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Purchased by	:	INSIGNIA CLINICAL SERVICES PVT LTD
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Memorandum of Understanding (MoU)
to Undertake Clinical Research in India by/and between

Santosh Deemed to be University,
No.1, Santosh Nagar,
Ghaziabad, (NCR Delhi)

And

Insignia Clinical Services Pvt. Ltd.
512, Best Sky Tower, Netaji Subhash Place,
Pitampur, New Delhi- 110034

as of 19th **October, 2020**
(effective date)

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This Memorandum of Understanding (hereinafter referred to as "**MoU**") has been executed on day of October 2020, at Delhi, INDIA by and between:

Insignia Clinical Services Private Ltd., a company incorporated under the laws of India as registered under the Indian Companies Act, 1956 having its business address at Unit No. 512, 5th Floor, Best Sky Tower, Netaji Subhash Place, Pitampura, New Delhi-110034 (hereinafter referred to as "**ICS**") (which expression unless repugnant to the context includes its associates, administrators, successors in interest and permitted assigns) through **Mr. Kartik Sahni**, who has been authorized to execute this MoU on behalf of ICS.

And

Santosh Deemed to be University, notified by Ministry of Human Resource Development, Govt. of India which is owning and managing Santosh Medical College at No.1, Santosh Nagar, Ghaziabad - 201 009 (U.P.) (hereinafter referred to as "**Institution**") and Santosh Medical College & Hospital i.e. Teaching and Training Hospital at No.1, Ambedkar Road, Ghaziabad - 201 001 (U.P.) (hereinafter referred to as "**Trial Site**") (which expression unless repugnant to the context includes its associates, administrators, successors in interest and permitted assigns) through **Dr. V.P. Gupta (Registrar)**, who has been authorized to execute this MoU on behalf of Trial Site.

WHEREAS

A. ICS is a Delhi-based Contract Research Organization (CRO) providing services primarily in India, directly or through its affiliates, associates, agents and subsidiaries. The major activities conducted by ICS include design, setup and management of clinical studies with human beings for the

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owners and / or manufacturers of pharmaceutical products, medical devices and food supplements / nutraceuticals.

B. Institution is a duly recognized educational –university offering courses of medical science, dental sciences, etc. and owns and operates a world-class multi-specialty hospital and state of the art research facilities under the name **"Santosh Medical College & Hospital"**

C. Trial Site has facilities and personnel with the requisite skills, experience, and knowledge required to support the performance of the clinical trials

D. ICS has shown intent to work with the Institution for conduct of clinical studies (Phase II, III & IV) at Trial Site location and premises and the Institution management has shown expression of interest for working with ICS to allow the conduct of said clinical studies due approvals from applicable authorities.

E. ICS and Trial Site hereinafter collectively referred to as the "**Parties**" and individually referred to as a "**Party**".

F. Both Parties have mutually agreed that ICS will provide operational support expertise, knowledge and know-how for conduct of any kinds of sponsored Clinical Trials at Institution/Trial Site..

G. Both parties recognize that mutual collaboration given each other's strengths in respective areas, knowledge / know-how of technologies under discussion thereof, will mutually benefit each other and in

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consideration of the mutual covenants contained herein the parties agree have agreed to enter into this MoU, which shall be legally binding henceforth,

1. DEFINITIONS

The following words and phrases have the following meanings:

"**Auditor**" means a person who is authorised to carry out a systematic review and independent examination of clinical trial related activities and documents to determine whether the evaluated clinical trial related activities were conducted, and the data were recorded, analysed and accurately reported according to the Protocol, the Standard Operating Procedures of Sponsor and/or CRO, ICH GCP and the applicable regulatory requirements

"**Adverse event**" means any untoward medical occurrence (including a symptom or disease or an abnormal laboratory finding) during treatment with an investigational drug or a pharmaceutical product in a patient or a Clinical Trial Subject

"**Central Licencing Authority**" means the Drugs Controller General of India

"**Clinical Trial**" means the investigation to be conducted at the Trial Site

"**Clinical Trial Subject**" means a person enrolled to participate in the Clinical Trial

"**CRF**" means the case report form in a format prepared by Sponsor and/or CRO for documenting the administration of the drug to Clinical Trial Subjects as well as all tests and observations related to the Clinical Trial;

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"Ethics Committee" means the accredited medical research ethics committee competent to review the Clinical Trial in accordance with applicable Law

"Good Clinical Practices Guidelines" means the Good Clinical Practices Guidelines for conduct of clinical studies in India, formulated by the Central Drugs Standard Control Organisation and adopted by the Drugs Technical Advisory Board

"ICF" means the Informed Consent Form as approved by the Ethics Committee, in which the Clinical Trial Subject consents to his participation in the Clinical Trial;

"Principal Investigator" means the person who will take primary responsibility for the conduct of the Clinical Trial at the Trial Site or any other person as may be agreed between the Parties as a replacement;

"Research Staff" means the persons who will undertake the conduct of the Clinical Trial activities at the Trial Site on behalf of the Principal Investigator and under the supervision of the Principal Investigator;

"Trial Site" means the premises at the Institution where the Clinical Trial will be conducted;

"Informed Consent" shall mean a process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate

"Protocol" shall mean a document that describes the objective(s), design, methodology, statistical considerations, and organization of a Clinical Trial.

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"Sponsor/CRO" shall mean an individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a Clinical Trial and the one who shall appoint ICS for undertaking such activities.

"Standard Operating Procedures (SOPs)" shall mean detailed, written instructions to achieve uniformity of the performance of a specific function

"Serious Adverse Event" means an untoward medical occurrence during Clinical Trial resulting in death or permanent disability, or hospitalisation of the Clinical Trial Subject where the trial subject is an outdoor patient or a healthy person, prolongation of hospitalisation where the trial subject is an indoor-patient, persistent or significant disability or incapacity, congenital anomaly, birth defect or life threatening event;

2. **ENGAGEMENT**

ICS and Institution hereby mutually agrees to enter into this binding MoU with below mentioned obligations to be performed by both Parties:

Obligations of ICS

a) To undertake Study Protocol Feasibility, Site Initiation, Site Monitoring, Site Management, Project Management, Documentation, Investigational Product Accountability and Safety reporting activities in trial projects.

b) To provide support in audits, monitoring and inspections related to Clinical Trial Projects at Trial Site.

c) To undertake Site Close Out Duties for clinical study projects and prepare reports of all the communication between the investigator and

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"CRO/Sponsor".

d) To provide investigator's brochure, Protocol, Case Report Form (CRF) draft Clinical Trial Agreement (CTA), insurance policy from an Indian Insurance company, regulatory approvals and other study related documents before initiation of Clinical Trial.

e) To make sure that adequate supplies of trial drug are being supplied by the Sponsor.

f) To ensure that the Sponsor has obtained Insurance cover for treatment and compensation of Serious Adverse Event (SAE).Institution

g) Appropriate acknowledgement of contribution of Institution investigators in any resulting publication.

h) To ensure compliance with Good Clinical Practices Guidelines and applicable regulations during conduct of Clinical Trials .

i) To submit status report on the Clinical Trial to the Central Licencing Authority at the prescribed periodicity.

j) To submit summary report within 3 (three) months in case of Clinical Trial prematurely discontinued for any reason.

k) To provide support in audits, monitoring and inspections

l) To maintain the Site Master File (**SMF**) in all clinical study projects including all the essential documents & log books etc.

m) To provide complete support to the investigators / Research Staff for conduct of Clinical Trials on the Clinical Trial Subjects after getting the

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due informed consent in writing and strictly in accordance with the Clinical Trial Rules 2019 as annexed to Drug and Cosmetics Act, 1940 and the Drug and Cosmetics Rules, 1945, as amended from time to time and other guidelines like ICH guidelines issued in this regard or any other instructions/circulars issued by the office of Director General Health Services and DCG(I) in this regard.

n) To ensure the compliance of Import/Export policy for Human Biological Samples for commercial purposes: amendment Schedule – 1 (Import Policy) and Schedule – 2 (Export Policy) of ITC (HS), 2012 notified by Directorate General of Foreign Trade, Department of Commerce, Ministry of Commerce and Industry vide its Notification No. 19/2015-2020 dated 4th August 2016 published in the Gazette of India. The relevant clause extracted from the Notification is reproduced hereinbelow:

> **"The import of human biological sample by the Indian Diagnostic Laboratories / Indian Clinical Research Centres for lab analysis / R&D testing of export of these materials to foreign laboratories should be permitted by Customs authorities at the port of entry /exit without prior approvals (import license / export permit) from any other Government agency, provided the concerned Indian Company / agency submits an undertaking that they are following and will follow all the applicable rules, regulations & procedures for safe transfer and disposal of the biological samples being imported / exported as per related norms / regulations set by WHO/DGFT** (SCOMET items in Export Policy of ITC (HS), 2012, Schedule – 2**

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(Export Policy) / Ministry of Environment, Forests and Climate Change*, Government of India, to the Customs authorities at the port of entry / exit along with the details of such samples."**

o) To ensure that during the Clinical Trial, the products shall be administered to the Clinical Trial Subject, keeping strictly in view, the product's literature and indication as supplied by the Sponsor and/or CRO.

p) To ensure approval for Clinical Trial from an Ethics Committee Duly Registered with CDSCO prior to initiation of every such trial.

q) To prepare Ethics committee at Institution/Trial Site (if required) OR to co-ordinate with an external Independent Ethics Committee duly registered with CDSCO which can provide regular monitoring oversight and approvals after due review process for such Clinical Trials.

r) To timely report the Adverse Events as per applicable guidelines and regulations.

s) To keep track of payments for Institution, Principal Investigator, Ethics Committee and to co-ordinate with Sponsor for timely disbursement of payments.

t) To ensure that all Clinical Trials are insured with a relevant civil liability insurance before the Clinical Trial is initiated and the Institution/Trial Site is indemnified of any financial liability in case of any clinical study related Adverse Events or any trial related injury.

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u) To register Trial Site in relevant registries of ICMR and WHO as specified in Clinical Trial Protocol after due approval from Sponsor

Obligations of Institution

a) Institution shall ensure that Clinical Trial be conducted in strict compliance with the Protocol, Standard Operating Procedure (SOP) and applicable regulatory requirements and GCP Guidelines.

b) Institution shall ensure that rights, safety and well-being of Clinical Trials Subject are protected.

c) Institution to make sure that respective obligations are fulfilled by Principal Investigator and Research Staff at all times before, during and after completion of such Clinical Trials at Trial Site

d) To ensure necessary infrastructure support to Principal Investigator and Research Staff.

e) Protection of confidentiality, rights, safety and wellbeing of Clinical Trial Subjects.

f) Ensuring accuracy, completeness, legibility and timelines of the data reported to the Sponsor in the CRFs

g) To make available upon request all Clinical Trial related material and records to auditor, Ethics Committee or applicable regulatory agencies.

h) To ensure that Trial Site provides all the relevant documents and

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cooperate with ICS in feasibility, site initiation, site monitoring, site management, project management, investigational product accountability and safety reporting of Clinical Trial projects.

i) To undertake laboratory investigations of all the Clinical Trial Subject on screening & various intervals as specified in study plan/Protocol including amendment(s) thereof. All laboratory investigations will be done in only in those labs which are NABL or CAP (College of American Pathologists) accredited. Institutional laboratory may be used for investigations necessary to be done locally or bedside, however proper SOPs and reference values should be available with the laboratory in accordance with the Indian and International Good Clinical Laboratory Practices.

j) To ensure that the product shall be administered to the Clinical Trial Subject by the doctors/Research Staff who will be responsible for conducting the Clinical Trials and who have consented for the same.

k) To ensure timely report of Adverse Events / Serious Adverse Events as per applicable Indian and ICH GCP guidelines to ICS for onward submission to concerned authorities.

l) To ensure that Trial Site /Principal Investigator/Research Staff participates in routine training programme conducted by ICS for Clinical Trial Projects and GCP.

3. **TERM**

This MoU shall commence on the date mentioned above and shall, unless sooner terminated in accordance with the provisions hereof, be valid for a period of next five (5) years, subject to extension, as may be agreed upon in

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writing between the Parties. All Clinical Trial projects conducted at Trial Site during the term of said MoU will be under the supervision of ICS subject to the obligations specified at serial no. 2 above.

4. **TRIAL DRUG; MATERIALS TRANSFER; RECORDS RETENTION; INSPECTION**

a. Trial drug:

i. Institution acknowledge that the trial drug/device is owned or controlled by Sponsor and that neither the terms of this MoU nor the Protocol, nor any activities conducted by Institution or Principal Investigator for the Clinical Trial, shall be construed to grant to either Institution or Principal Investigator any rights in or to the drug/device.

ii. Except as otherwise agreed by the Parties, Sponsor will provide the drug/device and any control/placebo material to be administered to Clinical Trial Subjects as part of the Clinical Trial (collectively, the **"Trial Drug"**) free of charge to Institution for administering or dispensing solely by or under the supervision of Principal Investigator or sub-investigator to Clinical Trial Subjects at the Trial Site in strict compliance with the Protocol.

iii. Institution shall ensure that Principal Investigator use the Trial Drug solely to conduct the Clinical Trial in strict compliance with the Protocol and for no other purpose, and shall not transfer the Trial drug to any third parties. Institution and Principal Investigator shall handle, store, ship and dispose of the

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Trial drug as directed by Sponsor or its designee and in compliance with all applicable laws, rules and regulations.

iv. Institution and Principal Investigator will ensure that empty and partially used Trial Drug container and any Trial Drug remaining at the Trial close-out visit at the Trial Site or upon early termination of this Agreement are disposed of or returned to Sponsor in accordance with the Protocol.

v. Neither support of the Clinical Trial, nor Institution's participation in the Clinical Trial, impose any obligation,

express or implied, on Institution or Principal Investigator to purchase, prescribe, provide favorable formulary status for or otherwise support Sponsor's products.

vi. Unless required by the Protocol, Institution will not modify the Trial Drug or its container. If the Institution policy requires any modification to the Trial Drug container, such modification must be approved in advance in writing by Sponsor.

b. **Records Maintenance and Retention**

Institution shall ensure that the Principal Investigator and research staff at Trial Site will maintain adequate and accurate records relating to the disposition of the Trial Drug and the performance of all required Protocol procedures on Clinical Trial Subjects including but not limited to, written and audiovisual documents, medical records, charts pertaining to individual Clinical Trial Subjects, CRFs, accounting records, notes, reports, and data. Institution will

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retain these documents for the longer period of at least 5(five) years after completion or earlier termination of the Clinical Trial.

5. WARRANTIES AND REPRESENTATIONS

Both Parties represent and warrant that:

(a) it is a company / institution duly incorporated under the laws, as stated above;

(b) it has power and authority to enter into and perform this MoU and the study and services contemplated by it and its entry into and performance of this MoU and the acts contemplated by it, do not constitute a breach of any obligation or default of any other agreement/arrangement by which it is bound or of any applicable law, regulation or policy;

(c) the person executing this MoU is duly authorized to do so;

(d) nothing contained herein conflicts with any of the provisions of the Memorandum and Articles of Association or similar or other documents relating to the incorporation;

Both Parties warrant that, to the best of its knowledge, neither it, nor its employees, nor any other person retained by it to conduct the study itself or provide the services pursuant to this MoU (1) is under investigation by the Central Drugs Standard Control Organisation (CDSCO)/Food and Drug Administration (FDA), or other applicable/equivalent agency for India for debarment action, or other applicable rules, regulations or laws of India or other countries under which they are registered and licensed (The

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"Acts"), (2) has a disqualification hearing pending or has been disqualified by the CDSCO/FDA, or other applicable agency or (3) has been convicted of a crime for which a person can be debarred under any of the "Acts". If during the term of this MoU, any person employed or retained by either Party to conduct this study or perform services under this MoU (1) comes under investigation by the CDSCO/FDA, or other applicable agency for debarment or disqualification, (2) is debarred or disqualified, or (3) engages in any conduct or activity which could lead to any of the above mentioned disqualification or debarment actions, the Party shall immediately notify the other Party of the same. For the purposes of this section, reference to the CDSCO/FDA, or the Acts shall also be deemed a reference to any other governmental or regulatory authorities having jurisdiction over the subject matter of the particular study or any other laws and regulations applicable to the study.

Institution represents and warrants that the Principal Investigator is qualified as a medical practitioner under applicable laws and regulations.

6 **CONFIDENTIAL INFORMATION:**

Both Parties agree to treat any confidential information obtained from the other Party, or generated by the Party or its representatives as a sole and direct result of performing the services under this MoU including, without limitation, confidential commercial, business, scientific, medical and technical information, the study drug, Protocol, investigator brochure, CRFs, safety information, and any other data or information generated or resulting from the study recorded and available in any form or on any media (paper, disc, photos, computer systems) (hereinafter "**the Confidential Information**")

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Both Parties agree not to divulge the Confidential Information to any third party or parties, unless necessary as it relates to the performance of duties outlined in the scope of services or use said Confidential Information for any purposes other than understanding and evaluating the performance of those services. Parties further agrees to limit disclosure only to those of its officers, employees, agents, affiliates and consultants as are necessary to carry out the services under this MoU. Parties shall take all reasonable steps to prevent the disclosure of the Confidential Information as provided herein.

Parties will ensure that it will incorporate similar confidentiality language (no less restrictive than this MoU) in its written contracts with all representatives, agents, affiliates and consultants to protect Confidential Information. Any Confidential Information or IP produced for performing services under this MoU can only be used by the Sponsor and /or CRO for the specific study.

The above provisions of confidentiality shall not apply to that part of the information which any party is able to demonstrate by documentary evidence:

- was fully in their possession prior to receipt from the other Party; or
- was in the public domain at the time of receipt;
- or becomes part of the public domain through no fault of the Party; or
- is lawfully received by it from a third party having a right of further disclosure; or
- is developed by it independent of the information; or
- is required by law or upon a court injunction to be disclosed.

Parties agree that upon termination or expiration of this MoU, at the other Party's request, it shall return to the other Party all Confidential Information,

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retaining copies of any such Confidential Information as is reasonably necessary for regulatory and insurance purposes or as it deems necessary to demonstrate the satisfaction of its obligations hereunder, all subject to the ongoing obligation to maintain the confidentiality of such Confidential Information.

Notwithstanding any other provision of this MoU, Institution and Principal Investigator may disclose Confidential Information to the extent required.

(i) To comply with an applicable law, rule regulation or government order, after prompt notice to Sponsor provided that Principal Investigator and Institution cooperate with Sponsor and CRO efforts to limit such disclosure by appropriate legal means:

(ii) To protect any Clinical Trial Subject's safety or provide appropriate medical care for any Clinical Trial Subject, or to prevent a public health emergency with prompt notice to Sponsor and CRO.

7 COMPENSATION

For all clinical studies a separate study specific agreement will be prepared between Institution/Trial Site, Principal Investigator & ICS/ Sponsor. The study specific agreement will cover the amount of compensation to be provided for each study to the Institution/Trial Site which will include details of cost and payment milestones for lab. charges, patient treatment costs, investigator compensation, institutional payments etc. ICS will be responsible for execution of such agreement prior to initiation of each and every clinical trial project.

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In cases of multi-centric clinical studies where Institution is being enrolled as one of the Trial Site and ICS is the central co-coordinating CRO, ICS shall directly reimburse the costs to the Institution account for investigator / site fees and lab charges upon receipt of invoice / bills. Details of Institution bank Account are:

Payee Name	**Santosh Trust**
PAN Number	**AAITS6921N**
Account Number	**6786557633**
Bank Name and Details	**Indian Bank**
Branch	**Navyug Market**
IFSC Code	**IDIB000G007**

In certain cases, wherein, the study specific clinical trial agreement will require tri-party agreement (Institution/Trial Site, Principal Investigator & ICS/Sponsor) and the cumulative payment including the ICS service charges for operational management is to be made in single account of Institution as per request of Sponsor. In such cases, ICS will cross charge the Institution for payment of such dues to ICS. The details of such dues / expenses and the total study budget will be discussed promptly before initiation of such study and payment terms will be recorded in writing as part of study specific clinical trial agreement. Details of ICS Bank Account for payment of such dues are:

Payee Name	Insignia Clinical Services Private Limited
PAN Number	AADCI0529A
Account Number	071405500516
Bank Name and Details	ICICI Bank
Branch	Lajpat Nagar IV
IFSC Code	ICIC0000714

Ethics Committee Fees: Ethics Committee review fees will be paid by Sponsor as determined and upon its failure the same shall be paid by ICS.

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Each study specific Clinical Trial agreement should incorporate detailed compensation schedule covering necessary charges to be paid by Sponsor for services to be rendered by Institution

It is expected that out of good faith, since both parties are now entering the MoU and ICS will make its best efforts to increase the number of clinical trials projects at the Institution/Trial Site which will in-turn add to financial revenue for the Intuition/Trial Site. Therefore, in good faith it is expected that the Institution/Trial Site will provide preferred/discounted rates for various investigations for such which will be part of Clinical Trial Protocols. The quantum of such discounts will be discussed promptly between ICS and institution and the same shall be recorded in Study Specific Clinical Trial Agreement.

8. **INVENTIONS AND PATENTS**

Any invention, discovery, or improvement related to Sponsor's products or technology which is conceived or reduced to practice as a consequence of Institution/Trial Site performance of the services hereunder (the "**Inventions**") shall be the sole and exclusive property of Sponsor and shall be used by Sponsor as Sponsor deems appropriate. Institution/Trial Site agrees to execute, at Sponsor's cost, assignments of the Inventions to Sponsor (including ensuring contracts between Institution/Trial Site and its representatives include appropriate assignment language to require its representatives to comply with the terms of this assignment provision and this MoU), along with other documents that may be necessary or helpful to Sponsor in filing patent applications, or which may relate to any litigation or interference and/or controversy in connection therewith. The entire control, prosecution, and conduct of any patent application filed by Sponsor shall be outside the jurisdiction of, and without expense to, Institution/Trial Site or

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its representatives. Institution/Trial Site acknowledges that Sponsor has the exclusive right to file patent applications in connection with the Inventions. Institution/Trial Site warrants that it will not, and will ensure (including incorporating similar language in its contracts with study sites and investigators) that its representatives will not prevent Sponsor from filing patent applications for, or from applying the results of research carried out for Sponsor hereunder.

All reports, data, technical information, original works of authorship and all other information, furnished by or on behalf of Sponsor, or created specifically for Sponsor as a deliverable under this MoU ("Work Product"), shall be the sole and exclusive property of Sponsor.

Notwithstanding the foregoing, Sponsor/ICS acknowledges that Institution possesses certain inventions, processes, know-how, trade secrets, improvements, other intellectual properties and other assets, including but not limited to analytical methods, procedures and techniques, procedure manuals, personnel data, financial information, computer technical expertise and software, which have been independently developed by Institution and which relate to its business or operations (collectively "**Institution Property**"). Sponsor / ICS and Trial Site agree that any Institution Property or improvements thereto which are used, improved, modified or developed by Institution under or during the term of this MoU are the sole and exclusive property of Institution and Sponsor / ICS shall be liable for any misuse or unauthorized use/ dissemination of the same. In no event shall Institution be precluded from use of this Institution Property and its general knowledge, skills and experience, and any of its ideas, concepts, know-how and techniques used or developed by it in the course of providing services under this MoU.

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9. TERMINATION

This MoU may be terminated by any Party upon giving at least ninety (90) days written notice to that effect to the other Party. The day following the 90th day of such notice shall be "**Effective Date of Termination**". A reasonable adjustment will be made between the Parties to ensure the Principal Investigator and Institution is reimbursed for project costs incurred to the date of termination of this MoU for completing the study as per Protocol on already enrolled Clinical Trial Subjects. In case such termination occurs, Institution/Trial Site will have obligation to complete procedures as per study protocol for any on-going patient(s) who may be under treatment in Clinical Trials at Trial Site at that point of time.

Either Party is entitled to terminate the MoU forthwith in the event the other becomes insolvent or bankrupt or enters into any arrangement with its creditors for relief of debt or takes any advantage of any law for the benefit of debtors or goes into liquidation or receivership whether compulsory or voluntary.

Either Party has the right to terminate this MoU immediately if other Party significantly violates any obligations relating to the ethics of clinical research or GCP guidelines or any other applicable law, regulation or policy and/or their representatives commit any act of negligence or wilful misconduct in relation to the study.

Upon termination above, both Parties shall mutually discuss in good faith to settle on the payment for all services performed and out-of-pocket costs incurred or irrevocably committed to third parties up to the Effective Date of Termination.

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Upon termination of this MoU for any reason, Institution shall cooperate with Sponsor / ICS, at the cost of Sponsor / ICS, in the transfer of duties/responsibilities, study data, documents, etc., as the case may be, to either Sponsor / ICS or a third party, as authorized by Sponsor / ICS. All such transfer of study data, documents, duties, responsibilities, etc. shall all be in a form and with content reasonably satisfactory to Sponsor / ICS (and within reasonable timeframes requested by Sponsor / ICS). Sponsor / ICS shall also pay Institution for its reasonable personnel costs to assist in any such transfer.

10 **LIMITATION ON LIABILITY, INDEMNIFICATION, USE OF NAME:**

Sponsor/ICS shall indemnify Institution, its representatives, the Principal Investigator and any of their agents, employees and/or the Trial Site/facility involved in the study for any and all damages, costs, expenses and other liabilities, including reasonable attorney's fees and court costs, incurred in connection with any third-party claim, action or proceeding to have arisen from (i) conducting the study in accordance with the Protocol and/or the study specifications attached hereto and/or any other instructions given by Sponsor relating to the study, (ii) the infringement of third parties' intellectual property rights due to the performance of this MoU and/or the relevant attachments, or (iii) negligence or intentional misconduct of Sponsor of any of its obligations under this Agreement. ICS shall ensure that Sponsor maintains adequate insurance cover covering liability for death or injury of a Clinical Trial Subject resulting from the study, fully in accordance with the applicable rules in India, upto an amount agreed with regard to the performance of the study as set out in the Protocol.

Institution shall indemnify Sponsor and ICS, its directors, officers, and

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employees for any and all damages, costs, expenses and other liabilities, including reasonable attorney's fees and court costs, incurred in connection with any third-party claim, action or proceeding to have arisen from negligence or intentional misconduct of Institution, or of its representatives of any of its obligations under this MoU.

Any Party liable to provide indemnification hereunder shall be entitled, at its option, to control the defense and settlement of any claim on which it is liable, provided that the indemnifying party shall act reasonably and in good faith with respect to all matters relating to the settlement or disposition of the claim as the disposition or settlement relates to the party being indemnified. The indemnified party shall reasonably cooperate in the investigation, defense and settlement of any claim for which indemnification is sought hereunder and shall provide prompt notice of any such claim or reasonably expected claim to the indemnifying party.

Institution/Trial Site agrees not to use and to ensure (including incorporating similar language in its contracts with study sites, investigators and other Representatives) that its Representatives will not use the name of Sponsor / ICS or any of its employees, agents or affiliates, or reference any of Sponsor's products or Sponsor / ICS Confidential Information, in any publicity, advertising, or other publication or presentation without Sponsor / ICS prior written consent.

ICS agrees not to use Institution's name in a manner that could reasonably be construed as an endorsement. Sponsor / ICS may issue press releases as to the progress of the study under this MoU in the ordinary course of business.

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Institution will ensure that their contracts with investigators and study sties staff contain clear restrictions concerning publication. Institution agrees, and shall ensure that study sites and investigators shall all agree in their written contracts, that no interim, preliminary, partial or complete study results will be made public by an investigator, group of investigators, or institution prior to receiving the explicit written consent of Sponsor.

11. NOTICE

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

To ICS:

- Insignia Clinical Services Private Ltd., Unit No. 512, 5th Floor, Best Sky Tower, Netaji Subhash Place, Pitampura, New Delhi-110034.

To Institution:

- Santosh Deemed to be University, No.1, Santosh Nagar, Ghaziabad – 201

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12. GENERAL

Governing law: This MoU, and any disputes arising hereunder, shall be governed by and interpreted in accordance with the laws of the State of New Delhi, India.

Entire MoU: This MoU sets forth the entire understanding of the Parties relating to the subject matter hereof, and supersedes all prior agreements, arrangements and understandings, written or oral, between the Parties. The terms and conditions mentioned in this MoU shall be binding on both the Parties.

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

ARBITRATION

If any dispute arises between the Parties hereto during the subsistence or thereafter, in connection with the validity, interpretation, implementation or alleged material breach of any of the provisions of this MoU or regarding any question, including the question as to whether the termination of the Agreement by any of the Parties hereto has been legitimate, the Parties hereto shall endeavour to settle such disputes amicably by referring the matter to a sole arbitrator selected jointly by the Parties. In case the Parties are unable to agree, on the name of the sole arbitrator, then either Party may make application to Delhi High Court for appointment of sole arbitrator under the

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provisions of the Arbitration and Conciliation Act 1996. The arbitration proceedings shall be conducted in accordance with the Arbitration and Conciliation Act 1996 or any enactment or modification thereof for the time being in force and its decision shall be final and binding. The Place of arbitration shall be New Delhi and the proceeding shall be held in English Language only

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

Assignment: ICS may assign its obligations under this MoU to a partner, licensee, purchaser or the like, provided ICS shall provide Institution with prompt written notice of such assignment, and such assignee agrees to assume all of ICS obligations hereunder.

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

Force Majeure: No Party hereto shall be liable in damages or have the right to cancel this MoU for any delay or default in performing hereunder if such delay or default is caused by conditions beyond its control, including but not limited to natural disasters, acts of God, government restrictions/policy, laws, wars, terrorist acts, or insurrections

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IN WITNESS WHEREOF the Parties hereto have accepted and executed this MoU as of the day and year first set above. This MoU has been executed in duplicate, each Party having received one original

Insignia Clinical Services Pvt. Ltd.	**Santosh Deemed to be University**
Signed:	Signed:
Date: 19-OCT-2020	Date: 19.10.2020
Name:	Name:
Title:	Title:
Seal / Stamp:	Seal / Stamp:

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