सत्यमेव जयते

INDIA NON JUDICIAL

Government of Uttarakhand

e-Stamp

Certificate No.	:	IN-UK066209206373 20U
Certificate Issued Date	:	09-Sep-2022 11:12 AM
Account Reference	:	NONACC (SV)/ uk1264704/ DOIWALA/ UK-DH
Unique Doc. Reference	:	SUBIN-UKUK126470418486761257902U
Purchased by	:	SWAMI RAMA HIMALAYAN UNIVERSITY
Description of Document	:	Article Miscellaneous
Property Description	:	NA
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	SOMAYA RESERACH AND HEALTH SERVICES LLP
Second Party	:	SWAMI RAMA HIMALAYAN UNIVERSITY
Stamp Duty Paid By	:	SWAMI RAMA HIMALAYAN UNIVERSITY
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (herein after referred to as **"Agreement"**) is made on this 13th Sept. 2022 ("herein after referred to as **"Effective Date"**) **By and Between**

Somaya Research and Health Services LLP (A Site management Organization -SMO) a private company incorporated under the Companies Act,2008, The LLP Identification Number (LLPIN)

Swami Rama Himalayan University Registrar

SOMAYA RESEARCH AND HEALTH SERVICES LLP

of the company is AAK-5114 and registered office address is Chow Mandi, Tiraha, Opp Govt College Roorkee Urban, Haridwar, Uttarakhand, India, 247667 (hereinafter referred to as "SRHS LLP") represented by **Mrs. Priti Pal, SMO, Director** (which expression shall, unless otherwise required in the context, shall mean and include its successors, assigns and affiliates);

AND

Swami Rama Himalayan University (SRHU), a University established under section 2(f) of UGC Act, 1956 and enacted vide Uttarakhand Act no. 12 of year 2013, having its registered office at Swami Ram Nagar, Jolly Grant, Dehradun, Uttarakhand for its teaching hospital i.e. "Himalayan Hospital" (hereinafter referred to as "SRHU" or " Study Site" or "Institution") represented by its Registrar, Dr. Susheela Sharma, (which expression shall, unless otherwise required in the context, shall mean and include its successors, assigns and affiliates)

SRHS LLP and **SRHU,** are individually referred to as **"Party"** collectively referred to as the **"Parties".**

SRHS LLP and **SRHU** to enter a sole exclusive agreement and conclude to facilitate the Clinical Trials at Hospitals hereinafter defined.

Himalayan Institute of Medical Sciences (HIMS) is a constituent medical college of Swami Rama Himalayan University (SRHU), which is well equipped with modern medical facilities and renowned for excellent patient care and treatment to the rural/urban population.

SRHS LLP is a Site Management Organization (SMO) that provides clinical trial related services to various medical institutions. It has high moral values towards the Commitment of work and to achieve excellence in documentation and maintenance and also ensure to maintain & concentrate on safety & efficacy of all research participants.

SRHS LLP is desirous of working with clinical investigators of the medical college of Swami Rama Himalayan University under for the purpose of conducting ICH-GCP (International Conference on Harmonisation-Good Clinical Practice) compliant- Phase III to IV Clinical Trials, BA/BE Studies, Instrumentation Studies, Epidemiology Studies for new drugs & treatments.

SRHS LLP and SRHU have considered & reached an understanding on the following terms & conditions mutually agreed as follows.

1. DEFINITIONS AND INTERPRETATION

1.1 **"Agreement"** means this Clinical Trail Agreement (including the Annexure) as amended modified and/or supplemented from time to time;
"Effective Date" means 13th Sept. 2022

Swami Rama Himalayan University Registrar

Priti Pal

SOMAYA RESEARCH AND HEALTH SERVICES LLP

1.2 **"Intellectual Property"** mean patents, trade- marks, rights in domain names, designs, copyrights, database rights (whether or not any of these is registered and including applications for registration of any such thing) and all rights or forms of protection of a similar nature of having equivalent or similar effect to any of these which may subsist anywhere in the world;

1.3 **"Institution"** means Swami Rama Himalayan University (SRHU), Jolly Grant, Dehradun

1.4 **"Study Sites"** means and include Swami Rama Himalayan University (SRHU), Jolly Grant, Dehradun

1.5 **"Trial site(s)"** means any premises in which the Clinical Trial is being or will be conducted.

1.6 **"Investigator(s)"** shall mean the physicians primarily responsible for the conduct of the study at the Trial site(s), and shall include "Sub-Investigators" and "Co-investigators".

1.7 **"Sub-Investigator"** means any individual member of the Clinical Trial team designated and supervised by the Principal Investigator and the Co-investigator at the Trial site(s) to perform trial-related critical procedures.

1.8 **"Clinical Trials"** means an investigation to be conducted at a Trial site in accordance to an approved Protocol,

1.9 **"Contract Research Organization or Clinical Research Organization (CRO)"** is a service organization that provides support to the pharmaceutical and biotechnology industries in the form of outsourced pharmaceutical research services (for both drugs and medical devices)

1.10 **"Principal Investigator**" shall mean the person who has been mutually agreed upon by the Parties and who will lead and co-ordinate the work of the Clinical Trial at the Trial site(s) on behalf of the CRO or any other person as may be mutually agreed from time to time between the Parties as a replacement for the purpose of this Agreement.

1.11 **Serious Adverse Event (SAE)"** shall mean only any untoward medical condition that occurs at any dose:

a. Results in death,
b. Is Life-threatening,
c. Requires inpatient hospitalization or prolongation of existing hospitalization,
d. Results in persistent or significant disability/incapacity, or
e. Is a congenital anomaly/birth defect.

2 ROLES AND RESPONSIBLIIES OF INSTITUTION

2.1 Institution agrees to enter into a confidentiality agreement with Sponsor and Somaya Research and Health Services LLP**.**

2.2 The space and required facility (eg. Electricity, water, sanitation facility) for conducting clinical trials will be provided by the Institution. The electricity will be provided on payment basis.

2.3 Execution of the required documentation and undertake other actions to ensure that the required permissions from the Ethics Committee authorities are obtained in a prompt and timely manner.

2.4 Shall provide suitably qualified Investigator and Sub investigators who will devote the necessary time and be responsible for the medical care and safety of the patients.

Swami Rama Himalayan University Registrar

SOMAYA RESEARCH AND HEALTH SERVICES LLP

2.5 The Investigator or Sub Investigator should follow ICH GCP, NDCT rules 2019, ICMR Guidelines and the protocol as amended from time to time.

2.6 The Institute agrees to share the database of (OPD/IPD) patients with SRHS LLP for research purpose only. The confidentiality of the data would be maintained by SRHS LLP personnel.

2.7 The Institute will provide one Electronic Medical Record (EMR) access to the SRHS LLP personnel for research after special permission from CMS (Chief Medical Superintendent/Director as the case may be) for accessing the clinical trial enrolled subjects data bases.

2.8 The Institute will provide the letter head to the SRHS LLP personnel for research data purpose only if required.

2.9 The Institute would provide the services of Principal Investigator and will be responsible for medical care to the subjects.

2.10 The Institute will be responsible to archive all clinical trial documents. (Payments as per site Standard Operating Procedure -SOP).

2.11 The Institute will be responsible to archive all clinical trial documents for the duration of 15 year after each trial. (Payments as per site SOP).

2.12 All Invoices made and payments received will be notified to the **Somaya Research and Health Services LLP** Free and full access to all parts of the Site.

2.13 Study site and Sponsor will enter into a clinical trial agreement before/ at the time of placement of above study at the study site, where by the total fee will be shared between the Institution & Somaya Research and Health Services LLP, the share shall be due and payable on the basis of funds received from the Sponsor on actual work done i.e., number of patients randomized or visits completed. All payment shall be routed through the **SRHU**.

2.14 **SRHS LLP** will be responsible to obtain the study related payments from Sponsor to the account of SRHU (Study Site) and SRHU (Study site) will pay the part of SRHS LLP (as agreed) to the SRHS LLP in a timely manner.

2.15 Institute will appoint single point of contact or say Clinical Trial Centre Coordinator/ Incharge for the smooth running of the all trials undertaken at the Study site.

3 ROLES AND RESPONSIBLIIES OF SOMAYA RESEARCH AND HEALTH SERVICES LLP (SRHS LLP)

3.1 **SRHS LLP** shall be responsible to furnish/sanction the Clinical Trials to **the hospitals functioning under the Institution** –Swami Rama Himalayan University (SRHU). *The hospital in which the clinical trial is conducted is referred as study site.*

3.2 **SRHS LLP** will appoint an off-site **Project Manager** (here in after referred as PM) who will be responsible to coordinate and over-see the progress and management of Clinical Research Coordinator (CRC) activities and shall ensure data- quality and resolve screening/recruitment/

Swami Rama Himalayan University Registrar

SOMAYA RESEARCH AND HEALTH SERVICES LLP

general issues, if any, follow-up on post- monitoring action elements and study specific training needs and provide regular back-up to study site and Sponsor on trial progress.

3.3 **SRHS LLP** will appoint an off-site **Quality Manager** (hereinafter referred as QM) who will be responsible to check and ensure adherence to the protocol, record keeping and record retention as per the protocol and applicable regulatory requirements.

3.4 Project Management team and Quality Management team (from off-site) will assist study site and sponsor in all trial related activities. The salaries of the Project Manager, Quality Manager & or any other staff (Coordinators) will be paid by Somaya Research and Health Services LLP.

3.5 **SRHS LLP** will bear all the administrative cost related to the various activities undertaken by PM, QM or any other staff placed by Somaya Research and Health Services LLP, which includes telecommunication, travel cost to meet various clients across India and abroad, training cost at various centres across India and abroad.

3.6 The period of agreement will be 5 years, and will be extended, if deems fit with concerned authorized people.

4 BUDGETS AND PAYMENT

The variable detail of study budget in INR is as follows & bifurcation of all the charges is as tabulated.

S.No	Particulars for each clinical trial	Amount	Comment
1.	Swami Rama Himalayan University (SRHU)	65%	Will be paid directly by sponsor/CROs
2.	Somaya Research and Health Services LL	35%	Will be paid through SRHU
3.	Lab Charges & Investigations	As per Actuals	Will be paid through Sponsor/CRO
4.	In Patient Charges / Hospitalization	As per Actuals	Will be paid through Sponsor/CRO
5.	Subject Travel Reimbursements	As per Protocol	Will be paid through Sponsor/CRO
6.	EC Charges + Archival fee	As per SOP	Will be paid directly from Sponsor to Institution (EC).
Invoice for each Study will be raised by Somaya Research and Health Services LL through the Institution.			

Swami Rama Himalayan University Registrar

SOMAYA RESEARCH AND HEALTH SERVICES LLP

4.1 **SRHS LLP** shall be conducting/ managing Clinical Research activities of the Clinical trial protocols as sanctioned at the study site during the tenure of the study. **SRHS LLP** shall not terminate this agreement during an ongoing study trail.

4.2 **SRHS LLP** shall not interfere in any Institutional Ethics Committee (IEC) procedures. If IEC will need any assistance from **SRHS LLP LL,** then Somaya Research and Health Services LLP will assist to IEC.

4.3 All payments shall be made by SRHU **to SRHS LLP** within 15 days of receiving its payment to its account from the Sponsors.

4.4 The **Somaya Research and Health Services LLP** will pay its **Project Managers, study Coordinators, other staffs employed** by it for the conduct of the studies at site.

4.5 The SRHS LLP shall give opportunity preferably to *in house* skilled clinical research personnel if available and also provide the internship for the outside student on fee basis (3k/month) and fee will be paid to the institute.

5 STUDY SPECIFIC MATERIALS & RIGHT OF USE

The SRHS LLP or the sponsor shall provide the institution with the data and documents needed for conducting the clinical research activities and guaranteeing the safety of the subjects.

The data and documents provided by the sponsor may be used solely for the conduct of clinical trials in accordance with this agreement.

6 CONFIDENTIAL INFORMATION

6.1 During the term of this Study Agreement, for a period of Five (05) years & after termination of this Study, neither party shall disclose or use for any purpose other than performance of the Study, any information including, but not limited to, any and all trade secrets, know-how, privileged records or other confidential or proprietary information and data both technical and non-technical (except as required under law disclosure to any governmental authority or any other person under the provisions of any applicable law, and also disclosure to their professional advisors/auditors and the like), disclosed by either Party to the other ("Confidential Information"). Confidential Information shall be in writing, clearly marked "Confidential Information" and sent by the either party directly to the Principal Investigator for this Study.

6.2 Both parties shall hold in confidence the identity of any Subject and shall comply with all applicable law(s) regarding the confidentiality of such Subject's records.

6.3 Each party shall promptly return to the other party any Confidential Information no longer needed for the purposes of this agreement or if so requested by the other party.

7 DISCLOSURE OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION

SRHS LLP & SPONSOR shall comply with all applicable laws and regulations regarding subject data privacy. In addition, SPONSOR will review and approve the Informed Consent and

Swami Rama Himalayan University Registrar

SOMAYA RESEARCH AND HEALTH SERVICES LLP

Authorization documents (collectively, the "Authorization Documents") relating to the use and disclosure of individually identifiable health information of subjects enrolled in the Study ("Health Information"), including receipt and use of Health Information by SPONSOR.

SPONSOR will require that any party to whom SPONSOR discloses Health Information ("Recipient") agrees, to use and disclose the Health Information only as permitted in the Authorization Documents and in accordance with all applicable laws and regulations. The Authorization Documents will not authorize the SPONSOR or any Recipient to use Health Information to recruit research subjects to additional studies, to advertise additional studies or products or to perform marketing or marketing research.

8 REPRESENTATION AND WARRANTIES

8.1 Each Party represents to the other that it has the necessary right and authority to enter into this Agreement and to the best of its knowledge, it is not party to any agreement which would prevent it from fulfilling its obligations under this Agreement.

8.2 SRHS LLP warrants to SRHU that it shall have and maintain appropriate/applicable licences, approvals, permits, certifications and the like necessary to lawfully perform its obligations under this Agreement.

9 TERM & TERMINATION

9.1 This agreement will be effective for the period of five years from **29 Aug 2022 to 28 Aug 2027** and can be further be extended as mutually agreed between both the parties.

9.2 This Agreement can be terminated by either Party, with or without mentioning any reason by giving at least thirty days notice in writing to the other Party. No compensation or damages shall be payable by either Party in the event of such termination but such termination shall be subject to the rights, obligations and liabilities already accrued in favour or against the Parties under this Agreement.

9.3 Either party may forthwith terminate this Agreement by written intimation to the other Party if the other Party goes into liquidation or is wound up or dissolution proceedings are initiated or if a provisional liquidator or receiver is appointed to take possession of its undertakings, business or assets.

10 DUTY TO UPDATE REGARDING SAFETY INFORMATION

SRHS LLP/SPONSOR shall notify Investigator in writing of any subject safety issues that may arise during the course of the Study and, thereafter, in accordance with concerned authorities requirements. In addition, if SRHS LLP/SPONSOR becomes aware of any findings through its site monitoring process that may possibly affect the safety or welfare of subjects enrolled in the Study, SRHS LLP/SPONSOR will notify the Institution/investigator through the Institution's authorized representative.

Swami Rama Himalayan University Registrar

SOMAYA RESEARCH AND HEALTH SERVICES LLP

11 INDEMNIFICATION

11.1 SRHS LLP/SPONSOR shall jointly and/or individually indemnify, defend and hold harmless the Institution, Investigator, and/or other affiliated and cooperating hospitals and institutions, as well as the directors, officers, agents, employees, students, the members of their Institutional Review Boards, and others holding appointments within those institutions and their respective heirs, successors, and assigns (collectively "Institution Indemnities"), from any liability, loss, or damage they may suffer as a result of claims or judgments that arise from the Institution Indemnities' participation in and/or performance of the subject Study. SRHS LLP/SPONSOR shall employ attorneys of its own selection and will be responsible for all expenses that result from employing a vigorous, diligent defense of Institution Indemnities, regardless of whether any claims are rightfully or wrongfully brought or filed.

11.2 Sponsor/CRO shall indemnify all Subjects for any damage or loss, including all medical expenses incurred for the emergency and/or long-term treatment of any injury that is directly a result of Subjects' participation in the Study and/or the use of the Study Drug/Device or the performance of any other intervention required by the Protocol or any SAE (Serious Adverse Event) routed through study site.

11.3 SRHU/Hospitals functioning under Institutions will not be responsible for any emergency/casualty/Serious Adverse Event happened during the ongoing trail. Notwithstanding any other terms contained in this Agreement, the Sponsor/CRO will reimburse the Institution for any reasonable, necessary and properly documented medical expenses directly as well indirectly related to a Study Subject's SAE in accordance with the provisions of the agreement.

12 AMENDMENTS

This Agreement may only be amended by the mutual written consent of both the parties.

13 INTELLECTUAL PROPERTY

It is expressly agreed that Institution does not transfer by operation of this Agreement to the other party hereto any patent right, copyright, nor other proprietary right that it owns or controls. All other inventions developed under this Agreement ("Other Inventions") that are developed solely by Institution shall be owned by Institution.

14 SEVERABILITY

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

15 FORCE MAJEURE

Any delay or failure of a party hereto to perform its obligations hereunder will be excused if and to the extent that it was caused by an event or occurrence beyond such party's reasonable control and without its fault or negligence ("Force Majeure"). Force Majeure includes, but is not limited to, acts of God, actions by any government authority, fires, floods, windstorms, explosions, riots,

Swami Rama Himalayan University Registrar

SOMAYA RESEARCH AND HEALTH SERVICES LLP

natural disasters, wars, sabotage or acts of terrorism, pandemic. A party claiming Force Majeure must provide the other party with written notice of such delay (including the anticipated duration of the delay) within ten (10) days of the occurrence of Force Majeure. If the delay lasts more than ninety (90) days, either Party may terminate this Agreement upon written notice. Regardless of whether this Agreement is terminated or naturally expires, SPONSOR shall be responsible for payment for all services or procedures actually performed in compliance with the study protocol and all non-cancellable Institution expenses incurred or obligated prior to termination or expiration and shall remit such total within thirty (30) days of Institution's written request for final payment. In the event of any overpayment by SPONSOR/CRO, Institution shall refund such overpayment to SPONSOR/CRO.

16 WAIVER

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

17 RELATIONSHIP OF THE PARTIES

The relationship of SPONSOR/CRO to Institution and Investigator shall be that of an Independent entity and none of the parties shall hold itself out to third parties as purporting to act as, or on behalf of, the other party hereto.

18 USE OF OTHER PARTIES' NAMES

Neither the SPONSOR nor the Institution shall use directly or by implication the names of the other party, nor any of the other party's affiliates or contractors, nor any abbreviations thereof, or of any staff member, faculty member, student, or employee of the other party in connection with any products, publicity, promotion, financing, advertising, or other public disclosure without the prior written permission of the other party.

19 NOTICES

That any notice, consent, waiver and/or other communication pursuant to this Agreement must be in writing signed by the person serving it, or by a person duly authorized by the person serving it, and will be deemed to have been duly given when (a) delivered by hand (with written confirmation of receipt); or (b) when received by the addressee, if sent by a recognized overnight delivery service (receipt requested), in each case to the designated persons and the appropriate addresses mentioned at the end of this agreement.

20 That this agreement will be executed simultaneously in two counterparts, each of which will be deemed to be an original but all of which together will constitute one and the same instrument.

Swami Rama Himalayan University Registrar

SOMAYA RESEARCH AND HEALTH SERVICES LLP

21 GOVERNING LAW AND DISPUTE RESOLUTION

The provisions and implementation of this Agreement shall be governed by the laws of India & courts at Dehradun, Uttarakhand alone shall have jurisdiction in the event of any dispute arising out of this agreement.

In the event of any dispute or difference between the parties hereto, whether arising during the currency or after the completion of this Agreement, or after the determination thereof (whether for breach or for any other reason) in regard to any matter or thing of whatsoever nature arising out of this Agreement or in / connection therewith, such disputes shall be resolved amicably by mutual discussion of both the parties, failing which, such dispute or difference shall be referred for arbitration, which shall be conducted a sole arbitrator, who shall be appointed by the mutual consent of both the parties. In case parties fail to appoint a sole arbitrator then the Parties shall appoint one arbitrator each who shall in turn jointly appoint the third arbitrator. The arbitration shall be conducted in accordance with provisions of the Arbitration and Conciliation Act, 1996, or any modification or any succeeding Act, at Dehradun Uttarakhand. The said arbitration shall be conducted in English Language & the award passed by the arbitrator shall be final & binding on the parties.

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Agreement as of the date first written above.

Registrar
Name: Dr. Susheela Sharma
Signature & Date: 13/9/22
Seal: Swami Rama Himalayan University – Registrar

Jolly Grant Dehradun

Director (SRHS LLP)
Name: PRITI PAL
Signature & Date: Priti Pal. 13/09/2022
Seal: Somaya Research and Health Services LLP

Somaya Research and Health Services LLP

Witnesses:
Name: Dr Nikku Yadav
Signature & Date: 13/09/22
Seal:

Witness:
Name:
Signature & Date: 13/09/2022
Seal: