

⑈185939⑈ 411234015⑆ 100124⑈ 29

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

MAHATMA GANDHI MISSION

Mahatma Gandhi Mission's Medical College & Hospital
N-6 CIDCO, Aurangabad - 431003
DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS
(CLINICAL RESEARCH UNIT)

Office: Dr. Deepak Bhosle, Prof & Head, Dept. of Clinical Pharmacology & Therapeutics, MGM Medical College & Hospital N-6,CIDCO,Aurangabad – 431003. Ph. No: 0240-6601423, 0240-6601174, Email: pharmacolgy@mgmmcha.org

Date:- 18 Jan 2020

To,
Dean,
MGM Medical College and Hospital,
N-6 Cidco, Aurangabad -431003,
Maharashtra India.

Protocol Number: LUF-44-001

Protocol Title: Safety and Efficacy of Lipiodol ® Ultra Fluid in Association with Surgical Glues During Vascular Embolization, a phase IV study.

Subject: Submission of Procedural fees (Sub No:- 012013 & Sub No:- 012014)

Respected Sir,

With Reference to the above Subject Here by I am submitting cheque towards procedural fees of Protocol LUF-44-001.

Details:-

Sr No.	Payment	Cheque No	Amount Rs	10 % TDS	Payable Amount
01	Procedural Fees of Sub No:- 012013 & Sub No:- 012014)	000782	13,975	NA	13,975

Kindly acknowledge the receipt of the same by signing the box below.

With best regards,

18/1/2020

Principal Investigator

Dr. Shivaji Pole

Interventional Radiologist

N-6, CIDCO, Aurangabad-431003

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

Page 01

MAHATMA GANDHI MISSION
Mahatma Gandhi Mission's Medical College & Hospital
N-6 CIDCO, Aurangabad - 431003
DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS
(CLINICAL RESEARCH UNIT)

Office: Dr. Deepak Bhosle, Prof & Head, Dept. of Clinical Pharmacology & Therapeutics, MGM Medical College & Hospital N-6,CIDCO,Aurangabad – 431003. Ph. No: 0240-6601423, 0240-6601174, Email: pharmacolgy@mgmmcha.org

Acknowledgement of Receipt	
Received By Authorized Person Signature and Stamp	Date:-

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
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Authorised Signatories

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Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
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NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

Mahatma Gandhi Mission
Medical College & Hospital
N-6 CIDCO, Aurangabad-431003 (Maharashtra)
Phone: +91-0240-6601100, Fax: 0240-2487727, web: www.mgmmcha.org

Date:-7 Jan 2018

To,
Member Secretary
MGM-ECRHS
MGM Campus, N-6 Cidco,
Aurangabad. 431003.
India.

Protocol Number: LUF-44-001

Protocol Title: Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization Phase IV study.

Subject: Submission of Expedited EC Fees.

Respected Sir/Ma'am,

With Reference to above Subject Here by me submitting details of cheque done towards EC Payment,

Remaining 20,000 Rs will submit as earliest.

Payment Details:

Sr. No	Payment	Cheque No	Amount Rs	Net Amount Rs	Date
01	EC Payment	006672	40,000	40,000	13-12-2018

Kindly acknowledge the receipt of the same by signing the box below and attesting the stamp of the Ethics Committee

Thanking You,

Principal Investigator
Dr Shivaji Pole,
Asso proff & Interventional Radiologist.
Mahatma Gandhi Mission's Medical College & Hospital,
N-6; CIDCO, Aurangabad-431003. Maharashtra, India

Dean
MGM Medical College,
Aurangabad.

Mahatma Gandhi Mission
Medical College & Hospital
N-6 CIDCO, Aurangabad-431003 (Maharashtra)
Phone: +91-0240-6601100, Fax: 0240-2487727, web: www.mgmmcha.org

Acknowledgement		
Name	**Designation**	**Signature & date**
Dr. Deepali Jaybhaye	Member Secretary.	7/1/19

Member Secretary
MGM-ECR
MGM's Medical College, Aurangabad

MGM INSTITUTION AURANGABAD

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

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Pay MGM Medical College Aurangabad — या धारक को Or Bearer

रुपए Rupees Forty Thousand only

अदा करें ₹ 40,000/-

Seshaasai (M) CTS - 2010

खाता सं॰ A/c No. 409000111316

For SIRO CLINPHARM PRIVATE LIMITED

Rakesh Kumar
Authorised Signatory
Please sign above

Payable at par at all RBL Bank Branch/es in India

⑈006672⑈ 400176020⑆ 010139⑈ 29

Dr. Shashank D. Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

Mahatma Gandhi Mission
Medical College & Hospital
N-6 CIDCO, Aurangabad-431003 (Maharashtra)
Phone: +91-0240-6601100, Fax: 0240-2487727, web: www.mgmmcha.org

Date:-14 Jan 2019

To,
Member Secretary
MGM-ECRHS
MGM Campus, N-6 Cidco,
Aurangabad. 431003.
India.

Protocol Number: LUF-44-001

Protocol Title: Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization, a phase IV study.

Subject: Submission of EC Fees for review and approval.

Respected Sir/Ma'am,

With Reference to above Subject Here by I am submitting details of Cheque done towards EC Payment,

Payment Details:

Sr. No	Payment	Cheque No.	Amount Rs	Net Amount Rs	Date
01	EC Payment	006725	20,000	20,000	09 Jan 2019

Kindly acknowledge the receipt of the same by signing the box below and attesting the stamp of the Ethics Committee

Thanking You,

Principal Investigator
Dr. Shivaji Pole
Asso Prof & Interventional Radiologist,
Mahatma Gandhi Mission's Medical College & Hospital,
N-6, CIDCO, Aurangabad-431003,
Maharashtra, India.

Dean
MGM Medical College,
Aurangabad.

Mahatma Gandhi Mission
Medical College & Hospital
N-6 CIDCO, Aurangabad-431003 (Maharashtra)
Phone: +91-0240-6601100, Fax: 0240-2487727, web: www.mgmmcha.org

Acknowledgement		
Name	**Designation**	**Signature & date**
Dr Deepali Jaybhaye	Member Secretary	14/Jan/2019

MGM-ECRHS AURANGABAD

Member Secretary
MGM-ECRHS
MGM's Medical College,Aurangabad

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
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Dr.Shashank D.Dalvi
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MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
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Opp. Cine Wonder, Kapurbawadi, Thane (W) 400601
IFSC Code : RATN0000097

A/C Payee Only

दिनांक Date 0 9 0 1 2 0 1 9
D D M M Y Y Y Y

Valid for 3 months from the date of issue

Pay MGM Medical College, Aurangabad या धारक को Or Bearer

रुपए Rupees Twenty Thousand only अदा करें ₹ 20,000/-

For SIRO CLINPHARM PRIVATE LIMITED

Rakesh Kumar

Authorised Signatory
Please sign above

खाता सं. A/c No. 409000111316

Seshaasai (M) CTS - 2010

Payable at par at all RBL Bank Branch/es in India

"006725" 400176020: 010139" 29

Dr. Rajesh B. Goel
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Dr.Shashank D.Dalvi
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KAMOTHE, NAVI MUMBAI

Mahatma Gandhi Mission
Medical College & Hospital
N-6 CIDCO, Aurangabad-431003 (Maharashtra)
Phone: +91-0240-6601100, Fax: 0240-2487727, web: www.mgmmcha.org

Date:-08 May 2019

To,
Member Secretary
MGM-ECRHS
MGM Campus, N-6 Cidco,
Aurangabad. 431003.
India.

Protocol Number: LUF-44-001

Protocol Title: Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization, a phase IV study.

Subject: Submission of amendment EC Fees for review and approval.

Respected Sir/Ma'am,

With Reference to above Subject Here by I am submitting details of Cheque done towards EC Payment,

Payment Details:

Sr. No	Payment	Cheque No.	Amount Rs	Net Amount Rs	Date
01	EC Payment	006999	20,000	20,000	02/05/2019

Kindly acknowledge the receipt of the same by signing the box below and attesting the stamp of the Ethics Committee

Thanking You,

08/5/19

Principal Investigator
Dr. Shivaji Pole
Asso Prof & Interventional Radiologist,
Mahatma Gandhi Mission's Medical College & Hospital,
N-6, CIDCO, Aurangabad-431003,
Maharashtra, India.

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Medical College & Hospital
N-6 CIDCO, Aurangabad-431003 (Maharashtra)
Phone: +91-0240-6601100, Fax: 0240-2487727, web: www.mgmmcha.org

EC Acknowledgement		
Name	**Designation**	**Signature & date**
Dr Deepali Jaybhaye	Member Secretary	08/5/19

MGM-ECRHS AURANGABAD

Member Secretary
MGM-ECRHS
MGM's Medical College,Aurangabad

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
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Opp. Cine Wonder, Kapurbawadi, Thane (W) 400601
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A/C Payee Only

Valid for 3 months from the date of issue

दिनांक Date: 0 2 0 5 2 0 1 9
D D M M Y Y Y Y

Pay MGM Medical College Aurangabad या धारक को Or Bearer

रुपए Rupees Twenty Two Thousand Two Hundred Twenty Two only अदा करें ₹ 22222/-

खाता सं॰ A/c No. 409000111316

For SIRO CLINPHARM PRIVATE LIMITED

Rakesh Kumar

Authorised Signatory
Please sign above

Payable at par at all RBL Bank Branch/es in India

Seshaasai (M) CTS - 2010

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Dr. Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
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KAMOTHE, NAVI MUMBAI

Dr. Rajesh B. Goel
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NAVI MUMBAI- 410 209

(9)

RBL BANK

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Opp. Cine Wonder, Kapurbawadi, Thane (W) 400601
IFSC Code : RATN0000097

A/C Payee Only

दिनांक Date 13 08 2019
D D M M Y Y Y Y

Pay MGM Medical College, Aurangabad

या धारक को Or Bearer

रुपए Rupees Twenty Thousand only

अदा करें ₹ 20,000/-

खाता सं. A/c No. 409000111316

For SIRO CLINPHARM PRIVATE LIMITED

Rakesh Kumar
Authorised Signatory
Please sign above

Payable at par at all RBL Bank Branch/es in India

Seshaasai (M) CTS - 2010

⑈007227⑈ ⑆400176020⑆ 010139⑈ 29

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Dr. Rajesh B. Goel
Registrar
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MAHATMA GANDHI MISSION

Mahatma Gandhi Mission's Medical College & Hospital
N-6 CIDCO, Aurangabad - 431003

DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS
(CLINICAL RESEARCH UNIT)

Office: Dr. Deepak Bhosle, Prof & Head, Dept. of Clinical Pharmacology & Therapeutics, MGM Medical College & Hospital
N-6,CIDCO,Aurangabad – 431003. Ph. No: 0240-6601423, 0240-6601174, Email: pharmacolgy@mgmmcha.org

Date:-19Aug 2019

To,
Member Secretary
MGM-ECRHS
MGM Campus, N-6 Cidco,
Aurangabad. 431003.
India.

Protocol Number: LUF-44-001

Protocol Title: Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization, a phase IV study.

Subject: Submission of EC Fees for review and approval (SmPC submission)

Respected Sir/Ma'am,

With Reference to above Subject Here by I am submitting details of Cheque done towards EC Payment,

Payment Details:

Sr. No	Payment	Cheque No.	Amount Rs	Net Amount Rs	Date
01	EC Payment	007227	20,000	20,000	13 Aug 2019

Kindly acknowledge the receipt of the same by signing the box below and attesting the stamp of the Ethics Committee.

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
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Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

Testing Agreement

This Testing Agreement ("**Agreement**") dated 13th day of September Two Thousand Eighteen ("**Effective Date**")

by and between Sancheti Institute College Of Physiotherapy, Sancheti Healthcare Academy, 12, Thube Park, Shivajinagar, Pune – 411005 represented by its authorized signatory Dr Nilima Bedekar **(Hereinafter referred to as the Institute)**

AND

MGM Institute of Health Sciences, Navi Mumbai through the MGM School of Physiotherapy having its office at MGM Educational Campus, Sector 1, Kamothe, Navi Mumbai, 410209 **(Hereinafter referred to as the Organization).**

WHEREAS

1. The Institute has submitted an exercise protocol which involves three types of Suryanamaskar namely traditional, chair and wall Suryanamaskar (the "**Exercise protocol**") which could be used for enabling mobility in persons with impairments (the "**Purpose**")

2. Dr Apurv Shimpi(PT), Professor, from Sancheti Institute College Of Physiotherapy, Sancheti Healthcare Academy, Pune at the Institute together with certain research scholars at the Institute have developed the Exercise Protocol, the intellectual property which is owned exclusively by the Institute.

3. The Institute contemplates that after the development of the **Exercise protocol**, it will be necessary to test the said **Exercise protocol** in certain controlled conditions (the "**Testing**").

4. The Organization has the facilities to conduct the test and is willing to participate in the Testing of the **Exercise protocol** with the Institute upon terms and conditions as set out herein. The Institute has inspected the said available infrastructure, facilities, interacted with the staff and employees, is satisfied with and has approved the same.

The Parties hereto have therefore mutually agreed as follows:

1. SCOPE OF WORK

1.1 Conduct of the Testing.

The parties agree to conduct the Testing in a controlled environment based upon the

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terms and conditions contained in this Agreement and in terms of the protocol to be mutually agreed between the Institute and the Organization prior to the time of the Testing. The organization shall get clearance from the Institutional Review Board and Ethics committee and communicate the same to the Institute, which will be final and binding on both the parties.

1.2 Care and Skill:

The Organization, its employees and staff will:-

a) exercise all due care, diligence and skill necessary for carrying out testing activities;
b) use reasonable endeavours to complete the agreed work within the time specified or extended time as agreed by the parties in writing;
c) allocate sufficient staff time during one year between January 2018 to December 2018 (amounting to 360 hrs/ 50 working days) (with suitable qualification/experience) for the testing;
d) obtain the Informed Consent of the concerned participants ;
e) keep the records of the participants and the Institute confidential;

1.3 Principal Investigator.

Dr. Apurv Shimpi, Professor, Sancheti Institute College Of Physiotherapy, of the Institute will serve as the principal investigator ("**Principal Investigator**") for the Testing. The Principal Investigator is not a party to this Agreement and acts solely as an employee of Institute.

1.4 The Institute will supply the necessary materials to conduct the Testing, and also information for the purpose of the Testing. The Organization is responsible for proper conduct of the Testing under the supervision of its domain expert. The parties agree that their respective authorized representative shall remain present at the time of testing, participate therein and sign the daily report/daily work done report as a mark of approval of the quality and procedure of testing done by the Organization. The said daily report/daily work done report shall be evidence of the fact that the testing has been done as per the approved procedure, methods and standards operating procedures of MGM Center of Human Movement Science, Navi Mumbai.

1.5 The Organization shall provide a list of participants who have provided their written consent for participating in the testing of the Exercise Protocol after being informed by the organization of the Exercise Protocol , its purposes, the probable inherent risks involved in the use of the Exercise Protocol etc (the "**Informed Consent**") to the Testing of the Exercise Protocol. The Organization acknowledges that it has been and shall ensure that it will fully inform the participants about the Exercise Protocol, the Testing Protocol and the Purpose of the Exercise Protocol before obtaining the participants Informed Written Consent. The Testing Protocol will contain the details of the number of Exercise Protocols to be used during the Testing. The written consent format as approved by the parties hereto and generally accepted by the Ethical Committee for Research on Human Subjects, MGMIHS is enclosed herewith. A short write up of the information (as approved by the parties) to be provided to the participants is annexed hereto as Annexure 1.

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Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
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1.6 **Testing Report.**

All the reports (including the Testing Report) testing data and materials used for the purpose of this Agreement shall be owned by the Institute and the Organization. With the prior mutual consent, the Institute or the Organization may use the Testing Report for any purpose as deemed necessary including internal research, teaching, archival purposes and publication. The Organization will keep, maintain and regularly update the testing report and shall upon demand in writing by the Institute, through their authorized representatives provide copies as requested. The final testing report will be submitted to the Institute as required by the Institute. The Organization will create a testing report at the beginning of the Testing and will include in the report the details in terms of the Testing Protocol including outputs of the Testing, financial reports, the originals of the Informed Consent obtained, comments from the participants etc (the "**Testing Report**").

2. **MEETING OF THE EXPENSES**

Costs and Expenses.

The Institute will pay an amount of INR 86,000 (50% of the cost of testing which is INR 1,72,000) at the time of signing the agreement. Further, the Institute will meet the costs of testing (to the extent of the approved budget), within a period of 30 -45 days from date of receipt of the bills from the Organization. The payments shall be made in the name of MGM Centre of Human Movement Science. The Institute agrees and undertakes to pay interest @ of 18% for the delay in payment of the bills beyond the period of 45 days from the date of receipt of the bills from the Organization.

3. **INTELLECTUAL PROPERTY**

3.1 **Pre-existing Intellectual Property.**

Ownership of inventions, discoveries, works of authorship, and other developments existing as of the Effective Date and all patents, ("**Pre-existing Intellectual Property**") is not affected by this Agreement. Neither party shall have any claims to or rights in any Pre-existing Intellectual Property of the other party, except as may be expressly provided in any other written agreement between the parties.

3.2 **Intellectual Property Agreements.**

Intellectual Property (IP) generated as part of or as a consequence of the Testing shall be jointly owned by the parties. The Organization and the Institute will inform each other if any IP is created and will co-operate and provide consent for sharing of IP rights, making applications for registration including provisional registration etc.

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Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

4. TESTING DATA

4.1 Testing Data.

Organization shall own and maintain all the Testing results and may use it for any purpose including for research, teaching, educational, archival or auditing purposes. Original Testing data in entirety remains the sole property of the organization. The Institute cannot share these results with any third party without prior written consent of the Organization.

4.2 Exercise Protocol for Testing.

Institute shall provide the Exercise Protocol to enable the Organization to conduct the Testing. The Organization is responsible for proper conduct of the test under the supervision of domain expert. Title and ownership of the **Exercise Protocol** will at all times remain with the Institute.

5. CONFIDENTIAL INFORMATION

5.1 Institute and Organization recognize that conducting the Testing may require the transfer of confidential or proprietary information between the parties. All documents, information, materials and data provided to Organization by the Institute will be considered confidential information of the Institute only if marked as "confidential" ("**Confidential Information**"). The Organization shall ensure that the information is shared only with those employees, staff or parties who have a need to know the Confidential Information and shall procure confirmation that all such parties agree to be bound by this Confidentiality Clause and terms of this Agreement. In consideration of the disclosure of any Confidential Information to the other, the Institute and the Organization agree that, for a period of this Agreement, which is one year from January 2018 to December 2018, and for a further period of three (3) years from the date of expiry of this Agreement, they will:

(a) Not use the Confidential Information except as allowed in this Agreement;
(b) Not use the Institute's Confidential Information without an appropriate participant authorization and/or consent and as allowed in this Agreement.
(c) Not disclose to third parties any of the Confidential Information belonging to the other party without the express written consent of the disclosing party except in accordance with this Agreement; and
(d) Take precautions as normally taken with the receiving party's own confidential and proprietary information to prevent disclosure to third parties.

5.2 The obligation of confidentiality does not apply to Confidential Information that is:
(a) publicly available through no fault of recipient;
(b) disclosed to the recipient by a third party;
(c) already known to the recipient at the time of disclosure;
(d) developed by the recipient without reference to the Confidential

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NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

Information; or

(e) required to be disclosed by law, regulation, or court order.

For the purposes of this Agreement, the Testing Report shall be deemed to be the Confidential Information of the Institute, however original data in entirety shall be deemed to be Confidential Information of the Organization.

6. PUBLICATION

6.1 The basic objective of research activities at Institute is the generation of new knowledge and its expeditious dissemination for the public's benefit. Organization will provide all reasonable cooperation with Institute in meeting this objective.

6.2 Notwithstanding any terms to the contrary in this Agreement, Institute and Organization retain the right at their discretion to publish/present results of the Testing with mutual consent. The parties agree that the publication is a joint publication.

7. TERMINATION

The Testing will continue until the Testing is completed by the Organization or to the maximum limit of one year extending from January 2018 to December 2018. Similarly the termination can be done by the Organization, if the Institute fails to make payment of bills within the specified period of 30—45 days after testing, from the date of receipt of the bill by the Institute, or if the Institute fails to provide appropriate and proper information for carrying out the testing, or for any breach of the terms of this testing agreement and it becomes effective upon e-mail communication from the person who had signed this agreement or equivalent or above authorized person. The Institute may terminate this Agreement if the Organization breaches this Agreement or does anything to delay or hinder the Testing process; termination will be immediately effective upon the receipt of written notice from the Institute to the Organization. It is further provided that such notice will not be served unless there is serious breach by the Institute.

8. NOTICES

Any notices given under this Agreement will be in writing and delivered by e-mail or speed post or by hand addressed to the parties as follows:

Sancheti Institute College of Physiotherapy,
Sancheti Healthcare Academy,
12, Thube Park, Shivajinagar, Pune – 411005

MGM School of Physiotherapy
MGM Institute of Health Sciences
Sector 1, Plot No 1&2,Kamothe, Navi Mumbai, India

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
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NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
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9. PUBLICITY

9.1 Neither party will identify the other in any promotional advertising or other promotional materials to be disseminated to the public or use the name of any faculty member, employee, or student or any trademark, service mark, trade name, or symbol of the other, including without the other party's prior written consent.

9.2 Notwithstanding anything to the contrary, Organisation agrees to allow publicly registered information about the Testing to appear on Institute Directory website.

10. INDEMNITY

The Institute will indemnify and hold harmless the Organization, its employees, Investigator, staff and students from any loss, damage, claim (including legal costs) that may arise due to the negligence or default of the Organization.

11. NO WARRANTIES

The Institute/Organization make no warranties, express or implied, as to any matter whatsoever, including, without limitation, on the Exercise Protocol or the results of the testing or any invention, process or product, whether tangible or intangible, conceived, discovered, or developed by it.

12. LIMITATION OF LIABLITY

The Organization shall not be liable for any indirect, consequential or other damages suffered by Institute or any of the testing participants including, damages arising from loss of data or delay or termination of the testing, or from the use of the results of the testing, or any such invention or exercise protocol.

13. FORCE MAJEURE

The parties will not be liable for any failure to perform as required by this Agreement, if the failure to perform is caused by circumstances reasonably beyond Organization's control, such as accidents, failure of any governmental approval required for full performance, civil disorders or commotions, acts of aggression, acts of God, energy or other conservation measures, explosions, failure of utilities, mechanical breakdowns, material shortages, disease, thefts, or other such occurrences.

14. MISCELLANEOUS

14.1 **Assignment.** Neither party may assign this Agreement without the prior written consent of the other party.

14.2 **Survival.**

Dr. Rajesh B. Goel
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Any of the sections that include any other rights and obligations under this Agreement which by their nature should survive, shall survive the expiration or termination of this Agreement.

14.3 **Divisibility.**
If any provision of this Agreement becomes or is declared illegal, invalid, or unenforceable, such provision will be divisible from this Agreement and will be deemed to be deleted from this Agreement. If such deletion substantially alters the basis of this Agreement, the parties will negotiate in good faith to amend the provisions of this Agreement to give effect to the original intent of the parties.

14.4 **Independent Contractors.**
Institute and Organisation are independent contractors and neither is an agent, joint venture partners, or partner of the other.

14.5 **Order of Precedence.**
In the event of any inconsistency between the terms of this Agreement and the documents referenced or incorporated herein or any other agreement concerning this Testing between the Parties and their employees, the terms of this Agreement will prevail.

14.6 **Entirety.**
This Agreement represents the entire agreement and understanding between the parties and their employees with respect to its subject matter and supersedes any prior and/or contemporaneous discussions, representations, or agreements, whether written or oral, of the parties regarding this subject matter.

14.7 **Amendments.**
The Amendments or changes to this Agreement must be in writing and signed by duly authorized representatives of the parties.

14.8 **Counterparts.**
This Agreement may be executed in multiple counterparts, each of which will be deemed an original, but all of which will constitute one and the same Agreement, and the signature pages from any counterpart may be appended to any other counterpart to assemble fully executed counterparts.

IN WITNESS WHEREOF, these duly authorized representatives of the parties hereby execute this Agreement, including all the terms and conditions which follow.

Dr. Rajesh B. Goel
Registrar
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Sancheti Institute College Of Physiotherapy
Sancheti Healthcare Academy,
12, Thube Park, Shivajinagar,
Pune – 411005

MGM Institute of Health Sciences,
Navi Mumbai

Mrs. Nilima Bedekar
Sancheti Institute College of Physiotherapy
16, Shivajinagar, Pune - 5.
PRINCIPAL

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai- 410 209

Name : Dr Nilima Bedekar

Designation : Principal

Date : 15/10/2018

Dr Rajesh Goel

Registrar

28/9/2018

Principal Investigator

Institute:

Name : Dr. Apurv Shimpi
Department :
Sancheti Institute College Of Physiotherapy , Pune

Date : 15/10/2018

Organization:

Dr. Rajani Mullerpatan

MGM School of Physiotherapy, Navi Mumbai.

Date : 28-9-2018

Professor - Director
MGM School of Physiotherapy
MGMIHS, Navi Mumbai

Dr. Rajesh B. Goel
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(Deemed University u/s 3 of UGC Act, 1956)
Grade 'A' Accredited by NAAC
MGM SCHOOL OF PHYSIOTHERAPY
Sector-1, Kamothe, Navi Mumbai 410209

Letter No.:MGM/SOP/ 5 5 /2018

Date:19.12.2018

To,
The Principal Co-Ordinator,
Apurv Shimpi,
Sancheti Institute of Physiotherapy,
Pune.

Subject : Submission of final bill for "Research Testing Consultancy Fee"

Dear Sir,

Please find enclosed bill for "Research Testing Consultancy Fee" for the project titled "Biomedical Analysis and Energy expenditure of traditional .chair and wall Suryanamskar " for Rs.1,72,000/- (Rs One Lac Seventy Two Thousand Only').

Part payment of Rs.86,000/- has been received via cheque No.131381 dt. 20.10.18 , awaiting the receipt of remained payment of Rs.86,000/- in the view of completion of the project.

Thanking You,

Dr.Rajani Mullerpatan
Professor & Director
MGM School of Physiotherapy
Kamothe

Encl: Original bill of Rs.1,72,000/-

Sector 1, Kamothe, Navi Mumbai . Tel.:022 65143108, E-mail: mgmschoolofphysiotherapy@gmail.com

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

RESEARCH TESTING CONSULTANCY FEES

MGM School of Physiotherapy,MGM Institute of Health Sciences,Kamothe MGM Educational Campus, Sector-01,Kamothe ,Navi Mumbai-410209	Document No. CHMS/2018/01	Dated 1-DEC-2018
Research Collaborator Sancheti Institute of Physiotherapy,Pune Sancheti Healthcare Academy,12,Thube Park, Shivajinagar,Pune-411005		Mode/Terms of Payment CHEQUE/DD/NEFT
		Other Reference(s)
		Dated 01.12.2018

Sl No	Description	Testing cost per Participant	No.of Participants	Amount
1	Testing Cost as per Testing agreement Titled: Biomedical Analysis and Energy expenditure of traditional ,chair and wall Suryanamskar	3D Gait analysis	10	70,000.00
		EMG	10	30,000.00
		Consumables	10	72,000.00
		Total Rs.		172,000.00
2	ADVANCE 50% Received by chq no.131381 dt 20.10.18			-86000.00
	Balance Amount Payable			₹ 86000.00

E & O E

Amount Chargeable (in words):
INR Eighty Six Thousand Only

PAN No. AACTM0014C

for MGM School of Physiotherapy, Kamothe, Navi Mumbai

MGM School of Physiotherapy NAVI MUMBAI

Authorised Signatory

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
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KAMOTHE, NAVI MUMBAI

A/c. No	0306104000079417	CCY / SOL ID	INR /.306
Names	MGM CENTRE FOR HUMAN MOVEMENT SCIENCES		
GL Sub Head	10400	Balance	4,03,642.00 Cr
Opening Bal.	3,11,042.00 Cr	Closing Bal.	4,03,642.00 Cr
Float Balance	0.00 Cr	Funds In Clearing	0.00
Available Amt.	4,03,642.00 Cr	Eff. Available Amt	4,03,642.00 Cr
Cust. Status	GEN GENERAL	A/c. Open Date	13-05-2016
A/c. Status	A Active	A/c. Status Date	13-05-2016
Last Purge Date	12-05-2016		

Address	3RD FLOOR MGM MEDICAL COLLEGE SECTOR 18 KAMOTHE		
City	NMU NAVI MUMBAI	State	MH MAHARASHTRA
Country	IN INDIA	Postal Code	410209
Phone No.	27422471 / 27421994	Telex No.	
Email ID	mgmuniversity@yahoo.com		

Tran. Date	Value Date	Chq. No.	Withdrawl	Deposit	Balance	Narration
26-11-2019	26-11-2019			4,100.00 Cr	4,03,642.00 Cr	NAVI MUMBAI -BELAPUR :- CASH RECEIPT
14-11-2019	14-11-2019			1,500.00 Cr	3,99,542.00 Cr	NAVI MUMBAI -BELAPUR :- CASH RECEIPT
07-11-2019	07-11-2019			86,000.00 Cr	3,98,042.00 Cr	193930-BOM-SANCHETI COLLEGE PHYSIOTHER APY
04-11-2019	04-11-2019			1,000.00 Cr	3,12,042.00 Cr	IMPS/930815920132/Mrs MONIC/State B/XX0001/INETIM

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

A/c. No 306104000079417

Names MGM CENTRE FOR HUMAN MOVEMENT SCIENCES

GL Sub Head 10400 Balance 4,44,977.00 Cr

Opening Bal. 3,54,877.00 Cr Closing Bal. 4,44,977.00 Cr

Tran. Date	Value Date	Chq. No.	Withdrawl	Deposit	Balance	Narration
26-11-2018	26-11-2018			4,100.00 Cr	4,44,977.00 Cr	NAVI MUMBAI -BELAPUR :- CASH RECEIPT
06-11-2018	06-11-2018			86,000.00 Cr	4,40,877.00 Cr	131381-BOM-SANCHETI COLLEGE

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

MGM Centre of Human Movement Science

MGM Institute's
University Department of Physiotherapy

(Deemed University u/s 3 of UGC Act, 1956)
Grade 'A' Accredited by NAAC
Sector-1, Plot No. 1 & 2, Kamothe, Navi Mumbai - 410209.

No. 069 Date: 03/11/13

Received with thanks from Mr/Mrs/Ms. Sancheti college of physio Pune

for amount of 86,000/-

Sr.No.	Tests Particulars	Amount INR
1	Gait Analysis	
2	Balance Assessment	
3	Foot Pressure Analysis	
4	Walking Activity Monitoring	
5	Energy Cost	
6	Any Other	
7	50% cost of testing for the project "Exercise protocol"	86,000/-
	Chq NO 131381 TOTAL	86000/-

In words Eighty Six Thousand only-

Accountant

Faculty In Charge

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

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KAMOTHE, NAVI MUMBAI

महाराष्ट्र MAHARASHTRA ◑ 2018 ◑ TR 792496

PRODUCT CODE:	Sotagliflozin/SAR439954
STUDY CODE:	EFC14875
STUDY NAME:	THE SCORED TRIAL

INVESTIGATOR/INSTITUTION/SMO CONTRACT

Site Name & City: MGM Medical College and Hospital, Aurangabad

Study Code/ Name: EFC14875 / The SCORED Trial

Initials SPONSOR Initials INSTITUTION Initials INVESTIGATOR Initials SMO

This Contract (hereinafter "the Contract") is made on this **30th day of August 2018,** by and among:

DOCTOR PRASHANT UDGIRE, Principal Investigator, having his address at Department of Cardiology, MGM Medical College and Hospital, N-6 CIDCO, Aurangabad, Maharashtra-431003, INDIA

Hereinafter the "**INVESTIGATOR**",

AND

MGM MEDICAL COLLEGE AND HOSPITAL, having its address at N-6 CIDCO, Aurangabad, Maharashtra-431003, INDIA represented for the purposes hereof by Dr. Rajendra B. Bohra, Dean

Hereinafter the "**INSTITUTION**"

AND

ARDENT CLINICAL RESEARCH SERVICES a private Site Management Organization, having its registered office at 318, Level-3, Connaught Place, Bund Garden Road, Pune - 411 001, Maharashtra, *India* represented for the purposes hereof by Chandu Devanpally, Managing Director,

Hereinafter the "**SMO**",

AND

SANOFI-SYNTHELABO (INDIA) PRIVATE LIMITED, a private limited company having its registered office at Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai – 400072, represented for the purposes hereof by Dr. Chirag Trivedi, Clinical Study Unit, Director

Hereinafter the "**SPONSOR**"

The INVESTIGATOR, the INSTITUTION, the SMO and the SPONSOR are hereinafter individually referred to as a "Party "or collectively referred to as the "Parties".

WITNESSETH:

WHEREAS, the SPONSOR is to perform a clinical trial "A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Demonstrate the Effects of Sotagliflozin on Cardiovascular and Renal Events in Patients with Type 2 Diabetes, Cardiovascular Risk Factors and Moderately Impaired Renal Function" (hereinafter the « Study ») to evaluate Sanofi drug **Sotagliflozin/SAR439954** (hereafter the « Investigational Medicinal Product ») in accordance with a protocol entitled "The SCORED Trial, EFC14875" and its amendments (hereinafter collectively the « Protocol»), and

WHEREAS, the INSTITUTION is a Hospital known for its medical excellence, having the highest caliber faculty, high class education, research and patient care;

WHEREAS the INVESTIGATOR is a doctor attached to the INSTITUTION and is specialized in the field of Cardiology, and

WHEREAS, the SMO is a site management organization which is taking care of site management activities for studies of the INVESTIGATOR and is responsible for clinical trials/clinical activities/coordination etc. at the INSTITUTION and has accordingly provided the Sponsor a certificate, a copy of which is attached hereto as "**Annexure 1**", and

WHEREAS the SPONSOR shall have no liability whatsoever arising out of selection and appointment of SMO and payments made to the SMO, including but not limited to any claims, demands, actions, causes of action, judgments, damages, expenses and costs,

including attorney's fees, which arise out of, result from, occur during or are connected in any manner with the Study or any related activities or Investigator meetings, irrespective of whether or not they are sponsored, supervised or controlled by the SPONSOR, except such liability arising directly and solely from gross negligence on the part of the SPONSOR, and

WHEREAS, the INSTITUTION, the INVESTIGATOR and the SMO having each reviewed the Protocol for the Study, the Clinical Investigator Brochure and sufficient information regarding the Investigational Medicinal Product to evaluate their interest in participating in the Study, wish to participate in the Study and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Study, and

WHEREAS the INVESTIGATOR is responsible for ensuring that the Ethics Committee is registered before starting the Study;

In consideration of the undertakings and commitments set forth herein, the Parties agree to enter into the Contract, which provisions shall apply in compliance with those of the Protocol.

ARTICLE 1. PROTOCOL.

INVESTIGATOR/INSTITUTION/SMO shall perform the Study in strict compliance with the Protocol and a copy of the same has been provided and signed by the INVESTIGATOR and is submitted to the relevant Independent Ethic Committee («IEC/IRB»)/Health Authority («HA»)/Competent Authority («CA») for favorable opinion/approval and as the Protocol may be amended from time to time thereafter.

Any amendment to the Protocol shall be notified to the relevant IEC/IRB/HA/CA according to local regulations. All of the terms of the Protocol and any further amendments to the Protocol are incorporated hereunder and are part of the Contract.

To the extent that there may be any inconsistency between this Contract and the Protocol, this Contract shall control, except with respect to medical or clinical matters, for which the provisions of the Protocol shall take precedence.

ARTICLE 2. STUDY SITE.

The Study shall be performed at the INSTITUTION **MGM Medical College and Hospital having its address at N-6 CIDCO, Aurangabad, Maharashtra-431003, India** (hereafter the «Study Site»). The INVESTIGATOR and the SMO shall be responsible for obtaining any authorization from the representatives of the Study Site where the Study is performed.

For the avoidance of doubt, the sums paid under Exhibit 1 of the Contract to the INVESTIGATOR and/or the INSTITUTION and/or the SMO include global compensation for the performance of the Study carried out at the Study Site.

The INVESTIGATOR hereby represents, warrants and covenants that he/she has and shall maintain all necessary authorizations from the Study Site representatives to perform the Study and that he/she shall take responsibility for the payment of any cost incurred by the Study Site in connection with the Study, the amount and terms of which shall be directly and exclusively handled by the INVESTIGATOR and the Study Site.

For the purpose of the Contract, the term «Collaborators» shall mean any person involved in the Study including but not limited to associates, sub-investigators, biologists, assistants and nurses.

It is agreed among the Parties that the INVESTIGATOR shall attend the mandatory training session(s) organized in relation with the Study. The Parties further agree to inform each other of the Study performance and discuss Study results and therefore agree to organize and to participate in meetings to be held at places and locations to be determined by SPONSOR as

well as participating in face to face meetings and teleconferences organized by the SPONSOR at its own expense in relation to the Study. Any and all travel arrangement, meeting arrangement, accommodation etc. for such meetings shall be done by the SPONSOR.

ARTICLE 3. COMPLIANCE.

3.1 The Study shall be performed in accordance with (i) the Protocol (ii) all applicable Central, State and Local laws, rules and regulations in India including the Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research and the Indian GCP Guidelines (iii) the Guideline for Good Clinical Practice of the International Conference on Harmonization (hereinafter the «ICH – GCP»), (iv) the principles laid down by the 18th World Medical Assembly (Helsinki, 1964) and all applicable amendments laid down by the World Medical Assemblies, and (v) the specific procedures provided by the SPONSOR applicable for conducting the Study.

3.2 The INVESTIGATOR, the INSTITUTION and the SMO shall ensure that all procedures defined in the Protocol are complied with, so that all data coming from the Study Site are reliable and have been processed correctly (especially the randomization lists, and the blind character of the Study as the case may be) and will ensure that the content of the case report form (CRF) / electronic case report form (e-CRF) will accurately reflect source documents.

3.3 The INVESTIGATOR and the INSTITUTION shall submit CRF/eCRFs to the SPONSOR.

The INVESTIGATOR and any Collaborator (as such term is defined at Article 5.2) will be trained by the SPONSOR with respect to the use of eCRFs.

The INVESTIGATOR, the INSTITUTION and the SMO agree that any and all equipments if provided to the INVESTIGATOR's Study Site and or to the INSTITUTION to complete eCRFs shall remain the sole property of the SPONSOR. The INVESTIGATOR, the INSTITUTION and the SMO shall promptly return any such equipment when all eCRFs for the Study have been completed by the INVESTIGATOR and/or the INSTITUTION.

ARTICLE 4. TERM.

This Contract is being entered into force from 17 September 2018 ("the Effective Date") and shall expire upon receipt by the SPONSOR of all data generated by the INVESTIGATOR and after completion of the close-out visit for the Study Site.

The Parties estimate that the whole Study will take approximately **51 (Fifty One) months** from the first visit of the first Subject to the last visit of the last Subject.

ARTICLE 5. ITEMS SUPPLIED BY THE SPONSOR.

5.1 The SPONSOR shall provide directly or indirectly the INVESTIGATOR, the INSTITUTION and the SMO with all necessary information, documents and materials, including but not limited to :

- the Investigator Brochure (IB) / SmPC data
- the Protocol,
- the Informed Consent Form
- the CRF/e-CRF
- the Investigational Medicinal Product manufactured in accordance with the applicable regulations and/or the Good Manufacturing Practice (GMP), suitably packaged and labeled and in sufficient quantity to conduct the Study.

5.2 The INVESTIGATOR, the Collaborators, the SMO and the INSTITUTION shall use the information, documents and Investigational Medicinal Product provided by the SPONSOR, solely for the purpose of the Study as per Protocol requirements, or to fulfill their own regulatory obligations, to the exclusion of any use for their own or for a third party's account.

The INVESTIGATOR shall bind the Collaborators with obligations at least as stringent as those provided for in the Contract. Therefore, the INVESTIGATOR shall be held liable should any of the Collaborators fail to comply with any of the obligations provided for in this Contract.

5.3 Unless otherwise instructed by the SPONSOR or required by applicable laws and regulations, the information, documents and Investigational Medicinal Product shall be returned or made available to the SPONSOR upon completion of the Study.

The Investigational Medicinal Product will not be made available to the investigator until the SPONSOR has received a copy of the written and dated approval/opinion of the IEC/IRB/HA/CA.

5.4 Should the Study require the use of a specific material, the SPONSOR (or its designee) may provide such material to the INVESTIGATOR and/or the INSTITUTION and/or the SMO under conditions (reference of the material, quantities, conditions of restitution, etc.) detailed in a separate agreement.

5.5 The INVESTIGATOR, the INSTITUTION and the SMO or its designee shall ensure that an accurate record of the quantity of Investigational Medicinal Product received and dispensed to each Subject is maintained. The INVESTIGATOR/INSTITUTION/SMO shall ensure that the Investigational Medicinal Product is stored and dispensed in accordance with the SPONSOR's specifications and applicable laws and regulations.

5.6 The INVESTIGATOR/INSTITUTION and the SMO agree to take responsibility for the safeguarding of such materials and to notify the SPONSOR promptly in case of any loss damage, or failure of these materials.

5.7 Upon termination or completion of the Study, all unused Study Drug, compounds, drugs devices, case report forms, whether or not completed, and other related materials that were furnished to the INVESTIGATOR/INSTITUTION and the SMO by or on behalf of the SPONSOR shall be returned to the SPONSOR.

ARTICLE 6. SUBJECTS RECRUITMENT.

6.1 The INVESTIGATOR has estimated that he/she can recruit a maximum of **30 (Thirty) Subjects** (the «Subjects »), within approximately **15 (Fifteen) months**. This target of recruitment can be increased only upon written agreement of the SPONSOR. In addition, the SPONSOR may establish a threshold number of Subjects and rate of accrual of Subjects (e.g., x Subjects per day/week/month) to allow for appropriate monitoring of the Study and will communicate this information to the INVESTIGATOR. The INVESTIGATOR undertakes to comply with these limitations and conditions for further recruitment at the Study Site as required by the SPONSOR.

6.2 A minimum of one (1) Subject must be enrolled within two (2) months of initiating the Study at the Study SITE. Subsequently, if no Subjects are enrolled over a period of three (3) months, or if the INVESTIGATOR cannot begin the Study at the STUDY Site, the SPONSOR may decide at its discretion to discontinue the Study at the Study SITE.

6.3 Especially in case of multicenter studies, the SPONSOR reserves the right to request the INVESTIGATOR to limit the recruitment of further Subjects or cease the recruitment, notably in case the global recruitment target for the Study has been reached. In such case, the SPONSOR shall inform the INVESTIGATOR to stop the recruitment of any subject who has not yet signed the informed consent. The INVESTIGATOR shall upon receipt of the notice stop immediately further recruitment of Subjects. Payments shall

only be made according to the number of Subjects recruited up to the date of receipt of the notice. The SPONSOR will not take any responsibility and make any payment for the Subjects recruited after this date.

ARTICLE 7. CONSENT OF THE SUBJECTS.

7.1 Before any Subject's participation in the Study, the INVESTIGATOR shall fully inform any subject and/or, as the case may be, her/his legal representative, in language understandable to them, of all pertinent aspects of the Study in accordance with the requirements stipulated under Indian laws/regulations (Article 3.1). The Privacy Rules of each country shall be followed in order to obtain consent from Subjects as required throughout the Study.

7.2 The INVESTIGATOR shall ensure that all Subjects participating in the Study and /or their legal representative (i) have received a copy of the Subject information leaflet, and (ii) have expressed their prior consent by signing the informed consent form, in such format as approved by DCGI or Other Authority, without the undue influence or coercion of any person directly involved in the Study, and only after having been duly informed.

ARTICLE 8. MONITORING OF THE STUDY.

8.1 The SPONSOR shall appoint monitor(s), bound by a professional confidentiality obligation, who will work with the INVESTIGATOR, the INSTITUTION and the SMO to ensure proper conduct of the Study (hereinafter the «Monitor(s)»). The INVESTIGATOR, the INSTITUTION and the SMO agree to fully cooperate with the SPONSOR's monitoring procedures and maintain all necessary Subject information.

8.2 The Monitor shall be entitled to visit the Study Site and be regularly informed about the performance of the Study and shall collect all the documents and information about the Study in accordance with the Protocol and the ICH-GCP. He/she shall have access to all records on the Subjects and all information pertaining to the Study, as well as, copies thereof, if needed.

ARTICLE 9. DUTY OF INFORMATION.

The INVESTIGATOR, the INSTITUTION and/or the SMO shall immediately inform the SPONSOR of any serious adverse event («SAE») or other events as defined in the Protocol.

ARTICLE 10. FINANCIAL TERMS AND CONDITIONS.

10.1 As consideration for the proper performance by the INVESTIGATOR, the INSTITUTION and the SMO of their obligations under the Contract, the SPONSOR shall pay the PAYEE as directed by the INVESTIGATOR and/or the INSTITUTION and/or the SMO in compliance with the payment terms defined in Exhibit 1. Payment terms may be modified only upon prior written consent of the Parties. Likewise, non-emergency additional tests or services (tests or services non-required by the Protocol or performed in excess of Protocol requirement) shall not be reimbursed hereunder without the prior written consent of the SPONSOR.

10.2 Out of pocket expenses authorized in advance by the SPONSOR that have been provided for in Exhibit 1 shall be reimbursed to the PAYEE as directed by the INVESTIGATOR and/or the INSTITUTION (without any mark-up) within 30 (thirty) days on receipt by the SPONSOR of an itemized invoice on the Letter Head of the PAYEE.

10.3 The PAYEE will bear the responsibility for the declaration of these sums and for the payment of all taxes and social contributions on the fees it will receive hereunder.

10.4 Fees/reimbursement of costs to the INVESTIGATOR and/or the INSTITUTION by the PAYEE will be an internal arrangement among themselves and the SPONSOR will not be liable to pay/reimburse any amount to the INVESTIGATOR and/or the INSTITUTION.

ARTICLE 11. CONFIDENTIALITY AND RESTRICTED USE.

11.1 All information disclosed or provided by the SPONSOR or produced during the Study, including but not limited to the Protocol, the Investigator's brochure and CRF/e-CRF, the results obtained during the course of the Study, the financial terms of the Contract (hereafter the « Confidential Information »), is confidential. The INVESTIGATOR, the INSTITUTION, the SMO agree to keep confidential and not to disclose the Confidential Information to any third party without the prior written approval of the SPONSOR. The INVESTIGATOR, the INSTITUTION, the SMO shall use the Confidential Information solely for the purposes of the Study.

Furthermore, the Parties agree to adhere to the principles of personal data confidentiality in relation to the Subjects, the INVESTIGATOR, the INSTITUTION, the SMO and Collaborators involved in the Study. Each Collaborator shall be subject to these obligations of confidentiality and restricted use. The INVESTIGATOR shall inform the Collaborators of the confidential nature of the Study and will only provide them with the information that is strictly necessary for the accomplishment of their acts.

11.2 Confidential Information shall not include information that: (1) is at the time of disclosure, or thereafter becomes, publicly available through no fault of the INVESTIGATOR/ INSTITUTION/SMO; (2) is disclosed to the INVESTIGATOR/INSTITUTION/SMO by a third party entitled to disclose such information in a non-confidential manner; (3) is known to the INVESTIGATOR/INSTITUTION/SMO prior to disclosure under this Contract, as shown by the INVESTIGATOR'/INSTITUTION's/SMO's prior written records; (4) can be documented to have been independently developed by Study Site's personnel without reliance on Confidential Information; or (5) is required by applicable law to be disclosed, provided that the INVESTIGATOR/INSTITUTION/SMO gives the SPONSOR prompt notice of such fact so that it may obtain a protective order or other appropriate remedy concerning any such disclosure, cooperate fully with the SPONSOR in connection with its efforts to obtain any such order or other remedy, and disclose, where disclosure is necessary, only the information legally required to be disclosed.

11.3 The obligations of confidentiality and restricted use contained herein are applicable during the term of the Contract and shall survive for 10 (ten) years from its date of termination, whether by expiration or by early termination.

ARTICLE 12. RECORD RETENTION.

The INVESTIGATOR and the INSTITUTION through the Study Site shall retain and preserve one (1) copy only of all data generated in the course of the Study for the longest of those two time periods:

- fifteen (15) years or,
- such longer period as required by applicable regulatory requirements, (the « Retention Period »).

The SPONSOR must be informed in writing of any change of address or relocation of the Study files and of the INVESTIGATOR /the INSTITUTION/the SMO during this period.

Following the Retention Period, as instructed by the SPONSOR, the INVESTIGATOR and/or the INSTITUTION and/or the SMO will either forward such records to the SPONSOR at the SPONSOR's expense, retain such records for a reasonable additional charge to be negotiated, or destroy the records, and send to the SPONSOR proof of such destruction. Subject files

should be retained as per GCP requirements as defined in the Protocol and in compliance with local regulations.

ARTICLE 13. PERSONAL DATA PROTECTION.

13.1 The Subject data and specific data regarding the INVESTIGATOR, the INSTITUTION, the SMO and Collaborators which may be collected by the SPONSOR and included in the SPONSOR's databases, shall be treated by both Parties in compliance with all applicable laws and regulations. These data may be transferred by the SPONSOR or its representative to Health Authorities or to the SPONSOR's representative located in a country where there is no personal data protection law, or where the level of protection imposed by local law is less stringent than requirements of the European Union under which Sanofi is governed.

13.2 As data controller, when processing or archiving data pertaining to the INVESTIGATOR, the INSTITUTION, the SMO, the Collaborators and/or the Subjects, the SPONSOR shall take all appropriate measures to safeguard and prevent access to this data by unauthorized third party.

13.3 The INVESTIGATOR, the INSTITUTION, the SMO, the Collaborators and/or the Subjects have the right to access and, where appropriate, to request the rectification and/or deletion of their personal data by sending a written notice to the address of the SPONSOR, to the attention of the Data Privacy/Compliance officer Dr. Chirag Trivedi (e-mail: chirag.trivedi@sanofi.com). Deletion of data is possible only for justifiable reason and if it is not required by law to keep it.

ARTICLE 14. PUBLICATIONS AND COMMUNICATIONS.

14.1 The INVESTIGATOR, the INSTITUTION and the SMO undertake not to make any publication or release pertaining to the Study and/or results of the Study without the SPONSOR's prior written consent, being understood that the SPONSOR will not unreasonably withhold its approval.

As the Study is being conducted at multiple sites, the SPONSOR agrees that, consistent with scientific standards, first presentation or publication of the results of the Study shall be made only as part of a publication of the results obtained by all sites performing the Study.

However, if no multicenter publication has occurred within twelve (12) months following the completion of the Study at all sites, the INVESTIGATOR shall have the right to publish or present independently the results of the Study subject to the review procedure set forth herein.

The INVESTIGATOR shall provide the SPONSOR with a copy of any such presentation or publication derived from the Study for review and comment at least thirty (30) days in advance of any presentation or submission for publication. In addition, if requested by the SPONSOR, any presentation or submission for publication shall be delayed for a limited time, not to exceed ninety (90) days, to allow for filing of a patent application or such other measures as the SPONSOR deems appropriate to establish and preserve its proprietary rights.

14.2 The INVESTIGATOR, the INSTITUTION and the SMO shall not use the name(s) of the SPONSOR and/or of its employees in advertising or promotional material or publication without the prior written consent of the SPONSOR. The SPONSOR shall not use the name(s) of the INVESTIGATOR, the INSTITUTION, the SMO, and/or the Collaborators in advertising or promotional material or publication without having received their prior written consent(s).

14.3 The SPONSOR has the right at any time to publish the results of the Study.

ARTICLE 15. PROPERTY RIGHTS.

15.1 All information, documents, materials (hereinafter collectively «Information») and Investigational Medicinal Product provided by the SPONSOR are and shall remain the sole and exclusive property of the SPONSOR or its designee.

15.2 The INVESTIGATOR, the INSTITUTION and the SMO shall not themselves and/or shall not permit any of its Collaborators to mention any Information or the Investigational Medicinal Product in any application for a patent or any other intellectual property rights whatsoever.

15.3 All the results, data, documents, discoveries and inventions which arise directly or indirectly from the Study in any form, shall be the immediate and exclusive property of the SPONSOR or its designee. For this purpose, the INVESTIGATOR, the Collaborators and the INSTITUTION presently assign to the SPONSOR (or its designee) all intellectual property rights (including all patents, copyrights, databases and any application or right to apply for registration of any of those rights) which may arise directly or indirectly from the Study and all existing or future materials created in relation to the Study.

15.4 The SPONSOR may use or exploit all the results at its own discretion, without any limitation to its property right (territory, field, continuance...), and without any additional payment. The SPONSOR shall be under no obligation to patent, develop, market or otherwise use the results of the Study, issued under this Contract.

15.5 As the case may be, the INVESTIGATOR, the INSTITUTION, the SMO and/or the Collaborators shall provide all assistance required by the SPONSOR, at the SPONSOR's expense, for obtaining and defending any patent, including signature of all legal documents.

ARTICLE 16. LIABILITY – INDEMNIFICATION – INSURANCE.

16.1 In accordance with Rule 122-DAB of the Drugs & Cosmetics Rules, 1945 in the event of injury to or death of a Subject during the Study, the following shall apply:

(1) In the case of an injury occurring to the Subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.

(2) In case the injury occurring to the Subject is related to the Study, such Subject shall also be entitled for financial compensation as determined by the Licensing Authority under the said Rules over and above the expenses incurred on the medical management of the Subject;

In case, there is no permanent injury, the quantum of compensation shall be commensurate with the nature of the non-permanent injury and loss of wages of the subject;

(3) In the case of Study related death of the Subject, his/her nominee(s) would be entitled for financial compensation as per the order of the Licensing Authority and the financial compensation will be over and above any expenses incurred on the medical management of the Subject;

(4) The expenses on medical management and financial compensation in the case of Study related injury or death of the Subject shall be borne by the SPONSOR;

(5) Any injury or death of the Subject occurring in the Study due to the following reasons shall be considered as Study related injury or death and the Subject or his/her nominee(s), as the case may be will be entitled for financial compensation for such injury or death :

(a) adverse effect of the Investigational Medicinal Product;

(b) violation of the Protocol, scientific misconduct or negligence by the SPONSOR or the INVESTIGATOR, Provided that if such violation of the Protocol, scientific misconduct or negligence is by the INVESTIGATOR, then the INVESTIGATOR will be liable to reimburse to the SPONSOR the expenses on such medical management and financial compensation that the SPONSOR shall have paid to the Subject or his/her nominee(s), as the case may be;

(c) failure of the Investigational Medicinal Product to provide intended therapeutic effect; where the standard care, though available, was not provided to the subject as per the clinical trial protocol;

(d) use of placebo in a placebo-controlled trial; where the standard care, though available, was not provided to the subject as per the clinical trial protocol;

(e) adverse effects due to concomitant medication excluding standard care, necessitated as part of the Protocol;

(f) for injury to a child in-utero because of the participation of parent in the Study;

(g) any clinical trial procedures involved in the Study.

16.2 The SPONSOR certifies it has subscribed a liability insurance policy to cover its liability as required by applicable law. The SPONSOR will provide the INVESTIGATOR and/or the INSTITUTION with a certificate of insurance in the countries where this document is required.

16.3 The insurance subscribed by the SPONSOR does not release either the INVESTIGATOR or the INSTITUTION from their obligation to maintain their own liability insurance policy.

16.4 The SPONSOR agrees to indemnify, hold harmless and defend the INVESTIGATOR, the INSTITUTION, and Collaborators (« Indemnities ») from and against any and all claims and suits, including reasonable attorneys' fees incurred in the defence thereof, arising out of an injury to a Subject (including death) caused by the administration of the Investigational Medicinal Product or the performance of any procedure required under the Protocol, except to the extent such claim or suit is attributable to:

(1) a failure to adhere to the terms of this Contract, the Protocol or any written instructions from the SPONSOR regarding the administration of the Investigational Medicinal Product or the performance of any required procedure; or

(2) a failure to comply with any applicable laws, regulations and government requirements (including, without limitation, obtaining informed consents); or

(3) the negligence or willful malfeasance of the Indemnities.

The SPONSOR shall have no obligation under this Article, however, unless: (i) the SPONSOR is promptly notified of any such claim or suit; (ii) the Indemnities cooperate fully in the handling thereof; and (iii) the SPONSOR has sole control over the disposition of such claim or suit, including the selection of counsel and any settlement thereof, provided, however, that no settlement shall include an admission of liability on the part of the Indemnities without their prior written consent, which consent shall not be unreasonably withheld.

ARTICLE 17. AUDITS AND INSPECTIONS.

17.1 For the purpose of ensuring compliance with the Protocol, Good Clinical Practice and applicable regulatory requirements, the INVESTIGATOR and/or the INSTITUTION / PAYEE shall permit audits by or on behalf of the SPONSOR and inspections by applicable regulatory authorities.

The INVESTIGATOR agrees to allow the auditors and/or inspectors to have direct access to his/her Study records and to Subjects files for review, being understood that this personnel is bound by professional secrecy, and as such will not disclose any personal identity or personal medical information.

17.2 The INVESTIGATOR, the INSTITUTION and the SMO shall devote their best efforts to facilitate the performance of any audit and inspection and shall give to the SPONSOR or to any person designated by the SPONSOR access to all necessary facilities, data and documents.

17.3 As soon as either the INVESTIGATOR, the INSTITUTION or the SMO is notified of a future inspection by the authorities, they shall inform the SPONSOR and authorize the SPONSOR to participate in this inspection. The information that arises from the inspections by the regulatory authorities will be immediately communicated by the INVESTIGATOR, the INSTITUTION or the SMO to the SPONSOR.

17.4 The INVESTIGATOR, the INSTITUTION and the SMO shall take appropriate measures required by the SPONSOR to take corrective actions without delay in order to solve all problems found during the audits or inspections.

17.5 It is expressly agreed between the Parties that the SPONSOR will not compensate the INVESTIGATOR/INSTITUTION/SMO for the audits and inspections and that the assistance and availability of the INVESTIGATOR/INSTITUTION/SMO for the audits and inspections is included in the amount mentioned in Exhibit 1.

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

ARTICLE 18. TERMINATION OF THE CONTRACT.

18.1 This Contract may be terminated: (1) by a joint decision of the INVESTIGATOR/the INSTITUTION and the SMO upon thirty (30) days prior written notice if the Study Site or the INVESTIGATOR for any reason becomes unable to perform or complete this Study; or (2) by the SPONSOR upon thirty (30) days prior written notice.

18.2 In the event this Contract is terminated, the SPONSOR will be responsible for compensating the INVESTIGATOR and/or the INSTITUTION and/or the SMO for actual activities performed hereunder in accordance with the terms of this Contract and reasonable non-cancellable expenses incurred prior to notice of termination if such expenses were required under the Protocol and contemplated within Exhibit 1. Any funds paid in advance will be prorated and any excess funds will be returned to the SPONSOR. The INVESTIGATOR shall provide the SPONSOR with all documentation required by the Protocol and applicable laws and regulations and any equipment provided by the SPONSOR in connection with the Study no later than ninety (90) days after the completion or early termination of the Contract.

The terms and conditions of Articles 3; 11; 12; 13; 14; 15; 16; 17; 19; 20, 21 and 22 shall survive the expiration or earlier termination of this Contract.

ARTICLE 19. DEBARMENT AND SENTENCING FOR MALPRACTICE.

19.1 The INVESTIGATOR, the INSTITUTION and the SMO represent and warrant that neither the INVESTIGATOR/INSTITUTION/SMO nor any Collaborators involved in conducting the Study or any member of the staff of the INSTITUTION/SMO has been debarred, excluded, disqualified or restricted in their ability to practice medicine, participate in a clinical trial/studies, or perform services in connection with the evaluation of a pharmaceutical product under any laws, regulations or professional code of conduct including without limitation United States 21 U.S.C. §335a and 21 CFR §312.70.

19.2 The INVESTIGATOR and/or the INSTITUTION and/or the SMO shall immediately notify the SPONSOR should he/she/it or any Collaborators involved in conducting the Study, be so debarred, excluded, disqualified or restricted, or should a procedure or action be initiated against any of them that could result in their being so debarred, excluded, disqualified or restricted, at any time during the term of this Contract and during the twelve (12) months following the expiration or termination of the Contract.

ARTICLE 20. FINANCIAL DISCLOSURE – TRANSPARENCY – CONFLICT OF INTEREST.

20.1 The INVESTIGATOR, the INSTITUTION/ the PAYEE and the Collaborators involved in this Study at the INVESTIGATOR's Study Site, shall ensure that they provide the SPONSOR with the appropriate financial disclosures required for compliance with 21 CFR Part 54, on such forms as the SPONSOR may supply or approve.

During the term of this Contract and for one (1) year following termination or completion of the Study, the INVESTIGATOR, the INSTITUTION and the SMO shall promptly notify the SPONSOR of any material change in the information disclosed on a previous form.

20.2 In the interest of transparency relating to the SPONSOR's financial relationships with the INVESTIGATOR/INSTITUTION/SMO, the SPONSOR may collect, publicly disclose, and communicate to relevant authorities/institutions, the funding, including payments made to the INVESTIGATOR/INSTITUTION/SMO and payments made to individuals, and/or any direct or indirect advantages and/or or any related information or document associated with this Contract, if required by applicable law.

20.3 The INVESTIGATOR represents and warrants to the SPONSOR that he/she:

(a) is not bound, at the date of signature of this Contract, by any obligation or commitment to a third party, including any legal entity of which he/she is an employee or to which he/she refers, that could conflict with the terms of this Contract and

(b) will not knowingly enter into any agreement with a third party that would in any way prevent him/her from participating as an investigator in the Study or could conflict with the terms of this Contract.

ARTICLE 21. ANTI-BRIBERY.

21.1 The INVESTIGATOR, the INSTITUTION and the SMO represent and warrant that neither they nor any of their personnel are officials, agents, representatives or employees of any government or political party or any international public organization where they may be in a position of official government authority able to use that position to help the SPONSOR obtain or maintain business or obtain a business advantage.

21.2 The INVESTIGATOR, the INSTITUTION and the SMO further represent and warrant that they have not made and agree that they shall not make any payment or any offer or promise for payment, either directly or indirectly, of money or other assets, or transfer anything of value, to government or political party officials, officials of international organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing for the purpose of influencing decisions or actions or where such payment or advantage would constitute violation of any applicable anti-bribery legislation, regulations and/or codes, both national and foreign, including but not limited to, the US Foreign Corrupt Practices Act and the UK Bribery Act (hereinafter and above designated by « Anti-Bribery Provisions »).

ARTICLE 22. MISCELLANEOUS

22.1 The Protocol, the Contract and all others documents exchanged between the Parties constitutes the whole undertaking of the Parties. All appendices attached hereto shall be deemed to be incorporated herein.

22.2 Any work performed by the INVESTIGATOR, the Collaborators and/or the INSTITUTION and/or the SMO under this Contract shall be considered to be performed by them as independent contractors and not as employees, partners or agents of the SPONSOR. No Party shall have the authority, either express, implied or apparent, to bind the other Party, except to the extent that same may be consistent with the performance of that Party's obligations in accordance with the terms of this Contract.

22.3 Except as otherwise expressly mentioned hereinabove, any notification shall be made by mail or fax.

22.4 If either Party is prevented from fulfilling its obligations in accordance with the terms of this Contract due to force majeure (as defined by applicable law and/or competent court), this Party shall be released from performance to the extent that it is so prevented from doing so for the duration of the intervening circumstances. The Party wishing to claim relief on the grounds of the said circumstances shall notify the other Party in writing without delay on the intervention or cessation thereof. The Party so prevented from fulfilling its obligation shall devote its best endeavors to remove or avoid the impediment as soon as possible. If the Party is prevented from fulfilling its obligations under this Contract due to force majeure for a period exceeding two (2) running months, each Party shall have the right to terminate this Contract by registered mail with acknowledgment of receipt. The termination will become effective forthwith.

22.5 No indulgence granted by either Party to the other in relation to any term hereof shall be deemed a waiver of such term or prejudice the later enforcement of that or any other term hereof.

22.6 Should a provision of this Contract in any manner whatsoever contravene any applicable laws and regulations, such provision shall be deemed to be severable and shall not affect any other provision of this Contract, nor affect the enforceability of those remaining provisions which are not in contravention of any law and regulation.

22.7 The Contract is concluded by the SPONSOR intuitu personae. Hence, the INVESTIGATOR, the INSTITUTION and the SMO shall not be allowed to transfer totally or partially the obligations the SPONSOR charged them with, nor to subcontract them without the prior written consent of the SPONSOR. The INVESTIGATOR, the INSTITUTION and the SMO shall, where applicable, transmit to the Collaborators the Contract and shall cause them to abide by its terms and conditions. The SPONSOR may transfer this Contract to an affiliate company or to a successor in interest to its business by reason of any merger, acquisition, partnership, license agreement or otherwise, provided that the assignee is subject to the terms and obligations provided in this Contract. For use herein, affiliated company shall mean Sanofi (B 395 030 844 R.C.S. PARIS, hereinafter "SANOFI") and any legal entity which controls SANOFI, is controlled by SANOFI or is under common control with SANOFI. "Control" means the ownership directly or indirectly of at least fifty percent (50%) of the capital stocks or the voting rights of such entity.

22.8 This Contract constitutes the entire agreement between the Parties relative to the subject matter hereof and supersedes all representations, warranties, agreements or undertakings previously made relative to such subject matter, and no such representations, warranties, agreements or undertakings shall be in any force and effect unless contained herein. No variation of any terms and conditions of this Contract will be binding upon the Parties unless committed in writing and signed by them respectively.

22.9 This Contract shall be governed by the law of India. Prior to taking any legal action, the Parties shall endeavor to settle by amicable arrangement any disputes arising between

them regarding this Contract. Should the Parties fail to reach an amicable settlement, the Parties agree to submit to the exclusive jurisdiction of the courts of Mumbai and the Parties waive any other forum to which they may be entitled by reason of their present or future address or for any other reason.

IN WITNESS WHEREOF, the Parties hereto have caused this Contract to be duly executed on their behalf in four counterparts, each of which shall be deemed to be an original, as of the Effective Date.

SANOFI-SYNTHELABO (INDIA) PRIVATE LIMITED (SPONSOR)		**INVESTIGATOR**	
[Signature]		**[Signature]**	
[Name]	**Dr. Chirag Trivedi**	**[Name]**	**DR. PRASHANT UDGIRE**
[Title]	**Clinical Study Unit Director**	**[Title]**	**Principal Investigator**
In presence of		In presence of	
[Signature]		**[Signature]**	
[Name]	**Y. J. Cama**	**[Name]**	Dr. Deepak S. Bhosle

MGM MEDICAL COLLEGE AND HOSPITAL (INSTITUTION)		**ARDENT CLINICAL RESEARCH SERVICES (SMO)**	
[Signature]		**[Signature]**	
[Name]	**Dr. Rajendra B. Bohra**	**[Name]**	**Mr. Chandu Devanpally**
[Title]	**Dean**	**[Title]**	**Managing Director**
In presence of		In presence of	
[Signature]		**[Signature]**	
[Name]	Dr. Rajesh D. Kadam	**[Name]**	Mrs. Pranjali Aurkar

EXHIBIT 1

CONDITIONS OF PAYMENT

Agreement Effective Date: - 17 September 2018

1) The SPONSOR will pay **Rs.4,51,700/- (Rupees Four Lakhs Fifty One Thousand Seven Hundred only)** per Subject included in accordance with the Protocol and who has completed the Study. The said amount is inclusive of audits and inspections compensation as referred to under Article 17.5.

   Such amount is divided as follows:

EFC 14875- Per Subject Cost Details			
Visits	**Investigator Fees (Rs.)**	**Site Coordinator Fees* (Rs.)**	**Subject reimbursement (for travel, meals during site visit)(Rs.)**
Screening (V1)	17,000	3,300	1,500
Week 0 Randomization (V2)	22,500	3,500	1,500
Week 4 (V3)	14,000	3,800	1,500
Week 8 (V4)	14,000	3,800	1,500
Week 26 (V5)	14,500	4,400	1,500
Week 35 (V6) Phone Visit	3,700	2,600	-
Week 44 (V7) Phone Visit	3,700	2,600	-
Week 52 (V8)	17,500	4,300	1,500
Week 61 (V9) phone visit	3,700	2,600	-
Week 70 (V10) Phone visit	3,700	2,600	-
Week 78 (V11)	17,200	4,400	1,500
Week 87 (V12) Phone Visit	3,700	2,600	-
Week 96 (V13) Phone visit	3,700	2,600	-
Week 104 (V14)	17,500	4,300	1,500
week 113 (V15) Phone Visit	3,700	2,600	-
week 122 (V16) phone visit	3,700	2,600	-
week 130 (V17)	17,200	4,400	1,500
week 139 (V18) phone visit	3,700	2,600	-
week 148 (V19) phone visit	3,700	2,600	-
week 156 (V20)	17,500	4,300	1,500
week 165 (V21) phone visit	3,700	2,600	-
week 174 (V22) phone visit	3,700	2,600	-
week 182 (V23)	17,200	4,400	1,500
week 191 (V24) phone visit	3,700	2,600	-
week 200 (V25) phone visit	3,700	2,600	-
week 208 (V26)	17,500	4,300	1,500
week 217 (V27) phone visit	3,700	2,600	-
week 226 (V28) phone visit	3,700	2,600	-
pEOT visit	14,900	3,100	1,500

EFC 14875- Per Subject Cost Details			
Visits	**Investigator Fees (Rs.)**	**Site Coordinator Fees* (Rs.)**	**Subject reimbursement (for travel, meals during site visit)(Rs.)**
Close-out visit	14,900	3,100	1,500
Follow-up visit	11,800	4,600	1,500
Unscheduled Visit (if done)**	17,000	4,700	1,500
Total Per Subject Cost	**321,400**	**106,300**	**24,000**

*In case, the Study Coordinator is to be provided by the SPONSOR, the study coordinator Fees will not be payable to the INSTITUTION/INVESTIGATOR and the same shall not be applicable.

**Unscheduled Visit- This cost does not apply to unscheduled phone calls made to the Subjects. Also, the unscheduled visit cost listed in table above is the maximum payable amount when all tests/procedures are done during unscheduled visit. In case all tests/procedures are not done, the payment will be commensurate to the actual work done by the site during Subject's unscheduled visit.

2) Cost of local lab tests, if any, shall be paid based on actuals and shall be payable on receipt by the SPONSOR of an itemized invoice. Additional investigations apart from protocol specified investigations will be reimbursed based on proper rational provided by the INVESTIGATOR and based on verification provided by the SPONSOR.

3) For screen failure, the SPONSOR will pay Rs.20,000/- (Rupees Twenty Thousand only) per screen failed subject (this is as per the expectation that the screen failure rate is in line with the country screen failure rate).

4) Ethics committee's fees, if any, shall be paid based on actuals and shall be payable on receipt by the SPONSOR of an itemized invoice, on the Letter Head of the Ethics Committee and/or the PAYEE.

5) 20% Institutional overheads on aforesaid Point 1 (except Subject reimbursement) & Point 3.

6) SPONSOR will pay one time lump sum of Rs.75,000/- (Rupees Seventy Five Thousand only) after the Study Closure to the PAYEE for archival and document storage for a period of 15 years from the date of site closure.

7) A close out fee of Rs.10,000/- (Rupees Ten Thousand only) will be paid towards close out efforts once the site close out visit has been conducted.

8) Concomitant medications that are standard of care for the underlying diseases are not reimbursable.

9) A onetime non-refundable start-up fee of Rs.50,000/- (Rupees Fifty Thousand only) shall be paid for the time spent for Health Authority documentation, undertaking study specific training, Subject identification, Ethics Committee submission, approval activities and shall cover the cost of any study related infrastructure if required. The payment shall be made on the receipt of Ethics Committee approval unless discontinued due to regulatory obligations.

10) All the payments for the study will be as per the break-up mentioned in **Annexure 1**.

11) All the devices or instruments provided by the SPONSOR will be returned to SPONSOR at the time of closeout.

12) Taxes, as applicable, will be paid on generation of valid invoice showing the amount of tax to be charged before any payment is made under this Contract.

13) Each payment made shall be inclusive of all applicable taxes and duties except for Goods and Service Tax ("GST") which shall be reimbursed by the SPONSOR to the PAYEE against presentation by the PAYEE of all relevant documentation.

The party who makes a taxable service under or in connection with this Contract shall be entitled to recover such taxes that it is required by law to collect from the other party to whom the services are made by issuing a valid tax invoice in the format prescribed under the relevant law. Notwithstanding anything contrary stated herein in this Contract, the other party to whom the services are made shall not be under any obligation to make any payment until the receipt of the tax invoice. In addition, if the PAYEE fails to upload its return on GSTN portal and is unable to pay GST within prescribed time period, the PAYEE shall indemnify the SPONSOR such GST amount along with applicable interest.

A Subject is considered as having completed the Study when he/she has completed the specified Study period, and is evaluated as per the Protocol.

In case of Subjects recruited but not having completed the Study, the amount to be paid will be calculated according to the fees of the visits actually performed by these Subjects. No payment will be made for an ineligible Subject incorrectly randomized into the Study or in case the Subject did not complete the Study due to negligence, malpractice, breach of Protocol, willfully wrong act or omission on the part of the INVESTIGATOR/INSTITUTION.

The payment for recruited Subjects will be made to the INVESTIGATOR/INSTITUTION/PAYEE on quarterly basis upon presentation of the invoices in Indian Rupees by a cheque/ bankwire transfer within 30 days (from the receipt of correct Invoice) on the following PAYEE account:

1) **For payments related to INSTITUTION:**

Bank Name & Branch:	IDBI Bank, New Osmanpura,
Bank IFSC	IBKL0000376
Account No.:	0376104000000107
PAYEE:	MGM Medical College
PAN No.:	AAATM4256E
GST No.:	27AAATM4256E1ZP

2) **For payments related to SMO:**

Bank Name & Branch:	HDFC Bank, B.T. Kawade Road, Ghorapadi, Pune
Bank IFSC	HDFC0003708
Account No.:	50200007013912
PAYEE:	Ardent Clinical Research Services
PAN No.:	APQPD7081M
GST No.:	27APQPD7081M1Z9

The final payment will occur only after:

- the delivery and review of the final data of the Study, provided that they shall be ready for statistical analysis;
- the completion of all CRF/e-CRF, including resolution of all DRF/e-DRF and after the positive opinion on the part of the SPONSOR regarding their filling;
- receipt of all responses to the DRF from the INVESTIGATOR/INSTITUTION;
- the INVESTIGATOR has returned all remaining Investigational Medicinal Product and applicable study material, if any, in compliance with Article 5).

Annexure 1

Mahatma Gandhi Mission
Medical College & Hospital
N-6 CIDCO, Aurangabad-431003 (Maharashtra)
Phone: +91-0240-6601100-Ext.423, Fax: 0240-2487727, web: www.mgmmcha.org

TO WHOMSOEVER IT MAY CONCERN

THIS IS TO CONFIRM that, Ardent Clinical Research Services is taking care of site management activities of my studies at our centre who is going to manage clinical trials/ clinical activities/coordination at MGM Medical College and Hospital, N-6, CIDCO, Aurangabad-431003, Maharashtra, INDIA. For the services being provided by the Ardent Clinical Research Services, the budget will be made as follows:

The breakup of the budget is as follows:

1. 65 % grant of total PI fees paid to hospital/Institution
2. 35 % grant of total PI fees paid to SMO
3. Institutional Overhead 20 % paid to hospital/Institution
4. 100 % grant of CRC fees paid to SMO
5. Archival fees will be paid to hospital/Institution
6. Study start up payment paid to SMO
7. Subject travel reimbursement paid to SMO
8. SAE reimbursement, Lab tests cost and others on actual paid to hospital/Institution

Thanking you,

16/8/2018

Dr. Prashant Prabhakar Udgire
(Principal Investigator)
MBBS MD (Medicine) DM Cardiology
MGM Medical College and Hospital, N-6, CIDCO,
Aurangabad-431 003, Maharashtra, INDIA
DR. PRASHANT P. UDGIRE
M.D. (Medicine), D.M.(Cardiology) Mumbai
Asst. Prof. & Interventional Cardiologist
MGM Medical College & MCRI
Aurangabad-431003
Reg. No 2002/03/

Dr. Deepak Bhosle

16/8/2018

Professor & H.O.D.
Department of Pharmacology
MGM's Medical College
Aurangabad.

Dr. Deepak Bhosle
[Head of Department]
MBBS MD Diabetologist
MGM Medical College &
Hospital, N-6 cidco, A'bad
Maharashtra, India

Page 1 of 1

Dr. Rajesh B. Goel
Registrar
MGM INSTITUTE OF HELATH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act,1956)
NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

Mahatma Gandhi Mission
Medical College & Hospital
N-6 CIDCO, Aurangabad-431003 (Maharashtra)
Phone : +91-0240-6601100, Fax: 0240-2487727, web:www.mgmmcha.org

Date:-04 Jun 2019.

To,
Member Secretary
MGM-ECRHS
MGM Campus, N-6 Cidco,
Aurangabad. 431003.
India.

Protocol Number: EFC14875/The SCORED Trial.

Protocol Title: A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Demonstrate the Effects of Sotagliflozin on Cardiovascular and Renal Events in Patients with Type 2 Diabetes, Cardiovascular Risk Factors and Moderately Impaired Renal Function.

Subject: Submission of EC Amendment Fees.

Respected Sir/Ma'am,

With Reference to above Subject Here by I am submitting details of NEFT done towards EC Payment, Payment Details:

Sr. No	Payment	NFT	Amount Rs	Net Amount Rs	Date
01	EC Payment	92019070470000000109X	22,223	20,000	04 Jun 2019

Kindly acknowledge the receipt of the same by signing the box below and attesting the stamp of the Ethics Committee

Thanking You,

4/6/19
Principal Investigator
Dr Prashant Udgire
Cardiology Department
Mahatma Gandhi Mission's Medical College & Hospital,
N-6, CIDCO, Aurangabad-431003. Maharashtra.

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

Acknowledgement		
Name	**Designation**	**Signature & date**
Dr. Deepali Jaybhaye	Member Secretary	04/06/19

MGM-ECRHS AURANGABAD

Member Secretary
MGM-ECRHS
MGM's Medical College, Aurangabad

Mahatma Gandhi Mission
Medical College & Hospital
N-6 CIDCO, Aurangabad-431003 (Maharashtra)
Phone : +91-0240-6601100, Fax: 0240-2487727, web:www.mgmmcha.org

Date:-24 Sep 2018

To,
Member Secretary
MGM-ECRHS
MGM Campus, N-6 Cidco,
Aurangabad. 431003.
India.

Protocol Number: EFC14875/The SCORED Trial.

Protocol Title: A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Demonstrate the Effects of Sotagliflozin on Cardiovascular and Renal Events in Patients with Type 2 Diabetes, Cardiovascular Risk Factors and Moderately Impaired Renal Function.

Subject: Submission of EC Amendment Fees.

Respected Sir/Ma'am,

With Reference to above Subject Here by I am submitting details of NEFT done towards EC Payment, Payment Details:

Sr. No	Payment	NEFT	Amount Rs	Net Amount Rs	Date
01	EC Payment	180912931GN00100	20,000	20,000	12 Sep 2018

Kindly acknowledge the receipt of the same by signing the box below and attesting the stamp of the Ethics Committee

Thanking You,

24/9/18

Principal Investigator
Dr Prashant Udgire
Cardiology Department
Mahatma Gandhi Mission's Medical College & Hospital,
N-6, CIDCO, Aurangabad-431003. Maharashtra.

Dean/Medical Director
MGM Medical College,
Aurangabad

Acknowledgement		
Name	**Designation**	**Signature & date**
Dr. Deepali Jaybhaye	Member Secretary	24/9/18

Member Secretary
MGM-ECRHS
MGM's Medical College, Aurangabad

MGM ECRHS AURANGABAD

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

Subject **EFC14875_ EC fees transfer details**
From <AhmedAziz.Khan@sanofi.com>
To <soni.agale511@gmail.com>, <soni@ardent-cro.com>
Cc <prashant_udgire@rediffmail.com>, <gaurav@ardent-cro.com>
Date 21/09/2018 03:26 PM

Dear Soni,

The EC payment of Rs. 20000/- was transferred to payee on 12 Sep 2018.

Reference number of this payment request was recorded as – NFT-180912931GN00100.

Do let me know if you need any other information.

Regards,
Ahmed Aziz

PI — Dr. prashant P. Udgire

Sponsor — Sanofi

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

Mahatma Gandhi Mission

Medical College & Hospital

N-6 CIDCO, Aurangabad-431003 (Maharashtra)
Phone : +91-0240-6601100, Fax: 0240-2487727, web:www.mgmmchà.org

Date:-24 Sep 2018

To,
Member Secretary
MGM-ECRHS
MGM Campus, N-6 Cidco,
Aurangabad. 431003.
India.

Protocol Number: EFC14875/The SCORED Trial.

Protocol Title: A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Demonstrate the Effects of Sotagliflozin on Cardiovascular and Renal Events in Patients with Type 2 Diabetes, Cardiovascular Risk Factors and Moderately Impaired Renal Function.

Subject: Submission of EC Amendment Fees.

Respected Sir/Ma'am,

With Reference to above Subject Here by I am submitting details of NEFT done towards EC Payment,
Payment Details:

Sr. No	Payment	NEFT	Amount Rs	Net Amount Rs	Date
01	EC Payment	180912931GN00100	20,000	20,000	12 Sep 2018

Kindly acknowledge the receipt of the same by signing the box below and attesting the stamp of the Ethics Committee

Thanking You,

24/9/18

Principal Investigator
Dr Prashant Udgire
Cardiology Department
Mahatma Gandhi Mission's Medical College & Hospital,
N-6, CIDCO, Aurangabad-431003. Maharashtra.

Ale
donesfpl

P2/10

Dean/Medical Director
MGM Medical College,

Acknowledgement		
Name	**Designation**	**Signature & date**
Dr. Deepali Jaybhaye	Member Secretary	24/9/18

Member Secretary
MGM-ECRHS
MGM's Medical College, Aurangabad

MGM ECRHS ★ AURANGABAD

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

Subject	**EFC14875_ EC fees transfer details**
From	<AhmedAziz.Khan@sanofi.com>
To	<soni.agale511@gmail.com>, <soni@ardent-cro.com>
Cc	<prashant_udgire@rediffmail.com>, <gaurav@ardent-cro.com>
Date	21/09/2018 03:26 PM

Dear Soni,

The EC payment of Rs. 20000/- was transferred to payee on 12 Sep 2018.

Reference number of this payment request was recorded as – NFT-180912931GN00100.

Do let me know if you need any other information.

Regards,
Ahmed Aziz

PI — Dr. prashant P. Udgire.

Sponsor — Sanofi.

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

LAMBDA THERAPEUTIC RESEARCH LTD
Corporate Office : Lambda House, Survey No. 388, Near Silver Oak College of Engineering,
Nr. Nirma, Gota, Ahmedabad – 382481
Tel : + 91 79 40202115/ 40202108 Fax : + 91 79 40202021

LAMBDA

To,

MGM Medical College
N-6, CIDCO, Aurangabad - 431 003
Tel: 0240-6601100 -174/329

Please find enclosed Cheque/DD bearing No. 369570 dated : 26-Jun-2018 for Rs. 40,000.00 (Forty Thousand Only). Drawn on Axis Bank Ltd. C.C.A/c for the following : MGM MEDICAL COLLEGE TOWARDS SITE IEC FEES PAYMENT AS PER REQUEST NO. 0384-18/009 TO PI: DR. CHANDRASHEKHAR TAMANE, SITE: MGM MEDICAL COLLEGE, AURANGABAD, GSTIN : NO GST, SAC: 0 LINE ITEM NO. 1.8 CHEQUE NO:369570

Sl. No.	Bill No.	Bill Date	Bill Amount Rs. P.	Deduction Rs. P.	Amount Passed Rs. P.
1	TDS 0384-18/009	25-Jun-2018	4,445.00		
2	0384-18/009	25-Jun-2018	44,445.00		
	Total		**(-)40,000.00**		**40,000.00**

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

Total (In Words) : Indian Rupees Forty Thousand Only.

AXIS BANK LTD
Ahmedabad, Ahmedabad, 380006
IFS Code : UTIB0000003

A/c Payee

DATE दिनांक 2 6 0 6 2 0 1 8
D D M M Y Y Y Y

PAY **MGM Medical College** OR ORDER / या उसके आदेश पर

RUPEES **Forty Thousand Only**

₹ **40,000.00**

For LAMBDA THERAPEUTIC RESEARCH LTD.

A/C NO. 003010300010608 CODE 393392

AUTHORISED SIGNATORY

⑈369570⑈ 380216002⑈ 003392⑈ 30

MAHATMA GANDHI MISSION
MEDICAL COLLEGE & HOSPITAL
N-6 CIDCO, Aurangabad-431003 (Maharashtra)
Phone : +91-0240-6601100-Ext.174/329, E-mail : mgmpharmacologydept@gmail.com

Date: 04 July 2018

To,

The Member Secretary,
MGMECRHS,
MGM Medical College,
N-6 Cidco. Aurangabad. -431003.

Protocol Number: 0384-18
Protocol Title: A Randomized, Open Label, Two Arm, Single Dose, Crossover, Bioequivalence Study of Ayana Pharma's Doxorubicin Hydrochloride Liposome Injection (Lc-101) (Investigational Product) and the us reference standard Doxorubicin Hydrochloride Liposome Injection (Sun Pharma), in subjects with Ovarian Cancer.

Subject: Submission of Ethics Committee fees.

Respected Sir,

With Reference to above Subject Here by I am submitting cheque towards study payment
Payment Details:

Sr.No	Payment	Cheque no.	Amount Rs.	Tax deducted Rs.	Net Amount Rs.	Date
01	EC Payment	369570; Axis Bank	44,445	4,445	40,000	26 June 2018

Kindly acknowledge the receipt of the same by signing the box below and attesting the stamp of the Ethics Committee.

With best regards,

Dr. Chandrashekhar Tamane,
Principal Investigator,
MGM's Medical College and Hospital.
N-6, Cidco, Aurangabad- 431003.

Dean
MGM Medical College,
Aurangabad.

Acknowledgement		
Name	**Designation**	**Signature & date**
Dr. Deepali Jaybhaye	Member Secretary	4/7/18

MGM-ECRHS AURANGABAD

Member Secretary
MGM-ECRHS
MGM Medical College, Aurangabad

Mahatma Gandhi Mission
Medical College & Hospital
N-6 CIDCO, Aurangabad-431003 (Maharashtra)
Phone : +91-0240-6601100-Ext.423, Fax: 0240-2487727, web:www.mgmmcha.org

Date: 21 May 2018

To
The Chairperson/ Member Secretary,
Institutional Ethics Committee
MGM Medical College.
N-6 Cidco. Aurangabad. -431003.

Protocol Number: EFC14875/The Scored Trial
Protocol Title: A randomized, Double blind, Placebo-controlled, Parallel Group, Multicenter Study to Demonstrate the Effects of Sotagliflozin on Cardiovascular and Renal Events in Patients with Type 2 diabetes, Cardiovascular Risk Factors and Moderately Impaired Renal Function.

Subject: Submission of EC Fees.

Respected Sir/Ma'am,

With Reference to above Subject Here by I am submitting Cheque towards EC payment,
Payment Details:

Sr.No	Payment	NFT	Amount Rs.	Net Amount Rs	Date
01	EC Payment	180516470GN 00116	40,000	40,000	16 May 2018

Kindly acknowledge the receipt of the same by signing the box below and attesting the stamp of the Ethics Committee.
With best regards,

29/5/18
Dr. Prashant Prabhakar Udgire
Principal Investigator
Mahatama Gandhi Mission's Medical College and Hospital.
N-6, Cidco, Aurangabad-431003.

DR. PRASHANT P. UDGIRE
M.D.(Medicine),D.M.Cardiology(Mumbai
Asst. Prof. & Interventional Cardiologist
MGM Medical College & MCRI,A'bad.
Reg. No.2002/03/

29/5/18
Member Secretary
MGM-ECRHS
MGM's Medical College,Aurangabad

MGM-ECRHS * AURANGABAD *

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

G/L Account	97100741	Clg A/c-Deutsche Bank-Mumbai
Company Code	0345	Sanofi-Synthelabo (I) Pvt

Doc. no. 200132217

Line Item 2 / Credit entry / 50

Amount	40,000.00	INR
Business Place		

Additional Account Assignments

Business Area	INAA	
Cost Center		
Profit Center		
Order		
Functional Area		More
Purchasing Doc.	0	
Quantity	0.000	
Value Date	16.05.2018	
Clearing date	16.05.2018 10323409	Auto. Created
Assignment	020013221718	
Text	NFT-180516470GN00116XXXXXXX	Long text

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

MAHATMA GANDHI MISSION

Mahatma Gandhi Mission's Medical College & Hospital

N-6 CIDCO, Aurangabad - 431003

DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS
(CLINICAL RESEARCH UNIT)

Office: Dr. Deepak Bhosle, Prof & Head, Dept. of Clinical Pharmacology & Therapeutics, MGM Medical College & Hospital
N-6,CIDCO,Aurangabad – 431003. Ph. No: 0240-6601423, 0240-6601174, Email: pharmacolgy@mgmmcha.org

Date: 30 Nov 2019

To,
Dean,
MGM Medical College and Hospital.
N-6 Cidco, Aurangabad -431003.

Protocol Number: EFC14875

Protocol Title: A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Demonstrate the Effects of Sotagliflozin on Cardiovascular and Renal Events in Patients with Type 2 Diabetes, Cardiovascular Risk Factors and Moderately Impaired Renal Function

Subject: Submission of PI fees- Study Payment.

Respected Sir,

With Reference to above Subject Here by I am submitting cheque towards study payment including Institutional overhead charges.

Payment Details:

Sr.No	Payment	Account Number	Transaction Description	Transaction Amount	Transaction Date
01	Study Payment	037610400000 0107	RTGS-DEUTR9201911130000 0447-Sanofi –SYNTH	451056.10	13 Nov 2019

Kindly acknowledge the receipt of the same by signing the box below and attesting the stamp of the Ethics Committee.

With best regards,

30/11/19

Dr. Prashant Udgire
Principal Investigator

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

Received 5/12/19

https://corp.dblbank.co.in/corp/BANKAWAY?RA

Cyber Receipt !

Date:14/11/2019 10:33:

Transaction Details

Account Number	0376104000000107
Transaction Date	13/11/2019
Transaction Amount	INR 4,51,056.10
Transaction Type	CR
Transaction Description	RTGS/DEUTR92019111300000447/SANOFI-SYNTH

Save Print Cancel

Dr Shashank D Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

MAHATMA GANDHI MISSION

Mahatma Gandhi Mission's Medical College & Hospital

N-6 CIDCO, Aurangabad - 431003

DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS
(CLINICAL RESEARCH UNIT)

Office: Dr. Deepak Bhosle, Prof & Head, Dept. of Clinical Pharmacology & Therapeutics, MGM Medical College & Hospital
N-6,CIDCO,Aurangabad – 431003. Ph. No: 0240-6601423, 0240-6601174, Email: pharmacolgy@mgmmcha.org

Date: 04 Jul 2019

To,
Dean,
MGM Medical College and Hospital.
N-6 Cidco, Aurangabad -431003.

Protocol Number: EFC14875

Protocol Title: A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Demonstrate the Effects of Sotagliflozin on Cardiovascular and Renal Events in Patients with Type 2 Diabetes, Cardiovascular Risk Factors and Moderately Impaired Renal Function

Subject: Submission of PI fees- Study Payment.

Respected Sir,

With Reference to above Subject Here by I am submitting cheque towards study payment including Institutional overhead charges.

Payment Details:

Sr.No	Payment	NEFT	Amount Rs.	TDS	Payable Amount
01	Study Payment	920190704000000109X	2,51,704.80	23,307	275,011

Kindly acknowledge the receipt of the same by signing the box below and attesting the stamp of the Ethics Committee.

With best regards,

Dr. Prashant Udgire
Principal Investigator
Mahtama Gandhi Mission's Medical College and Hospital.
N-6, Cidco .Aurangabad-431003.

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

Gmail soni agale <soni.agale511@gmail.com>

EFC14875_3560040_Payments release details

AhmedAziz.Khan@sanofi.com <AhmedAziz.Khan@sanofi.com> Tue, Jul 9, 2019 at 3:58 PM
To: soni.agale511@gmail.com
Cc: cdevanpally@ardent-cro.com, prashant_udgire@rediffmail.com, umarazmed@gmail.com

Dear Soni,

Please see below the NEFT details of the payments made against the invoices received. Request you to check with accounts and confirm the receipt.

PI Payment:

356040	PI Fees	MGM Medical College	29/May/2019	INR 275,011	INR 275,011	NEFT done on 3rd Jul DEUTR 920190704000000109X

EC Payment:

3560040	EC Sub for Protocol Amendment	MGM Medical College	190604AHFGN00001XXXXXXX	INR 22,223	4-Jun-19

Best regards,

Ahmed Aziz

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

MAHATMA GANDHI MISSION

Mahatma Gandhi Mission's Medical College & Hospital

N-6 CIDCO, Aurangabad - 431003

DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS

(CLINICAL RESEARCH UNIT)

Office: Dr. Deepak Bhosle, Prof & Head, Dept. of Clinical Pharmacology & Therapeutics, MGM Medical College & Hospital
N-6,CIDCO,Aurangabad – 431003. Ph. No: 0240-6601423, 0240-6601174, Email: pharmacolgy@mgmmcha.org

Date: 04 Jul 2019

To,
Dean,
MGM Medical College and Hospital.
N-6 Cidco, Aurangabad -431003.

Protocol Number: EFC14875

Protocol Title: A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Demonstrate the Effects of Sotagliflozin on Cardiovascular and Renal Events in Patients with Type 2 Diabetes, Cardiovascular Risk Factors and Moderately Impaired Renal Function

Subject: Submission of PI fees- Study Payment.

Respected Sir,

With Reference to above Subject Here by I am submitting cheque towards study payment including Institutional overhead charges.

Payment Details:

Sr.No	Payment	NEFT	Amount Rs.	TDS	Payable Amount
01	Study Payment	920190704000000109X	2,51,704.80	23,307	275,011

Kindly acknowledge the receipt of the same by signing the box below and attesting the stamp of the Ethics Committee.

With best regards,

Dr. Prashant Udgire
Principal Investigator
Mahtama Gandhi Mission's Medical College and Hospital.
N-6, Cidco .Aurangabad-431003.

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

Transactions Date from 01/08/2019 to 22/08/2019 A/c No. :0376104000000107

Sri	Txn Date	Value Date	Description	Cheque No	CR/DR	CCY	Trxn Amount	Balance
61	01/08/2019	01/08/2019	993829-SBI-SMITA JAISWAL		CR	INR	1,60,500.00	1,81,27,337.73
62	01/08/2019	01/08/2019	998676-SBI-NARSING		CR	INR	1,60,500.00	1,82,87,837.73
63	01/08/2019	01/08/2019	086726-SVC-ASHOK G		CR	INR	1,60,500.00	1,84,48,337.73
64	01/08/2019	01/08/2019	001432-UBI-RAJESH KUMAR		CR	INR	1,60,500.00	1,86,08,837.73
65	01/08/2019	01/08/2019	013304-UBI-KESHAVRA		CR	INR	1,60,500.00	1,87,69,337.73
66	01/08/2019	01/08/2019	077106-UBI-ABHAY		CR	INR	1,60,500.00	1,89,29,837.73
67	01/08/2019	01/08/2019	094448-UBI-BEENA		CR	INR	1,60,500.00	1,90,90,337.73
68	01/08/2019	01/08/2019	143997-UBI-SANJAY KUMAR		CR	INR	1,60,500.00	1,92,50,837.73
69	01/08/2019	01/08/2019	000008-YES-YES BANK		CR	INR	1,60,500.00	1,94,11,337.73
70	01/08/2019	01/08/2019	267349-YES-SUKTI SUBRATA		CR	INR	1,60,500.00	1,95,71,837.73
71	01/08/2019	01/08/2019	745333-YES-YES BANK		CR	INR	1,60,500.00	1,97,32,337.73
72	01/08/2019	01/08/2019	RTGS/HCBLR52019080100407706/PRATIT		CR	INR	10,25,000.00	2,07,57,337.73
73	01/08/2019	01/08/2019	RTGS/BKDNR52019080100391519/DAHYABH		CR	INR	5,25,000.00	2,12,82,337.73
74	01/08/2019	01/08/2019	OSR GROUP	13311	DR	INR	2,55,360.00	2,10,26,977.73
75	01/08/2019	01/08/2019	CHAIRMAN POLICE WELF	13317	DR	INR	15,100.00	2,10,11,877.73
76	01/08/2019	01/08/2019	REJECT:^674071^:^FUNDS INSUFFICIENT		DR	INR	1,60,500.00	2,08,51,377.73
77	01/08/2019	01/08/2019	REJECT:^993829^:^FUNDS INSUFFICIENT		DR	INR	1,60,500.00	2,06,90,877.73
78	01/08/2019	01/08/2019	REJECT:^79952^:^FUNDS INSUFFICIENT^		DR	INR	1,60,500.00	2,05,30,377.73
79	01/08/2019	01/08/2019	REJECT:^457302^:^FUNDS INSUFFICIENT		DR	INR	1,60,500.00	2,03,69,877.73
80	01/08/2019	01/08/2019	REJECT:^428310^:^FUNDS INSUFFICIENT		DR	INR	1,60,500.00	2,02,09,377.73
81	01/08/2019	01/08/2019	REJECT:^244188^:^FUNDS INSUFFICIENT		DR	INR	1,60,500.00	2,00,48,877.73
82	01/08/2019	01/08/2019	REJECT:^85127^:^FUNDS INSUFFICIENT^		DR	INR	1,60,500.00	1,98,88,377.73
83	01/08/2019	01/08/2019	SGST		DR	INR	2,065.00	1,98,86,312.73
84	01/08/2019	01/08/2019	INET/037610400000107To007610400069		DR	INR	50,00,000.00	1,48,86,312.73
85	01/08/2019	01/08/2019	RTGS/DEUTR92019080100000552/SANOFI-		CR	INR	3,52,300.90	1,52,38,613.63
86	02/08/2019	02/08/2019	NEFT-SBIN119214321515-Mr. JAGD		CR	INR	2,00,000.00	1,54,38,613.63
87	02/08/2019	02/08/2019	000287-BOB-GADE HOPSITAL		CR	INR	10,25,000.00	1,64,63,613.63
88	02/08/2019	02/08/2019	IPAY/INST/NEFT/225857166/0521662870		DR	INR	66,200.00	1,63,97,413.63
89	02/08/2019	02/08/2019	SHRI SAI CATERS	13318	DR	INR	1,46,387.00	1,62,51,026.63
90	02/08/2019	02/08/2019	SHRI SAI CATERS	13316	DR	INR	1,58,400.00	1,60,92,626.63
91	02/08/2019	02/08/2019	LATE RL NAGARI SAH PAT		CR	INR	10,25,000.00	1,71,17,626.63

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

MAHATMA GANDHI MISSION

Mahatma Gandhi Mission's Medical College & Hospital

N-6 CIDCO, Aurangabad - 431003

DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS
(CLINICAL RESEARCH UNIT)

Office: Dr. Deepak Bhosle, Prof & Head, Dept. of Clinical Pharmacology & Therapeutics, MGM Medical College & Hospital
N-6,CIDCO,Aurangabad – 431003. Ph. No: 0240-6601423, 0240-6601174, Email: pharmacolgy@mgmmcha.org

Date: 22 Aug 2019

To,
Dean,
MGM Medical College and Hospital.
N-6 Cidco, Aurangabad -431003.

Protocol Number: EFC14875

Protocol Title: A Randomized, Double-Blind, Placebo-controlled, Parallel-group, Multicentre Study To Demonstrate the effects of Sotagliflozin on Cardiovascular and Renal Events in Patients with Type 2 Diabetes , Cardiovascular Risk Factors and Moderately Impaired Renal Function.
Subject: Submission of Study Payment (2nd Invoice)

Respected Sir,

With Reference to above Subject Here by I am submitting cheque towards study payment including Institutional overhead charges.

Payment Details:

Sr.No	Payment	NEFT Details	Amount Rs.	TDS	Payable Amount
01	Study Payment	DEUTR920190 80100000552X	3849 21.9	32,621	352300.90

Kindly acknowledge the receipt of the same by signing the box below and attesting the stamp.

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

Gmail soni agale <soni.agale511@gmail.com>

Payment transfer details

1 message

AhmedAziz.Khan@sanofi.com <AhmedAziz.Khan@sanofi.com> Thu, Aug 22, 2019 at 2:22 PM
To: soni.agale511@gmail.com
Cc: gaurav@ardent-cro.com

Dear Soni,

Please find below the NEFT details;

UTR-DEUTR92019080100000552X

MGM Medical College

UTR-DEUTR92019080100000480X
Ardent Clinical Rese

Best regards,

Ahmed Aziz

Dr.Shashank D.Dalvi
Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI