MNR DENTAL COLLEGE AND HOSPITAL

"NAAC ACCREDITED"

(Recognized by MH&FW, Govt. of India & Affiliated to KNR University of Health Sciences)

MNR Nagar, Narsapur Road, Fasalwadi, Sangareddy 502294

CERTIFIED LIST OF GRANTS RECEIVED ALONG WITH E COPIES OF SANCTION LETTERS DURING THE ASSESSMENT PERIOD

Gmail

Vikas Sahu <sahu88vikas@gmail.com>

congratulations

6 messages

Viswanadham duppatla <viswanadham@ikpknowledgepark.com>
To: Vikas Sahu <sahu88vikas@gmail.com>

Thu, Jan 10, 2019 at 11:42 PM

Dear Vikas,

Hearty congratulations from IKP Knowledge Park upon successful selection for the BIG Grant in BIG 13 call.
IKP Team will have a detailed call to discuss further.

Now we request you to mentor at least 1 team towards applicant for BIG 14 call.
We will introduce the applicant and request your cooperation.

S. No.	11
Reference Number	BIRAC/IKP0723/BIG-13/18
Applicant Name	Vikas Sahu
PI Name	Vikas Sahu
Title of project	Handheld smart dental instrument to visualize dental pulp chamber and canal orifice" for root canal treatment."
Research Area	Healthcare-Devices and Diagnostics
ESC Recommendation	The aim of the proposal is to develop a handheld Root Canal Visualizer to improve the visualization of dental pulp chamber and canal orifice in root canal treatment. In the current proposal, the applicant intends to develop the prototype, test the prototype in pre-clinical setting using phantom head with jaw set, followed by design refinement and testing in clinical settings. The Committee ***recommended the proposal. It was suggested that during the development, the claimed product cost advantage should be retained together with reliability of the proposed solution.***
Objectives	• Prototyping and pre-clinical testing and optimization o Integrated Prototype development in consultation with engineers, designers and dentists o Integration of the design with optical sensors, CMOS and basic image processing software development o Integrated prototype developed • Prototype testing in Pre-clinical settings and design optimization o Testing of prototype in pre-clinical setting using phantom head with jaw set with atleast 3 dentists. o Further optimization of prototype with feedback from pre-clinical study. • Prototype testing in clinical setting and optimization o Prototype testing in dental clinics/dental college and hospitals (atleast 10 dentists) to get feedback from specialists o Optimization of design and software according to the feedback •
Milestone	**S. No** | Milestone | **Timelines**

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MNR MEDICAL COLLEGE & HOSPITAL
SANGAREDDY

Shilpa Medicare Limited
Ledger Account

1-Apr-2018 to 22-Aug-2023

Date	Particulars	Vch Type	Vch No.	Debit	Credit
10-3-2022	By HDFC BANK A/C # 50200007005508	Receipt	373		73,500.00
	By HDFC BANK A/C # 50200007005508	Receipt	374		4,45,116.00
					5,18,616.00
	To Closing Balance			5,18,616.00	
				5,18,616.00	5,18,616.00
1-4-2021	By Opening Balance				5,18,616.00
14-7-2022	By HDFC BANK A/C # 50200007005508	Receipt	110		2,70,192.00
3-12-2022	By HDFC BANK A/C # 50200007005508	Receipt	200		87,812.00
					8,76,620.00
	To Closing Balance			8,76,620.00	
				8,76,620.00	8,76,620.00

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AGREEMENT

THIS AGREEMENT ("Agreement") is made on this 15th day of March 2019, ("**Effective Date**") at Hyderabad by and between:

Mr.**Dr. N Vijay Kumar**, son of Mr. **M V Chalapathy**, aged about **31** years, having PAN **BAVPN7091L**, residing at **32-75/2-70A, SN 103, SainikNagar , R K Puram Post, Secunderabad,Telangan,500056**(which expression shall unless it be repugnant to the subject or context thereof, include his successors and assigns) of the ONE PART.

And

M/s. International Institute of Information Technology-Hyderabad Foundation (formerly known as Banyan Intellectual Initiatives), a Society registered under the AP Societies Registration Act, 2001 having its office at International Institute for Information Technology-Hyderabad, Gachibowli, Hyderabad – 500 032, Telangana, India (hereinafter referred to as "**PRAYAS CENTRE**"), represented by Mr. Ramesh Loganathan, Chief Operating Officer, (which expression shall unless it be repugnant to the subject or context thereof, include its successors and assigns) of the OTHER PART.

"Party" shall mean either the **PRAYASEE**or the**PRAYAS CENTRE** and "Parties" shall mean the **PRAYASEE**and the **PRAYAS CENTRE** together.

WHEREAS:

a) Department of Science and Technology (DST), has designed a program called NIDHI-PRAYAS specifically to support young innovators turn their ideas into proof-of-concepts. This support shall allow the innovators to try their ideas without fear of failure, hence allowing them to reach a stage where they have a ready product and are willing to approach incubators for commercialization.

b) PRAYAS CENTRE is a Technology Business Incubator (TBI) which has received funds from DST for disposal of the same to early stage startup companies and individual innovator to build their idea into prototype

c) The PRAYASEE is involved in the business of providing **High quality Smart Automated CPR which can over come the shot coming of manual CPR and by this we can increase the chances of survival** ("**Business**").

d) At the request of the PRAYASEE and relying on the representations and

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15/3/2019

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15/3/2019

warranties, covenants, undertakings and indemnities made by the PRAYASEE under this Agreement, PRAYAS CENTREhas agreed to provideRs. 10 Lakhs(RupeesTen Lakhs Only) as a grant to the PRAYASEE.

e) The PRAYASEE has conceived a Project entitled **Affordable High quality Automated CPR for Indian market** and submitted a proposal (hereinafter called "**the Project**") on the terms and conditions contained hereinafter in this Agreement.

f) For the abovementioned reasons, the Parties desire to enter into this Agreement to record the terms and other matters related thereto.

NOW THEREFORE THIS AGREEMENT WITNESSES AND IN CONSIDERATION OF THE PREMISES, MUTUAL PROMISES, COVENANTS, WARRANTIES SET FORTH HEREINAFTER, IT IS MUTUALLY AGREED AND DECLARED BY AND BETWEEN THE PARTIES AS UNDER:

1. **RESPONSIBILITY OF THE PRAYASEE**

(a) The PRAYASEE shall:

(i) Carry out the activities of the Project and conform to the specified objectives, outputs, milestones and targets;

(ii) Meet the resources on the Project activities to the extent as agreed to, as per details given in **Annexure-I**;

(iii) Submit the utilization certificate and statement of accounts duly audited and/or certified by a Chartered Accountant for the expenditure incurred on the Project for the half year, ending 30th September and 31st March, to IIIT-H Foundation within a month of 30th September and 31st March for respective half year;

(iv) Submit a milestones progress report to PRAYAS CENTRE as per the timeline and participate in the meetings organized by PRAYAS CENTRE to review the progress of the Project, as and when called for;

(v) Obtain all the necessary requisite approvals, clearance certificates, permissions and licenses from the Government/ local authorities for conducting its operations in connection with the Project;

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Vijay Kumar
05/3/2019

(vi) Keep the grant in a separate no-lien account in the name of the PRAYASEE with a scheduled bank, the payments from which account shall be subject to verification by PRAYAS CENTRE. It shall also obtain and furnish to PRAYAS CENTRE a letter from the said bank foregoing the right to set off or lien in respect of such account;

(vii) Utilize the amounts sanctioned by PRAYAS CENTRE for the Project only for the purposes as specified in the Project and shall not entrust the implementation of the Project to another agency or divert the grant assistance;

(viii) Abide by the decision of PRAYAS CENTRE to modify the objectives, outputs, milestones, targets, funding as also the foreclosure of the Project or of its components after mutual discussion;

(ix) Acknowledge the assistance of PRAYAS CENTRE while publishing or presenting in any manner the details of the Project, its progress or its success;

(b) The PRAYASEE warrants that:

(i) It shall obtain prior consent of PRAYAS CENTRE in writing before entering into any agreement or arrangement with any other party, national or international, on the Project having overlapping objectives or having impact on Intellectual Property for the Project duration;

(ii) It is under no contractual restrictions or legal disqualifications or other obligations which will prohibit the PRAYASEE from entering into this agreement or which will interfere with the execution of this agreement; and

(iii) Each statement and particulars herein contained n this Agreement and in the relevant and supporting documents to this Agreement are correct;

(c) The PRAYASEE acknowledges and agrees that:

(i) The duties, responsibilities and functions assigned or entrusted to it as specified in the Project document shall be deemed to be the duties, responsibilities and functions assigned and entrusted under thiis Agreement and unless for reasons beyond control under normal circumstances any

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Phone No:
Sold To/Issued To:
Karthik Koshetty
For Bhan/ID Proof:
MNR Dental college

₹ 0000100/-

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement ("Agreement"), made and effective as of the dated signature at the end of this Agreement ("04 Feb 2022"), is by and among.

"Agreement" made between

Shilpa Medicare Limited (**"Sponsor"**), having principal business address at #12-6-214/A1, Hyderabad Road, Raichur-584135, Karnataka, India.

AND

MNR Dental College and Hospital (Hereinafter referred as Institution), having principal business address at MNR Nagar, Fasalwadi, Sangareddy- 502294, Telangana, India

AND

Dr. Aditya Mohan. A, Professor, Department of Oral and Maxillofacial Surgery (Principal Investigator) having a place of business address at MNR Dental College & Hospital, MNR Nagar, Fasalwadi, Sangareddy- 502294, Telangana, India

DEFINITIONS:

"Agreement" means this agreement, including the payment provisions and budget in Attachment A, and any other attachments to this agreement. "Protocol" means the clinical protocol entitled **"AN OPEN LABEL, MULTICENTER, RANDOMIZED, PARALLEL, PLACEBO CONTROLLED, SAFETY AND EFFICACY OF TRANEXAMIC ACID SPRAY 10% w/v IN PATIENTS UNDERGOING DENTAL EXTRACTION"** as it may be modified from time to time by mutual agreement of Sponsor and Institution and approval of the institutional review board and applicable regulatory authorities.

"Study" means the clinical trial that is to be performed in accordance with this Agreement and the Protocol for purposes of gathering information about the compound/medical device identified in the Protocol.

"Sponsor Test Drug" has the meaning set forth in Section 8(b).

"Biological Sample" means (i) any material collected from a Study subject, including, without limitation, any blood, serum, urine, saliva, bone marrow or tissue sample and (ii) any tangible material isolated there from, including but not limited to any Deoxyribonucleic acid ("DNA"), Ribonucleic acid ("RNA") and other biological substances.

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PROTOCOL NUMBER:	CTS-21-005
PROTOCOL TITLE:	AN OPEN LABEL, MULTICENTER, RANDOMIZED, PARALLEL, PLACEBO CONTROLLED, SAFETY AND EFFICACY OF TRANEXAMIC ACID SPRAY 10% w/v IN PATIENTS UNDERGOING DENTAL EXTRACTION
PROTOCOL DATE:	15-12-2021
SPONSOR:	Shilpa Medicare Limited
PRINCIPAL INVESTIGATOR:	Dr. Aditya Mohan A

WHEREAS, "Shilpa Medicare Limited" Sponsor has to conduct the Study under a separate contract to protocol No "CTS-21-005" and which term shall include any amendments made to the Protocol from time to time across various countries including India. These services include contracting and conduction of study with clinical research sites;

Shilpa Medicare Limited is responsible for the selection of the principal investigator and institution to conduct the study:
Dr. Aditya Mohan A (Principal Investigator) has a place of business address at MNR Dental College & Hospital, MNR Nagar, Fasalwadi, Sangareddy- 502294, Telangana, India as the institution to conduct the study.

WHEREAS, the Institution and Principal Investigator (hereinafter, jointly, the "Site") are willing to conduct the Study and Sponsor request the Site to undertake the Study;

Hereinafter, the Institution, the Principal Investigator, and Sponsor are individually referred to as the "Party" or collectively referred to as the "Parties".

NOW THEREFORE, the undersigned parties have agreed upon the rights and obligations set forth below, which shall be apply between them in connection with the performance of the clinical study:

1. PERFORMANCE OF STUDY

a) Compliance with Laws

Institution, Investigator and their personnel including staff and/or contractual staff shall perform the Study at Institution's facility according to the Protocol and this Agreement, and shall comply with all requirements regarding the obligations of the investigator, the Declaration of Helsinki (WMA General Assembly, Fortaleza, BRAZIL, October 2013), ICMR Guidelines, Schedule Y (Drug and Cosmetics Rules 1945) USFDA guidelines and guidelines of ICH for Good Clinical Prattice set forth by applicable regulatory authorities. While exercising independent medical judgment as to the compatibility of each study subject with protocol requirements, and immediately notify the Sponsor and the relevant ethics committee of any failures to comply with the protocol
The Institution and the Investigator (to the extent that such representations, warranties and promises related to the Investigator) each represents, warrant and promises that

(i) Institution and the Investigator have, at all times during the course of the Study, the appropriate licenses, approvals and certifications necessary to safely, adequately and lawfully perform the Study in accordance with good clinical practice, CDSCO requirements and all Applicable Laws and have no notice of any investigations that would jeopardize such licenses, approvals or certifications;

(ii) None of the Institution, the Investigator, or any other person assisting in the Study has (a) any conflicting obligations, financial interest or other interest in the outcome of the Study, or (b) entered into any contract that might interfere with the performance of the Study or that might impair the acceptance of the resulting data by the CDSCO, or create a conflict of interest;

(iii) Institution and/ or Investigator is, at all times during the course of the Study, qualified by training and experience with appropriate expertise to conduct the Study;

Ethics Committee Approval

The Principal Investigator shall ensure that the Ethics Committee is registered under CDSCO as per current regulatory requirements. The Principal Investigator shall also ensure that prior to enrolling any patient in the Clinical Study, the Ethics Committee has approved in writing the conduct of Clinical Study at the Institution under the supervision of the Principal Investigator. If the Ethics Committee alters or withdraws its approval of the Clinical Study in any manner, or of the participation of the Principal Investigator or any Co-Investigators in the Clinical Study, the Principal Investigator shall promptly notify the sponsor in writing. The Principal Investigator shall comply with the terms and conditions laid down in Ethics Committee approval.

b) Informed Consent Form

(i) It is the intention of the parties that the informed consent form used by Institution with Study subjects shall be consistent in all respects with this Agreement, and Sponsor shall afford an opportunity to review the informed consent form before obtaining signed informed consent forms from any Study subjects.

(ii) The Principal Investigator shall ensure that adequate information is given to the patient (or guardian or legal representatives, if applicable) both in oral and written form in a language that the patient fully comprehends and, in a language, & manner that is non-technical.

(iii) Investigator shall ensure that, the patient's Informed Consent is signed, dated and obtained from each patient participating in this Clinical Study. The signed and dated consent must be obtained prior to the first procedure set forth in the Protocol and patients will be allowed sufficient time to decide whether or not they wish to participate.

(iv) The Principal Investigator shall keep the original Informed Consent Form in the patient's permanent records held by the Institution and hand over a copy to the patient.

(v) The Principal Investigator should make certain that the patient's information sheet and the Informed Consent Form has been approved by the Ethics Committee and they shall be furnished to the Licensing Authority appointed by the Central Government to perform the duties of the licensing authority.

c) Study Team

The Principal Investigator may appoint other individuals as Co-Investigators who are appropriate to assist in the conduct of the Clinical Study in accordance with the Protocol, provided that the

Principal Investigator shall be required to act in accordance with proper professional judgment in making all such appointments. The Principal Investigator shall be responsible for leading the team of Co-investigators, who in all respects shall be bound by the same obligations as the Principal Investigator, and the Principal Investigator shall keep informed in detail all Co-investigators about all such obligations as they may exist from time to time. The Principal Investigator may also appoint other staff such as site coordinator, phlebotomist etc. for study related activities. Further, the Principal Investigator shall be responsible for ensuring that the Co-investigator and all staff and personnel within the Institution who participate in the Clinical Study, have read and understood the Protocol and they are qualified, experienced and trained for conduct of Clinical Study.

d) <u>Use and Return of Investigational products ("Products") and Equipment</u>

(i) Sponsor or designee shall be responsible to supply "products" to Shilpa Medicare limited and to allow the completion of the study. Shilpa Medicare limited shall be responsible for shipment of sufficient products to site.

(ii) The Site shall use the Investigational products provided in connection with the Study, solely for the purpose of properly completing the Study and shall maintain the "products" in a locked, secured area at all times with a specified storage condition. Sponsor owns all Sponsor Test Drug, and comparator products.

(iii) Unused products must be returned or disposed as instructed by sponsor and must not be sold by the Institution and/or Investigator. Upon completion or termination of the Study, the Site shall return or destroy, at sponsor option, the Sponsor Test Drug, comparator products, and materials and all Confidential Information (as defined in Section 7) at Institution's sole expense.

(iv) Site shall also return any equipment provided by sponsor. The Investigator is responsible for maintenance of any equipment and sponsor will assist the Investigator in maintaining the equipment in good working order. Sponsor reserves the right to deduct from the final payment, the fair market value of any equipment not used or returned to sponsor at Site closure, or upon termination or expiration of this Agreement, or at sponsor' earlier request. In the event such deduction occurs, and thereafter Institution returns the equipment, sponsor shall pay Institution the fair market value of the returned equipment as of the date of receipt by sponsor.

(v) The Principal Investigator shall:

- not distribute the Products to any other person or entity,
- Allow access of the Products to persons within its organization having a "need to know" including but not limited to sponsor, Principle Investigator & Co-investigator.
- Use the Products only on Study Subjects under the Principal Investigator's supervision.
- Not analyze, decompose, amend or modify the properties of the products, and
- Principal Investigator and Institution shall not use the "Products" post the labeled expiration/retest date

(vi) The Institution and/or the Principal Investigator shall promptly provide to sponsor all required documentation with respect to the usage and the return of the Product. After completion or premature termination of the Clinical Study, the Institution and/or the Principal Investigator shall return unused Study Product pursuant to the procedures provided by Sponsor

e) <u>Enrollment</u>

The Principal Investigator shall not start enrolling patients prior to receiving written approval from the Ethics Committee (or equivalent) as well as written authorization from the sponsor to do so. Wherein sponsor shall inform the same to the Sponsor. The Principal Investigator shall use his best efforts to promptly enroll patients in the Clinical Study who meet the eligibility criteria set forth in the Protocol ("Study Subjects"), consistent with Standard of Care.
The Site understands and agrees that if Site has not enrolled/screened at least one (1) subject by the Key Enrollment Date then sponsor may terminate this Agreement in accordance with Section 5 of this Agreement. Sponsor has the right to limit enrollment at any time. The Institution acknowledges that if the Study is conducted by several investigators according to a single protocol at more than one Study site ("Multi-Center Study"), when the enrollment goal for the Multi-Center Study as a whole is reached, enrollment will be closed at all sites, including at the Institution, regardless of whether the Institution or any other site has reached its individual enrollment goal.

f) <u>Quality Assurance Audits, Government Inspections and Regulatory Inspections</u>

Site will permit Quality Assurance staff of sponsor to examine or audit the work performed under this Agreement during regular business hours to determine if Site is conducting the Study in accordance with the applicable regulatory requirements, provided reasonable prior written notice is given setting forth the nature and scope of the audit. Site shall immediately notify sponsor within one (1) business day of, and provide sponsor copies of, any inquiries, correspondence or communications to or from any governmental or regulatory authority relating to the Study, including, but not limited to, requests for inspection of the Site's facilities, and the Site shall permit Sponsor to attend any such inspections unless prohibited by law or regulatory authority. The Site shall provide Sponsor with any proposed communication to any governmental or regulatory authority prior to sending such communication. Sponsor shall have the right to review and approve in advance any responses to such authorities that pertain to the Study. No such response shall contain any false or misleading information with respect to the Study, the Sponsor and Test Drug, Institution and Investigator agree to assist with regulatory submissions, if necessary, subject to Sponsor paying a reasonable fee.

g) <u>Adverse Events & Compensation</u>

The Principal Investigator shall ensure that Adverse Events and, Serious Adverse Events ("AE/SAE") whether expected or unexpected are reported in writing to the Sponsor, Institution, regulatory and the Ethics Committee in a timely manner and as defined in the Protocol or equivalent. The Principal Investigator shall strictly adhere to the Applicable Laws, the current regulations of the licensing authority (DCGI), current Schedule Y (Drugs and Cosmetics Rules 1945) and provisions of ICH-GCP. The review of serious adverse events shall be undertaken by sponsor in close coordination with Principal Investigator.

"Serious" as used in this clause refers to an experience which results in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability / incapacity, or is a congenital anomaly / birth defect.

"Unexpected" as used in this clause, refers to conditions or developments not previously submitted to governmental agencies or encountered during clinical studies of the product, and

conditions or developments occurring at a rate higher than shown by information previously submitted to an agency or other governmental agencies or encountered during clinical studies of the Product or, if applicable, conditions or developments not identified in the approved Product information circular, and includes any other meaning under applicable law. In general, the AE/SAE not listed in Investigator Brochure /Protocol/Investigational Plan/Approved pack insert shall be considered as an unexpected event.

The Principal Investigator and Sponsor shall comply with the compensation requirements as per the current regulatory requirements in case of an injury occurring to the subject during the Clinical Study and shall provide free medical management as long as required or till such time it is established that the injury is not related to the Clinical Study, whichever is earlier in accordance with the applicable regulatory requirements.

h) Deviation to Protocol

The Principal Investigator shall not deviate from the approved Protocol unless patient's status deems this necessary. Any deviation and the reason(s) for such deviation to the Protocol shall be recorded and reported by the Principal Investigator to the Sponsor and to the Ethics Committee as applicable.

i) Shipping of Dangerous Goods and Infectious Materials

The shipment of dangerous goods and infectious materials (including infectious subject specimens) is subject to local, national, and international laws and regulations. Site is responsible for ensuring that each individual who packages or handles any dangerous goods or infectious materials for shipping from the Site complies with Applicable Law.

j) Survival

This Section 1 shall survive termination or expiration of the Agreement.

2. ATTENDANCE AT MEETINGS AND DISCLOSURE REQUIREMENTS

Investigator, Institution and/or Study personnel ("Permitted Attendees") may be invited to attend and participate in meetings regarding the Study, including, but not limited to, investigator, study coordinator and/or results meetings ("Study Meetings"). To the extent that Permitted Attendees attend a Study Meeting, the parties agree that there will be no additional compensation for attendance or participation at such Study Meeting. If the Investigator and/or Institution are retained by Sponsor to perform services at the meetings, the terms and obligations of such services will be subject to a separate Consulting or Professional Services Agreement.

Sponsor comply in all material respects with Applicable Law, and endorse the ethical standards. Sponsor may provide hotel accommodations, meals and transportation to and from the Study Meeting (collectively, "Accommodation"). The value of such Accommodation may be disclosed pursuant to Sponsor's state and legal reporting requirements. Sponsor will not provide Accommodation to individuals who do not attend Study Meetings or to spouses or guests of Permitted Attendees. Attendance at Study Meetings is restricted to Permitted Attendees only.

Institution and Investigator acknowledge and confirm that their attendance at a Study Meeting directly relates to their participation in the Study and is not an inducement to, or in return for, future or past prescribing, purchasing, use, preferential formulary status or dispensing of any Sponsor product.

When attending Study Meetings, Investigator and Institution, on behalf of itself and all Permitted Attendees, represent and warrant that their attendance is authorized by their employer and will not cause them to be in non-compliance with or in breach of any policy, procedure or contract of any institution or entity by which they are employed or with which they are affiliated.

3. SPONSOR TRANSPARENCY REQUIREMENTS

a) Legal Obligations

The terms of this Section are mandatory.

b) Definitions

"Healthcare Professional" or "HCP" means any person licensed to prescribe pharmaceutical products or who otherwise exercises skill or judgment or provides a service relating to the treatment or care of patients, including a Related Entity supporting the HCP (i.e., a Healthcare Organization ("HCO")). This includes, but is not limited to, physicians, physician assistants, nurse practitioners, nurses, pharmacists, hospital consultants, social workers, practice administrators, study coordinators and any other person or Related Entity performing clinical study-related procedures.

"Items of Value" means materials given to HCPs or HCOs that possess a value on the open market. Examples of Items of Value include but are not limited to, items such as: textbooks, charts, subscriptions, anatomical models, literature, brochures, and reprints.

"Payments" means all compensation, transfers of value and Items of Value provided to a HCP or HCO that are necessarily incurred or provided in the course of conducting the Study under this Agreement, which may include, but is not limited to, compensation for Study-related procedures, pass-through costs such as IRB fees and the value of Accommodations.

"Related Entity" means any entity by or in which any HCP receiving Payments is employed, has tenure, or has an ownership interest.

c) Requirements

All Payments made to the Institution and/or Investigator or, where approved by SPONSOR in writing, by the Institution and/or Investigator to a Healthcare Professionals (HCP) and Healthcare Organizations (HCO), the study budget including Principal Investigator,. Sub Investigator and coordinator grants, study assessments grant's and subject compensation must be documented in this Agreement. No Payments will be made unless such Payments are covered in this Agreement. All Payments will be made according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted and approved by sponsor. All funds paid must be in Indian currency. No Payments will be made unless it has been determined by SPONSOR that the services under this Agreement have actually been provided.

Further, Institution and Investigator acknowledge and agree that sponsor is required to maintain a business rationale and justification for all Payments to an HCP/HCO, including justification from the Institution and/or Investigator for proposed changes, if any, to the budget attached hereto. Such justification shall be maintained by the site for the length of time required to retain Study Documentation in this Agreement. Likewise, sponsor will maintain and archive such site justification.

4. **PAYMENTS**

In consideration for the performance of the Study by Site, Payments shall be made between Sponsor to site in accordance with the provisions set forth in Attachment A, with the last Payment being made after the Site completes all its obligations hereunder, and sponsor has received all completed CRFs and, if sponsor requests, all other Confidential Information (as defined in Section 7). The Budget and Payment Schedule attached hereto as Attachment A by sponsor to site represents the total funding amount for the Site's conduct of the Study hereunder and no other Payments will be made unless otherwise agreed by the Sponsor set forth in an amendment to this Agreement. Any amounts paid by sponsor to the Institution under this Agreement for services that have not been performed or expenses that have not been incurred shall promptly be refunded by institution/ principal investigator to sponsor upon the expiration or termination of this Agreement or earlier at the request of sponsor.

5. **TERM AND TERMINATION**

a) **Term**

This Agreement will become effective on the date on which it is last signed by the parties (the "Effective Date") and shall continue until the later of (i) the fifth anniversary of the Effective date or, (ii) completion of all outstanding study related services, or until terminated in accordance with this Section 5.

b) **Termination**

The Study may be terminated or suspended by Sponsor, or the Site immediately upon written notice to the others for safety concerns or as otherwise required by Applicable Laws, or to the extent that a party is declared insolvent or has an administrator or receiver appointed to oversee all or part of its assets or cease or threatens to cease to carry on its business. The Sponsor has reserved the right to terminate the study at any time for any reason. Accordingly, the Sponsor hereby reserves the right to terminate this agreement at any time on written notice to the investigator. The Sponsor has reserved the right to terminate this agreement on written notice to the investigator for the following reasons (i) the investigator has not included into the study at least 1 subject meeting inclusion/exclusion criteria defined in the protocol, before the end of the enrollment period (ii) The Investigator becomes no longer affiliated with the institution (iii) Investigator fails to adhere to the conditions of the protocol (iv) overall study enrolment has been met, even if the investigator's enrolment has not been completed. (v) If Sponsor makes changes to the Study that are not required by Applicable Laws and not agreed to by the Site and such changes materially increase the cost of performance of the Study by the Site.

Upon receipt of notice of termination, the Site shall immediately cease any subject recruitment and enrollment, follow the specified termination procedures, ensure that any required subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs, and the parties shall use their best efforts to minimize any inconvenience or harm to any subjects

in the Study. SPONSOR shall make a final payment for visits or milestones properly performed pursuant to this Agreement in the amounts specified in Attachment A; provided, however, that ten percent (10%) of this final payment will be withheld until final acceptance by SPONSOR of all subject case report form ("CRF") pages and all data clarifications issued and satisfaction of all other applicable conditions set forth in this Agreement. If a material breach of this Agreement appears to have occurred and termination may be required, then, except to the extent that subject safety may be jeopardized, SPONSOR may suspend performance of all or part of this Agreement, including, but not limited to, subject enrollment.

The Institution and/or the Principal Investigator shall notify the SPONSOR if the Principal Investigator ceases to be associated with the Institution where the Clinical Trial will be conducted or if he/she is otherwise unavailable to continue as Principal Investigator, and Institution and/or Principal Investigator shall use all reasonable endeavors to find a qualified successor acceptable to the SPONSOR, subject to the Principal Investigator's overriding obligations in relation to Clinical Trial Subjects and individual patient care. In the event Principal Investigator is for whatever reason unable or unwilling to appoint a successor personally, the Institution will have the right to recommend a suitable successor. SPONSOR is responsible to the share the information to Sponsor.

The site has to share a written prior intimation to SPONSOR and Sponsor, if any change in principal investigator and/or institution during clinical study and/or after the completion of study until the regulatory approval of the particular project.

SPONSOR will be responsible to comply the protocol and for any failures that may impact the study outcome.

6. DATA

a) Definitions

For purposes of this Agreement, the term "Medical Records" means the medical records of Study subjects in connection with the Study, including, without limitation, treatment entries, x-rays, biopsy reports, ultrasound photographs and other diagnostic images. The term "Study Documentation" means all records, accounts, notes, data and reports, and Medical Records collected, used or created pursuant to or prepared in connection with the Study, whether in written, electronic, optical or other form including, without limitation, all recorded original observations and notations of clinical activities necessary for the evaluation and reconstruction of the Study (e.g., case report forms, any data summaries, any interim reports and the final report) and required to be delivered to Sponsor pursuant to the Protocol, and all records regarding inventories and dispositions of all Sponsor Test Drug.

b) Collection and Storage

Institution and Investigator shall ensure the prompt, complete, and accurate collection, recording and classification of the Medical Records and Study Documentation. Institution and Investigator shall (i) maintain and store Medical Records and Study Documentation in a secure manner with physical and electronic access restrictions, and environmental controls appropriate to the applicable data type and in accordance with Applicable Law and industry standards; and (ii)

protect the Medical Records and Study Documentation from unauthorized use, access, duplication, disclosure, loss and damage.

c) **Retention and Destruction**

Institution and Investigator shall maintain all Medical Records and Study Documentation for as long as required by Applicable Law but in no event less than fifteen (15) years from completion or early termination of the Study unless otherwise agreed by Sponsor. Neither Institution nor Investigator shall destroy or permit the destruction of any Medical Records or Study Documentation without prior written approval of Sponsor, and Institution and Investigator shall continue to store Medical Records and Study Documentation, at the Sponsor's expense, for any period that the Sponsor may request in writing after retention is no longer required by any Applicable Law.

d) **Ownership**

Institution, on behalf of itself and its personnel, hereby assigns to Sponsor all of its respective rights, title and interest, including intellectual property rights, in and to Study Documentation, other than Medical Records, which shall remain the property of Institution, in accordance with Section 8 below.

e) **Access and Use**

Site shall provide copies of all Study Documentation to SPONSOR. Institution and Investigator shall afford Sponsor and their designee's reasonable access to their respective facilities and to Medical Records so as to permit Sponsor and SPONSOR and their designees to monitor the Study. Institution and Investigator shall, upon request, afford regulatory authorities' reasonable access to their respective facilities and to Medical Records and Study Documentation, and the right to copy Medical Records and Study Documentation.

f) **Survival**

This Section 6 shall survive termination or expiration of this Agreement.

7. CONFIDENTIALITY

a) **Definition**

"Confidential Information" means any data and information related to the terms of this Agreement, the Study, including without limitation, the Sponsor Test Drug and Study Documentation, all Background Intellectual Property (as defined in Section 8), Sponsor Intellectual Property and Institution Intellectual Property (as defined in Section 8), that is provided by either party or otherwise developed or generated in connection with the discussions and negotiations pertaining to, or in the course of performing, this Agreement.

b) **Obligations**

SPONSOR, Site and its personnel shall keep Confidential Information strictly confidential. SPONSOR, Site and its personnel shall not (i) use Confidential Information for any purpose other than the performance of the Study or (ii) disclose Confidential Information to any third party without the prior express written consent of SPONSOR or the Sponsor. SPONSOR and Site agrees to limit dissemination of Confidential Information to only those SPONSOR and Site personnel having a "need to know" such information for the conduct of the Study and who are bound by

confidentiality obligations at least as stringent as those contained herein. The parties agree to maintain the Confidential Information in a secure facility, taking commercially reasonable steps to protect the information from unauthorized use, access and disclosure.

Information will not be considered Confidential Information nor subject to this Agreement if: (a) it is or comes into the public domain without breach of this Agreement, (b) it is received by Site from a third party without any obligation of confidentiality and without breach of this Agreement, or (c) Site can prove it was already in its possession without any limitation on use or disclosure prior to the Effective Date. For the avoidance of doubt, in the event that Sponsor lists or discloses any information relating to the Sponsor Test Drug or the Study in a clinical trial registry (ies) or clinical results database(s), any aspects or details of Confidential Information concerning the Sponsor Test Drug or the Study that are not listed or disclosed in such registry (ies) or database(s) shall not be deemed to be or become part of the public domain.

This Agreement shall not restrict Site from complying with a lawfully issued governmental order or legal requirement to produce or disclose Confidential Information; provided, however, that Site shall promptly notify SPONSOR and Sponsor to enable Sponsor to oppose the order or obtain a protective order and Site shall cooperate fully with Sponsor in any such proceeding. If Site is legally required to disclose Confidential Information, Site and Sponsor will endeavor to agree to a mutually satisfactory means to disclose such information. Nothing contained herein shall prohibit Site from immediately disclosing results of the Study to the extent necessary to prevent or mitigate a serious health hazard; provided, however, that Site shall notify SPONSOR and Sponsor prior to making such a disclosure and immediately after it has made such a disclosure.

The Institution and the Investigator agree that, except as expressly permitted under this Agreement, they shall not discuss the Study or the Sponsor Test Drug with any person for any reason and shall not express any opinion that is informed, in whole or in part, whether directly or indirectly, by access to the Confidential Information. For the avoidance of doubt, neither the Institution nor the Investigator shall discuss the Study or the Sponsor Test Drug with any financial, securities or industry analyst or with the press or media.

c) **Return or Destruction**

Upon termination of this Agreement or upon any earlier written request by Sponsor at any time, Institution and Investigator shall return to Sponsor, or destroy, at SPONSOR' and/or Sponsor's option, all Confidential Information other than Study Documentation. Site shall have the right to retain, subject to the terms of this Agreement, a copy of such Confidential Information in accordance with Site's legal and audit requirements.

d) **Use of Name**

No party hereto shall use any other party's name, or Sponsor's name, in connection with any advertising, publication or promotion without prior written permission, except that the Sponsor and SPONSOR may use the Site's name in Study publications and communications, including clinical trial web sites and Study newsletters, and as stated in Section 14 of the Agreement.

e) **Survival**

This Section 7 shall survive termination or expiration of this Agreement for a period of ten (10) years thereafter.

8. INTELLECTUAL PROPERTY

a) Ownership

SPONSOR and Institution shall, and shall cause its personnel and/or the Principal Investigator, to make prompt and full disclosure to Sponsor of all Sponsor Intellectual Property (as defined below). Institution agrees that Sponsor shall own all rights and title in and to all Sponsor Intellectual Property. SPONSOR and Institution hereby assigns and transfers, and shall cause its personnel and/or the Principal Investigator to assign and transfer, without additional consideration, to Sponsor (or its nominated designee) all their rights and title in and to the Sponsor Intellectual Property throughout the world. Sponsor hereby grants Institution a non-exclusive, perpetual, royalty-free license, without the right to use the Study Documentation and know-how generated in the performance of this Agreement for its own (i) internal research and/or (ii) educational purposes and/or (iii) subject care purposes, provided that the restrictions with regards to Confidential Information and publication as set forth in Sections 7 and 9 are observed and adhered to. For the avoidance of doubt this grant does not include any rights to use Sponsor Test Drug Inventions. The terms used in this section are defined in Section 8(b).

b) Definitions

"Sponsor Intellectual Property" means Study Documentation (excluding Medical Records) and all Intellectual Property in and to any Sponsor Test Drug Invention.

"Sponsor Test Drug" means the Sponsor medicinal product being studied or tested in the Study.

"Sponsor Test Drug Invention" means all inventions relating to the Sponsor Test Drug including, without limitation, new indications or uses thereof, that are conceived, generated or otherwise made by the Institution, its personnel or the Investigator (other than Sponsor) whether solely or jointly with others, under or in connection with the Study. For the avoidance of doubt, Sponsor Test Drug Inventions also include any inventions relating (a) to the Sponsor Test Drug's metabolic activity, pharmacological activity, side effects, drug metabolism, mechanism of action, safety, or drug interactions, or (b) to biomarkers, assays, diagnostic methods or diagnostic products, which may be used to predict patient response or resistance to the Sponsor Test Drug or be used in any way to select patients for treatment with the Sponsor Test Drug.

"Background Intellectual Property" means any Intellectual Property that was owned or controlled, directly or indirectly, by a party prior to the Effective Date.

"Intellectual Property" means any and all rights in and to ideas, formula, trade secrets, inventions, discoveries, know-how, data, databases, documentation, reports, materials, writings, designs, computer software, processes, principles, methods, techniques and other information, including patents, trade-marks, service marks, trade names, registered designs, design rights, copyrights and any rights or property similar to any of the foregoing in any part of the world, whether registered, or not, together with the right to apply for the registration of any such rights.

"Institution Intellectual Property" means all Intellectual Property other than the Sponsor Intellectual Property that is conceived, generated or otherwise made by the Institution, its personnel and/or the Investigator (other than Sponsor) under or in connection with the Study.

c) **Site Cooperation**

Upon the request and at the sole expense and exclusive control of Sponsor, Institution shall, and shall cause its personnel and/or the Investigator to, apply for or to join with Sponsor (or its designee) in executing and delivering any and all instruments necessary or reasonably useful to enable Sponsor (or its designee) to apply for patents (and to obtain any patent term extension, supplementary protection certificate, divisional, validation, reissue, continuance or renewal), like privilege or any other protection on any of the Sponsor Intellectual Property anywhere in the world, as Sponsor (or its designee) may in its discretion determine. Institution shall, and shall cause its personnel and/or the Investigator to, execute or cause to be executed, all papers necessary to affect the foregoing, including assignments to Sponsor (or its designee) as necessary or useful to vest all rights in and to the Sponsor Intellectual Property in Sponsor, without additional consideration.

d) **Institution Intellectual Property**

Institution shall, and shall cause its personnel and/or the Investigator to, make prompt and full disclosure to Sponsor of all Institution Intellectual Property. Institution shall own all rights and title in and to all Institution Intellectual Property. Institution hereby grants to Sponsor a non-exclusive, world-wide, perpetual, royalty-free license, with the right to grant sub-licenses, to use the Institution Intellectual Property for any purpose.

e) **Background Intellectual Property**

Each party shall retain all rights in its respective Background Intellectual Property. This Agreement is not intended to and shall not infer any license grant or assignment, whether expressed or implied, with regard to such Background Intellectual Property. Notwithstanding the foregoing, the SPONSOR or Institution or Principal Investigator hereby grants to Sponsor a perpetual, worldwide, non-exclusive, royalty-free license, with the right to grant sub-license, to use the Institution's Background Intellectual Property to the extent required to use and exploit the Sponsor Test Drug and the Sponsor Intellectual Property and the license grant under Section 8(d).

f) **Government-funded Activities**

The Institution and Investigator acknowledge and agree that the activities they are to conduct under this Agreement will fall outside the scope of their planned and committed activities under any government-funded projects they have undertaken ("Government-funded Activities") and will not diminish or distract from their performance of Government-funded Activities. In the event that any Sponsor Test Drug Invention made hereunder is determined to have been conceived or first reduced to practice in the performance of Government-funded Activities, the Institution and the Investigator agree to take all steps reasonably necessary in order to obtain for Sponsor, to the maximum extent possible, the rights in such Sponsor Test Drug Invention contemplated by this Section 8 (without limitation of any other remedies available to Sponsor hereunder or under Applicable Laws).

g) **Survival**

This Section 8 shall survive termination or expiration of this Agreement.

9. PUBLICATION RIGHTS

a) **Publication and Use of Study Data**

Sponsor is committed to communicate information related to research and development in an accurate and objective fashion. These communication activities must be undertaken in a responsible and ethical manner, considering relevant external standards regarding the manner and content of scientific, technical and medical publications.

In the exercise of the rights of academic freedom, the Institution and the Investigator (but no other Study Site staff) shall, notwithstanding Section 7 above but subject to this Section 9, have the right to publish in scientific or other journals, or to present at professional conferences or other meetings the data contained within the Study Documentation from the Study Site (the "Site Data") and analyses of results from other sites participating in the Multi-Center Study (collectively "Multi-Center Study Results") solely for the purpose of the license granted under Section 8(a) above.

b) **Disclosure and Conflict of Interest**

SPONSOR and Site agrees that any author of a biomedical manuscript shall (i) fully comply with any ICMJE criteria regarding authorship and disclosure of any relationship with Sponsor and any potential conflicts of interest, including any financial or personal relationships that might be perceived to bias the author's work, (ii) disclose in any manuscript, journal submission or elsewhere as appropriate or required, any potential conflict of interest, including any financial or personal relationship with Sponsor, the names of any individuals who have provided editorial support for any manuscript or publication, and all funding sources for the study or publication; and (iii) provide any additional disclosure required by any medical or scientific institution, medical committee or other medical or scientific organization with which the author is affiliated.

The relationships between the author and Sponsor or any Sponsor affiliate, identification of all authors or contributors (including professional writers) associated with a publication, and the scope and breadth or research results made available to each author or contributor, must be subject to a separate agreement and must be disclosed in accordance with the terms of such agreement.

c) **Publication Procedures**

At least sixty (60) days prior to submission of any material for publication or presentation, SPONSOR or Institution shall provide Sponsor with such material for review. No such publication or presentation may include any Confidential Information without Sponsor's prior written approval. If requested in writing by Sponsor, SPONSOR and Institution shall withhold, or shall cause the Investigator to withhold, material from submission for publication or presentation to allow for the filing of a patent application or the taking of such measures as Sponsor deems appropriate to establish and preserve its proprietary rights in the material being submitted for publication or presentation.

Sponsor and its affiliates shall have the right to independently publish the Study, and provided that due acknowledgment is made for the intellectual contribution made by the Institution and the Investigator, in accordance with standard scientific practice.

d) **Multi-Center Publications**

SPONSOR or/and the Institution shall not externally publish or present any Multi-Center Study Results (defined in Section 9(a) above) until the earlier of (i) the date of the first Study results publication, or in case of a Multi-Center Study the first publication authorized by Sponsor; or (ii) the end of the eighteen (18) month period following the completion, or early termination, of the Multi-Center Study at all participating sites. Neither before nor after such date may the Institution or the Investigator publish or present any raw data (as distinguished from the results of any analyses of raw data) or make any publication or presentation that is false, misleading, and inconsistent with academic standards or for commercial purposes.

e) **Media Contacts**

SPONSOR or Institution shall not, and shall ensure that its personnel, including Investigator, do not, engage in interviews or other contacts with the media, including but not limited to newspapers, radio, television and the Internet, related to the Study, the Sponsor Test Drug, Inventions, or Study Documentation without the prior written consent of Sponsor. This provision does not prohibit publication or presentation of Study Documentation in accordance with Sections 9(a) and 9(c) above.

f) **Registry and Reporting**

Without limitation to any other right of Sponsor hereunder, the Institution and the Investigator acknowledge and agree that Sponsor may register the Study and, when available, post the Multi-Center Study Results in accordance with Sponsor internal policy on one or more publicly-accessible trial registries and websites (e.g., the publicly-funded website ctri.nic.in). The Institution and the Investigator should not undertake registration or posting of results to avoid duplication of entries. Sponsor personnel must comply with local/national law and/or regulations which require registration of study information to a publicly-accessible registry other than those named above. Where the Institution and the Investigator wish to use a publicly-accessible website on a voluntary basis (e.g. a university/hospital website) the information related to the Protocol must not exceed the information Sponsor has already posted and it should be sufficient to provide a hyperlink to the trial when registered on www.ctri.nic.in

g) **Survival**

This Section 9 shall survive termination or expiration of this Agreement.

10. SUBJECT INJURY

a) **Notification**

Sponsor shall reimburse Institution for all reasonable and necessary medical expenses for the diagnosis, care and treatment of any injury to a Study patient directly resulting from Study patient's participating in the Study ("Subject Injury"); provided, however, that: (a) the Subject Injury or illness was not caused by Investigator/Institution's deviation from the Protocol,

Applicable Law, or other written instructions provided by SPONSOR/SPONSOR (except for medically necessary deviations); (b) the Subject Injury or illness was not caused by the negligence or misconduct of the SITE and/or SITE staff; (c) the Subject injury or illness is not attributable to the natural progression of any underlying illness, any pre-existing abnormal medical condition or underlying disease of the Study patient, or treatment that would have been provided to the Study patient in the ordinary course of treatment notwithstanding participation in the Study; (d) the injury or illness was not covered by the Study patient's medical or hospital insurance, or any similar third-party payer providing such medical or hospital coverage; (e) the Subject injury or illness was not directly attributable to a failure of the SITE any of its personnel conducting the Study to adhere to the terms of the Protocol, directions of the SPONSOR and/or SPONSOR, or Applicable Law pertaining to the administration of the Study; (f) the injury or illness is not attributable to the Study patient's deviation from the reasonable direction of SITE, Study personnel or the Study patient's physician.

b) Survival

This Section 10 shall survive termination or expiration of this Agreement.

11. INDEMNIFICATION

a) By Institution or Principal Investigator

The Site shall defend, indemnify and hold harmless SPONSOR, Sponsor and their respective affiliates, officers, directors, partners, employees and agents (collectively, the "Indemnified Parties") from and against any liability, claim, loss, damages and expense (including lawyers' fees and costs of suit) incurred by them in connection with any and all third party suits, investigations, claims or demands to the extent caused by or arising out of the negligence or willful misconduct of, or a breach of this Agreement by, Site or its trustees, directors or personnel (including Investigator), including the negligence or willful misconduct of the Institution, the Investigator or any other person who assists in conducting the Study, in performing their obligations under this Agreement or the failure of the Institution, the Investigator or any other person who assists in conducting the Study, to comply with the provisions of this Agreement, the Protocol or any written instructions of Sponsor or SPONSOR concerning the Study.

b) Indemnification by SPONSOR

The SPONSOR shall defend, indemnify and hold harmless Sponsor, and their respective affiliates, officers, directors, partners, employees and agents (collectively, the "Indemnified Parties") from and against any liability, claim, loss, damages and expense (including lawyers' fees and costs of suit) incurred by them in connection with any and all third party suits, investigations, claims or demands to the extent caused by or arising out of the negligence or willful misconduct of, or a breach of this Agreement by, Site or its trustees, directors or personnel (including Investigator), including the negligence or willful misconduct of the Institution, the Investigator or any other person who assists in conducting the Study, in performing their obligations under this Agreement or the failure of the Institution, the Investigator or any other person who assists in conducting the Study, to comply with the provisions of this Agreement, the Protocol or any written instructions of Sponsor or SPONSOR concerning the Study

c) Insurance

SPONSOR shall maintain all adequate insurance coverage, including a (i) professional liability insurance, (ii) indemnity insurance covering SPONSOR, the PI and the Site, (iii) human clinical trial insurance covering SPONSOR, the PI and the Site during the Term: Institution will provide evidence of all such coverage upon request. Institution will notify SPONSOR within 20 (twenty) days of any notice of cancellation, non-renewal, or material change in its insurance coverage.

d) Survival

This Section 11 shall survive termination or expiration of this Agreement.

12. SPONSOR DISCLAIMER

SPONSOR DOES HEREBY DISCLAIM ANY AND ALL REPRESENTATIONS AND WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, WITH RESPECT TO THE SPONSOR TEST DRUG, INCLUDING ANY REPRESENTATION OR WARRANTY OF QUALITY, PERFORMANCE, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE, OR THAT THE USE OF THE SPONSOR TEST DRUG FOR PURPOSES OTHER THAN SPECIFIED IN THIS AGREEMENT WILL NOT INFRINGE THE RIGHTS, PATENT OR OTHERWISE, OF ANY THIRD PARTY. FURTHER, SPONSOR EXPRESSLY DISCLAIMS ANY LIABILITY IN CONNECTION WITH THE SPONSOR TEST DRUG, INCLUDING ANY LIABILITY FOR ANY PRODUCT CLAIM ARISING OUT OF A CONDITION CAUSED BY OR ALLEGEDLY CAUSED BY THE ADMINISTRATION OF SUCH PRODUCT EXCEPT TO THE EXTENT THAT SUCH LIABILITY IS CAUSED BY THE NEGLIGENCE, WILLFUL MISCONDUCT OR BREACH OF THIS AGREEMENT BY SPONSOR. THIS SECTION 12 SHALL SURVIVE TERMINATION OR EXPIRATION OF THIS AGREEMENT.

13. CONSEQUENTIAL DAMAGES

Neither SPONSOR nor Sponsor shall be responsible to the Site for any lost profits, lost opportunities, or other consequential damages, nor shall Site be responsible to SPONSOR or Sponsor for any lost profits, lost opportunities, or other consequential damages.

14. PERSONAL DATA

Both prior to and during the course of the Study, the Investigator and his/her teams may be called upon to provide Personal Data (as defined below). This data falls within the scope of the law and regulations relating to the protection of Personal Data. For the Investigator and his or her teams, this Personal Data may include names, contact information, work experience and professional qualifications, publications, resumes, and educational background for the following purposes: (i) the conduct of clinical trials, (ii) verification by governmental or regulatory agencies, the Sponsor, SPONSOR, their agents and affiliates, (iii) compliance with legal and regulatory requirements, (iv) publication on www.ctri.nic.in and websites and databases that serve a comparable purpose; Each party shall be responsible for its own processing of Personal Data and shall ensure that any Personal Data relating to a subject, the Investigator and/or the Study staff, is collected, stored, used, disclosed and transferred in accordance with all applicable national, federal, state, or local privacy laws and with the informed consents that are or will be obtained from subjects. As set forth in Section 9(e), the Investigator shall be responsible for obtaining and providing Sponsor and SPONSOR with consents from each Study staff for the collection, use and disclosure of their Personal Data. "**Personal Data**" means any information and data that is directly or indirectly referable to a human being.

15. DEBARMENT

Debarment and Exclusion: Institution and Principal Investigator certify that they are not debarred or restricted from conducting clinical research and will not use in any capacity the services of any person debarred or restricted from conducting clinical research under applicable law with respect to services to be performed under this Agreement. Institution and Principal Investigator further certify that they are not subject to a government mandated corporate integrity agreement and have not violated any applicable anti-kickback or false claims laws or regulations. During the term of this Agreement and for three (3) years after its termination, Principal Investigator and Institution will notify SPONSOR promptly in writing to the extent possible within two (2) business days if either of this certification needs to be amended in material issues related to the medical licensure of any associated researchers. Institution and Principal Investigator will cooperate with SPONSOR and /or Sponsor regarding any responsive action necessary. This Section 15 shall survive termination or expiration of this Agreement.

16. FINANCIAL DISCLOSURE

Site agrees that if SPONSOR or Sponsor provide financial disclosure forms to the Site pursuant to Sponsor's Indian regulatory obligations, then the Site will, for each listed or identified Investigator or sub-investigator who is directly involved in the treatment or evaluation of research subjects, promptly return to SPONSOR a financial disclosure form that has been completed and signed by such Investigator or sub-investigator, which shall disclose any applicable interests held by those Investigators or sub-investigators or their spouses or dependent children. Site agrees that SPONSOR may withhold payments if it does not receive a completed form from each such Investigator and sub-investigator. Site shall ensure that all such forms are promptly updated as needed to maintain their accuracy and completeness during the Study and for one (1) year after its completion. Site acknowledges that the completed forms may be subject to review by governmental or regulatory agencies, Sponsor, SPONSOR, and their agents, and the Institution and Investigator consent to such review.

17. ANTI KICKBACK AND ANTI FRAUD

Institution and Investigator agree that their judgment with respect to the advice and care of each Study subject will not be affected by the compensation received from this Agreement, that such compensation does not exceed the fair market value of the services that are being provided, and that no payments are being made for the purpose of inducing Institution or Investigator to purchase or prescribe any drugs, devices or products. If Sponsor or SPONSOR provides any free products or items for use in the Study, Institution and Investigator agree that they will not bill any Study subject, insurer or governmental agency, or any other third party, for such free products or items. Institution and Investigator agree that they will not bill any Study subject, insurer, or governmental agency for any visits, services or expenses incurred during the Study for which they have received compensation from SPONSOR or Sponsor, or which are not part of the ordinary care they would normally provide for the Study subject, and that neither Institution nor Investigator will pay another physician to refer subjects to the Study.

If during the term of this Agreement or within two (2) years of the termination of this Agreement, the Investigator is a member of a committee that sets formularies or develops clinical guidelines, the Investigator warrants that he/she will disclose to such committee the existence and nature of this Agreement and will follow the procedures set forth by the committee. Investigator further agrees

to fully comply with all applicable disclosure obligations relating to Investigator's relationship with Sponsor that may be externally imposed on Investigator based on the requirements of any institution, medical committee or other medical or scientific organization with which Investigator is affiliated.

18. ANTI BRIBERY

Institution and Investigator agree that the fees to be paid pursuant to this Agreement represent fair compensation for the services to be provided by Site. Institution and Investigator represent and warrant that payments received pursuant to this Agreement will not influence any decision that Institution, Investigator or any of their respective owners, directors, employees, agents, consultants, or any payee under this Agreement may make, as a government official or otherwise, in order to assist Sponsor or SPONSOR to secure an improper advantage or obtain or retain business.

Institution and Investigator further represent and warrant that neither they nor any of their respective owners, directors, employees, agents, or consultants, nor any payee under this agreement, will, in order to assist Sponsor or SPONSOR to secure an improper advantage or obtain or retain business, directly or indirectly pay, offer or promise to pay, or give anything of value to any person or entity for purposes of (i) influencing any act or decision, (ii) inducing such person or entity to do or omit to do any act in violation of their lawful duty; (iii) securing any improper advantage; or (iv) inducing such person or entity to use influence with the government or instrumentality thereof to affect or influence any act or decision of the government or instrumentality.

In addition to other rights or remedies under this Agreement or at law, SPONSOR may terminate this Agreement if Site breaches any of the representations or warranties contained in this Section or if SPONSOR or Sponsor learns that improper payments are being or have been made to or by Institution or Investigator or any individual or entity acting on its or their behalf.

19. INDEPENDENT CONTRACTORS

The Investigator and Institution and their staff are acting as independent contractors of SPONSOR and Sponsor and shall not be considered the employees or agents of SPONSOR or Sponsor. Neither SPONSOR nor Sponsor shall be responsible for any employee benefits, pensions, workers' compensation, withholding, or employment-related taxes as to the Investigator or Institution or their staff.

20. ENTIRE AGREEMENT

This Agreement constitutes the sole and complete agreement between the parties and replaces all other written and oral agreements relating to the Study. No amendments or modifications to this Agreement shall be valid unless in writing and signed by all the parties.

21. ORDER OF PRECEDENCE

In the event of any inconsistency between this Agreement and the Protocol, this Agreement shall govern and control as to any legal issue, and the Protocol shall govern and control as to the conduct of the Study and any issue regarding treatment of Study subjects.

22. NO WAIVER

Failure to enforce any term of this Agreement shall not constitute a waiver of such term. If any part of this Agreement is found to be unenforceable, the rest of this Agreement will remain in effect. This Agreement shall be binding upon the parties and their successors and assigns.

23. ASSIGNMENT

The SPONSOR or Site shall not assign or transfer any rights or obligations under this Agreement without the written consent of SPONSOR. Upon Sponsor's request, SPONSOR may assign this Agreement to Sponsor or to a third party, and SPONSOR shall not be responsible for any obligations or liabilities under this Agreement that arise after the date of the assignment, and the Site hereby consents to such an assignment. Site will be given prompt notice of such assignment by the assignee.

24. THIRD PARTY BENEFICIARY

The parties agree that Sponsor and its affiliates shall have an independent right to enforce any of the provisions of this Agreement as third party beneficiaries. Each party to this Agreement acknowledges that except for the Sponsor and its affiliates, there are no third party beneficiaries with any rights to enforce any of the provisions of this Agreement.

25. BUSINESS COMMUNICATIONS

The Institution and the Investigator consent to receive communications sent by or on behalf of SPONSOR or Sponsor via mail, e-mail at the Investigator and the Institution's mailing address, e-mail address number provided by the Study Site to SPONSOR.

26. CHOICE OF 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 of Hyderabad Jurisdification, Telangana, India. 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.

27. Concluding Conditions:

This Agreement is signed in three copies one for the SPONSOR, one for the Institution and one for the Investigator, all three copies being authentic and having the same force.

If there is any discrepancy or conflict between the terms contained in the Protocol and this Agreement the Protocol shall govern and control with respect to clinical matters and the terms of this Agreement shall govern and control with respect to all other matters.
This Agreement sets forth the entire understanding between the Parties with respect to the Study and supersedes all prior arrangements.

All notices necessary or appropriate to be given pursuant to this Agreement shall be effective when personally delivered, faxed with a confirmation of receipt, or sent by registered post, certified, to the appropriate Party at the address / number indicated in Section 27 "Addresses of the Parties".

Either Party may change its address, number or banking details by giving notice in accordance with this paragraph.

No change to the originally agreed wording of the Agreement, except changes valid upon giving of the written notice by the Party according to this Agreement, shall be valid unless agreed in writing and signed and dated by all three Parties.

All attachments to the Agreement and future amendments (if any) are an integral part of this Agreement.

If any provision(s) of this Agreement should be illegal or unenforceable in any respect, the legality and enforceability of the remaining provisions of this Agreement shall not in any way be affected.

If either Party fails to fulfill or properly fulfill its obligations under this Agreement, the defaulting Party shall indemnify the other Party for all damages in accordance with the laws of India. The Party, which failed to fulfill or properly fulfill its obligations under this Agreement, shall have to prove that such failure was not due to its willful act or negligence.

The Parties agree that the Sponsor may enforce its rights hereunder as a third party beneficiary. In the event that the Sponsor is not able to do so for any reason, Investigator agrees that SPONSOR may have the benefit of the Sponsor's rights hereunder (including without limitation those rights concerning publication, confidentiality and intellectual property) and may transfer such rights and benefits to the Sponsor.

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

To INSTITUTION:
MNR Dental College & Hospital, Sangareddy
Telangana- 502294

To SPONSOR:
Shilpa Medicare Private Limited
#12-6-214/A1, Hyderabad Road,
Raichur-584135, Karnataka, India.

or to such other address for either Party as is subsequently specified in writing.

28. Joint and Several Liability of SPONSOR, Principal Investigator and Institute

Notwithstanding anything in this Agreement or any Protocol or any other document; the SPONSOR, Principal Investigator and Institute shall be jointly and severally liable for their acts or omissions or obligations under this Agreement to Sponsor. Sponsor may take action against, or release or compromise the liability of either SPONSOR or Principal Investigator or Institute without affecting the liability of the other.

29. SURVIVAL OF PROVISIONS

The terms of this Agreement that contain obligations or rights that extend beyond the completion of the Study shall survive termination or completion of this Agreement, even if not expressly stated herein.

ACKNOWLEDGED AND AGREED BY SPONSOR

Name: P. Veerendra Kumar

Title: Head- Clinical Affairs Division

Position: Deputy General Manager

Signature & Date: 05/02/2022

ACKNOWLEDGED AND AGREED BY INVESTIGATOR

Name: Dr. Aditya Mohan A

Title: Principal Investigator

Signature & Date: 08/02/2022

ACKNOWLEDGED AND AGREED BY THE INSTITUTION

Name: Dr. Ravindra SV

Title: Principal

Signature & Date: 08/02/2022

PRINCIPAL
MNR Dental College & Hospital
MNR Nagar, Narsapur Road.
SANGAREDDY Dist. - 502 294 (T.S.)

ATTACHMENT A
BUDGET & PAYMENT SCHEDULE

A. PAYEE DETAILS

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

PAYEE NAME: *PLEASE NOTE: THIS SHOULD BE A BUSINESS NAME AND MUST MATCH THE BUSINESS NAME USED TO FILE FOR YOUR TAX ID NUMBER*	MNR MEDICAL COLLEGE AND HOSPITAL
PAYEE ADDRESS: *PLEASE NOTE: THIS SHOULD BE STREET ADDRESS, NOT A PO BOX*	FASALWADI, MNR NAGAR, MNR MEDICAL COLLEGE CAMPUS SANGAREDDY, Telangana
BANK DETAILS	Account Number: 50200007005508 Bank: HDFC IFSC Code: HDFC0000813

In case of changes in the Payee's address, Site is obliged to inform SPONSOR in writing. The parties agree that in case of changes in address which do not involve a change of Payee, tax numbers, or tax exempt status, no further amendments are required.

The Parties acknowledge that the designated Payee is authorized to receive all of the payments for the services performed under this Agreement.
If the Investigator is not the Payee, then the Payee's obligation to reimburse the Investigator, if any, is determined by a separate agreement between Investigator and Payee, which may involve different payment amounts and different payment intervals than the payments made by SPONSOR to the Payee. Investigator acknowledges that if Investigator is not the Payee, SPONSOR will not pay Investigator even if the Payee fails to reimburse Investigator.

B. PAYMENT DISPUTE

Site will have thirty (30) days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

C. PAYMENT TERMS

In accordance with the attached budget, SPONSOR will reimburse the Payee on a monthly basis for each completed visit per subject upon SPONSOR/Sponsor's receipt of completed Case Report Forms ("CRFs"). Payment should be made to the Investigator's account indicated above "Banking details of the Investigator".

Invoices: All invoices for Study payments, as outlined in this Attachment # 1, must be submitted to SPONSOR within 30 days of the Investigator's Study close-out visit. Invoices received after this time will not be reimbursed.

Ethics Committee Fees will be treated as pass-through expenses and will be reimbursed upon submission of a valid Invoice and their supportive bills.

Enrollment: Investigator acknowledges that this is a Study designed to evaluate a set number of subjects. Investigator will be expected to apply best efforts for enrollment as provided for under the Agreement. When enrollment of the target number of subjects for the entire Study is complete, Investigator will be notified and instructed not to continue enrolling subjects.

The Study shall be payable as follows:

Cost per Subject: Investigator will be paid per completed and evaluable subject as defined below based on the rates set forth in the Budget. Payments will be made on a quarterly basis in Indian Rupees as set above and will be based on completed visits verified in the subject case report forms (CRFs) and the appropriate invoice which shall include a correct itemization for all fees. A complete and evaluable patient is defined as follows:

1. All procedures must be performed according to the protocol and ICH GCP guidelines,
2. A patient will only be included according to the inclusion/exclusion criteria, and
3. If patient was randomized in the study deviating from protocol inclusion and exclusion criteria (without waiver, if applicable) then payment will not be made for such wrong randomization and subsequent visits,
4. All data are documented accurately, completely. In the event that a patient does not complete all visits as specified in the Protocol, SPONSOR shall only be obligated to make payment for such patient on a pro-rated, completed visit, and CRF basis.
5. Reimbursement for screen failures will be at the amount indicated on the screening visit of the attached budget, for a maximum of two (2) screen failures. To be eligible for reimbursement of screening visit, completed screening CRF pages must be submitted to SPONSOR and any additional information, which may be requested by SPONSOR to appropriately document the subject screening procedures.
6. In case of early termination of clinical trial, final payment calculation will be based on actual work completed. In case extra payment has been made, payee should refund the extra money.
7. SPONSOR 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 CRF's or where CRF's were not completed and/or provided to SPONSOR in a timely manner.
8. SUBJECT INJURY REIMBURSEMENT: SPONSOR shall reimburse Institution for all reasonable and necessary medical expenses for the diagnosis, care and treatment of any injury to a Study patient directly resulting from Study patient's participating in the Study ("Subject Injury"); provided, however, that: (a) the Subject Injury or illness was not caused by Investigator/Institution's deviation from the Protocol, Applicable Law, or other written instructions provided by SPONSOR/SPONSOR (except for medically necessary deviations); (b) the Subject injury or illness was not caused by the negligence or misconduct of the SITE and/or SITE staff; (c) the Subject injury or illness is not attributable to the natural progression of any underlying illness, any pre-existing abnormal medical condition or underlying disease of the Study patient, or treatment

that would have been provided to the Study patient in the ordinary course of treatment notwithstanding participation in the Study; (d) the injury or illness was not covered by the Study patient's medical or hospital insurance, or any similar third-party payer providing such medical or hospital coverage; (e) the Subject injury or illness was not directly attributable to a failure of the SITE any of its personnel conducting the Study to adhere to the terms of the Protocol, directions of the SPONSOR and/or SPONSOR, or Applicable Law pertaining to the administration of the Study; (f) the injury or illness is not attributable to the Study patient's deviation from the reasonable direction of SITE, Study personnel or the Study patient's physician.

The payments will be performed by the SPONSOR upon receipt of appropriate invoice.

Taxes: Payments for Services rendered under this Agreement shall be made in full in accordance with the Agreement. Any taxes due and payable as a result of the payments by SPONSOR to the Investigator shall be Investigator's sole responsibility and Investigator shall pay all such taxes for which it is liable in a timely manner. Should SPONSOR has to pay any tax due and payable as a result of the payments by SPONSOR to the Investigator, SPONSOR shall deduct this tax from Investigator's payment. Payment to Investigator shall be subject to tax deduction at source unless an exemption certificate issued by an appropriate authority is provided to SPONSOR.
Equipment Allocation: Equipment may be provided to the Investigator for use, in accordance with the Protocol, for this Study. If requested by the SPONSOR and/or Sponsor, such equipment shall be returned by the Investigator at the completion of the Study.
Patient travel arrangements and Reimbursement: The SPONSOR is not responsible to make any additional payments, such as patient travel arrangements and reimbursements.
Third Parties: Any other third parties designated by Investigator or Institution will be managed and paid by Investigator and/or Institution at their own expense.
Unscheduled Visits: The SPONSOR is not responsible to make any payments for unscheduled visits of the Study Subjects.
Final Payment: The final payment will be payable upon completion of the close-out visit and upon receipt of the following: (i) all Study documentation, (ii) the accountability of all unused Study Drug, (iii) all completed and correct CRFs/queries, (iv) any clarification to requests made by SPONSOR or Sponsor regarding Study data or records and (v) all study equipment and supplies returned as specified by SPONSOR and Sponsor. Investigator will have thirty (30) days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

No other additional funding requests will be considered without the prior written consent of SPONSOR.
Any expense or cost incurred by Site in performing this Agreement that is not specifically designated as reimbursable by SPONSOR or Sponsor under the Agreement (including this Budget and Payment Schedule) is Site's sole responsibility.
Major, disqualifying Protocol violations are not payable under this Agreement.

D. INVOICES

Original Invoices pertaining to this Study for the following items must be submitted to SPONSOR for reimbursement at the following address:

SPONSOR:

Mr. P. Veerendra Kumar
DGM-Clinical Affairs Division
Shilpa Medicare Private Limited
#12-6-214/A1, Hyderabad Road,
Raichur-584135, Karnataka, India

Please note that invoices will not be processed unless they reference the Sponsor name, Protocol number and Investigator name and site number. After receipt and verification, reimbursement for invoices will be included with the next regularly scheduled payment for subject activity.

NO OTHER ADDITIONAL FUNDING REQUESTS WILL BE CONSIDERED

These amounts include all applicable taxes.

ACKNOWLEDGED AND AGREED BY SPONSOR

Name: Mr. P. Veerendra Kumar

Title: Head- Clinical Affairs Division

Position: Deputy General Manager

Signature & Date: 05/02/2022

ACKNOWLEDGED AND AGREED BY INVESTIGATOR

Name: Dr. Aditya Mohan

Title: Principal Investigator

Signature & Date: 08/02/2022

ACKNOWLEDGED AND AGREED BY THE INSTITUTION

Name: Dr. Ravindra S. V

Title: Principal

Signature & Date: 08/02/2022

PRINCIPAL
MNR Dental College & Hospital
MNR Nagar, Narsapur Road
SANGAREDDY Dist. - 502 294 (T)

Annexure I

I. Payment Schedule/Milestones per patient

S No	Particulars	Unit Price	Visits	Grants	Total Cost
1	Investigator fee	700	3	2100	84000
2	CO PI	500	3	1500	60000
3	Clerk	200	3	600	24000
4	Serum Pregnancy Test	850	1	850	34000
5	Urine Pregnancy Test	150	1	150	6000
6	FBC (Full blood Count)	250	1	250	10000
7	G &S Test – Blood Grouping	100	1	100	4000
8	U&E-Urea and electrolyte	300	1	300	12000
9	Clotting screen for PT, APTT &fibrinogen	2000	2	4000	1,60,000
10	Radiologist Examination (IOPA and OPG)	500	1	500	20,000
11	12 – Lead ECG Recording	200	1	200	8000
12	HIV	250	1	250	10000
13	Rapid Antigen Covid	4900	1	4900	1,96,000
14	Stationary	100	1	100	4000
Total Cost per 40 completed subjects					6,32,000/-

II. Ethical Committee Charges – Rs. 75000/-
III. Archival Charges -Rs.50000/-

Payment Milestones:

Payment milestones with Institute (Shall enable agreement for your approval)

- **Milestone 1: 30% on signing of the agreement in total Rs 2,27,100/-**
- **Milestone 2: 30% on Ethical committee clearance in total Rs 2,27,100/-**
- **Milestone 3: 30% Completion of patient source information transcription in total Rs 2,27,100/-**
- **Milestone 4: 10% On Site Close Out and Successful audit completion by sponsor in total Rs 75,700/-**

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