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Certificate Issued Date	:	17-Jan-2024 10:16 AM
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Unique Doc. Reference	:	SUBIN-UKUK120140405033719527836W
Purchased by	:	SWAMI VIVEKANAND SUBHARTI UNIVERSITY
Description of Document	:	Article Miscellaneous
Property Description	:	NA
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First Party	:	SOMAYA RESEARCH AND HEALTH SARVICES LLP
Second Party	:	SWAMI VIVEKANAND SUBHARTI UNIVERSITY
Stamp Duty Paid By	:	SWAMI VIVEKANAND SUBHARTI UNIVERSITY
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Memorandum of Understanding (MoU)

This Memorandum of Understanding (herein after referred to as the "MoU") is made at Meerut, Uttar Pradesh on the **15th day of January 2024 ("Effective Date")** by and between **Somaya Research and Health Services LLP (SRHS),** (hereinafter referred to as "SMO") a private company incorporated under the Companies Act,2008, The LLP Identification Number (LLP IN) of the company is AAK-5114 and registered office address is Chowk Mandi, Tiraha, Opp. Govt. College Roorkee Urban, Haridwar, UK, India-247667. Also referred to as **First Party**

SOMAYA RESEARCH AND HEALTH SERVICES LLP

AND

Swami Vivekanand Subharti University, (SVSU) established under **section 2(f)** of the **University Grant Commission (U.G.C.) Act, 1956**, through **Swami Vivekanand Subharti Vishwavidhyalaya, Uttar Pradesh Adhiniyam, 2008 (U.P. Act No. 29 of 2008)** passed by Uttar Pradesh Legislature and assented by the honourable Governor of Uttar Pradesh in September 2008. University functions under the aegis of **Mahayana Theravada Vajrayana Buddhist Religious and Charitable Trust, Meerut** having its registered office at Subhartipuram, NH-58, Delhi-Haridwar Bypass Road, Meerut, India-250005 (Hereinafter referred to as "Site" or the **Second party).**

Somaya Research and Health Services LLP (SRHS) and **Swami Vivekanand Subharti University, (SVSU)** are individually referred to as **"Party"** collectively referred to as the **"Parties" .**

Somaya Research and Health Services LLP (SRHS) and Swami Vivekanand Subharti University, (SVSU) to enter a sole exclusive agreement and conclude to facilitate the Clinical Trials hereinafter define.

Subharti Medical College and Hospital, Meerut a duly recognised healthcare facility by National Medical Council, Govt. of India functions under the ambit of **Swami Vivekanand Subharti University (SVSU),** it is well equipped with modern medical facilities and renowned for its excellent healthcare services for the patient care and treatment to the rural/urban population

Somaya Research and Health Services LLP (SRHS) is a research organization 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.

Somaya Research and Health Services LLP (SRHS) is desirous of working with clinical investigators of the Institution under for the purpose of conducting ICH-GCP compliant- Phase I to IV Clinical Trials, BA/BE Studies, Instrumentation Studies, Epidemiology Studies for new drugs& treatments.
And **Somaya Research and Health Services LLP (SRHS)** have considered & reached an understanding on the following terms & conditions mutually agreed as follows.

19.02.2024

SOMAYA RESEARCH AND HEALTH SERVICES LLP

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 .....

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 hospital Swami Vivekanand Subharti University, (SVSU), Meerut UP

1.4 **"Study Sites"** means and include **Subharti Medical College and Hospital, Meerut** UP **"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".

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

1.6 **"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.

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

1.8 **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.

1.9 **"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.

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1.10 **"CRO (medical)'** Any public or private entity or agency or medical or dental facility where Clinical Trial(s) are conducted.

2 ROLES AND RESPONSIBLIIES OF ISTITUTION

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

2.1.1 The space and required facility (eg. Electricity, water, sanitation facility and one GDA) for conducting clinical trials will be provided by the Institution.

2.1.2 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.

2.1.3 The Investigator or Sub Investigator should follow ICH GCP, NDCT rules 2019, ICMR Guidelines and the protocol.

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

2.1.5 The Institute will provide EMR access to the SMO personnel for research if needed, subject to permission from CMS.

2.1.6 The Institute will provide the letter head to the SMO personnel for research data purpose only if required subject to approval of hon'ble VC of the University.

2.1.7 The institute will be responsible to archive all clinical trial documents if requested by the sponsor. In case the institute is requested for the archival then the services will be on a chargeable basis

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SOMAYA RESEARCH AND HEALTH SERVICES LLP

2.1.8 All Invoices made and payments received in regard to the concerned clinical trial will be notified to the **Somaya Research and Health Services LLP.**

2.1.9 Free and full access to all parts of the Site at reasonable time will be provided to first party.

2.1.10 Second party and Sponsor will enter into a clinical trial agreement before/ at the time of placement of above study at the study site,

2.2 After entering the clinical trial agreement, the total fee will be shared between the first and the second party. The payment will be payable on the basis of the actual receiving of funds from the Sponsor on actual work done i.e., number of patients randomized or visits completed. All payment shall be routed through the **site or SMO**.

3 ROLES AND RESPONSIBLIIES OF SOMAYA RESEARCH AND HEALTH SERVICES LLP

3.1 **Somaya Research and Health Services LLP** shall be is responsible for furnishing/ sanctioning the Clinical Trials to **the hospitals functioning under the Second party** – such as site *The hospital in which the clinical trial is conducted is referred as study site.*

3.2 **Somaya Research and Health Services LLP Project Manager** (here in after referred as PM) who will be responsible to coordinate and over-see the progress and management of CRC activities and trial to ensure data- quality and resolve screening/recruitment/ 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 **Somaya Research and Health Services 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, 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 **Somaya Research and Health Services 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

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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 extend if deems fit with authorized people concern.

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.	Overall Institution Fees (PI, CRC, Sub – I, & Other staff Including Over Head)	55 %	Will be paid directly by sponsor/CROs/SMO
2.	Somaya Research and Health Services LL Fees (PI, CRC, Sub – I, & Other staff Including Over Head)	45%	Will be paid directly by sponsor/CROs/Site
3.	Lab Charges & Investigations	As per Actuals	Will be paid direct to the Site
4.	In Patient Charges / Hospitalization	As per Actuals	Will be paid direct to the Site
5.	Subject Travel Reimbursements	As per Protocol	Will be paid direct to SMO
6.	EC Charges	As per SOP	Will be paid directly from Sponsor to Institution (EC).

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Invoice for each Study will be raised by Somaya Research and Health Services LL through the Institution.

4.1 **Somaya Research and Health Services 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. **Somaya Research and Health Services LLP** shall not terminate this agreement during an ongoing study trail.

4.2 **Somaya Research and Health Services LLP** shall not interfere in any IEC procedures. If IEC will need any assistance from **Somaya Research and Health Services LLP,** then Somaya Research and Health Services LLP will assist to IEC and Institute.

4.3 All payments shall be made by **Site to SRHS or SRHS to site** within 30 days of receiving its payment to its account from the Sponsors/CROs and vice versa.

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 is not bound give opportunity preferably to *in house* students.

5 CONFIDENTIAL INFORMATION

5.1 During the term of this Study Agreement, for a period of One (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, 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 TERM & TERMINATION

6.1 This agreement will be effective for the period of five years and can be further be extended as mutually agreed between both the parties.

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6.2 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.

6.3 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.

7 INDEMNIFICATION

7.1 Sponsor/CRO will indemnify all Subjects for 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.

7.2 **and** Hospitals functioning under Institutions will not be responsible for any 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 related to a Study Subject's SAE in accordance with the provisions of the agreement

8 AMENDMENTS

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

9 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.

10 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

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continuing waiver of the same term, provision or condition, or of any other term, provision or condition of this Agreement.

11 RELATIONSHIP OF THE PARTIES

In the activities connected with the trials Hospitals functioning under Institution agrees to act as an independent contractor without the capacity to legally bind Sponsor/CRO and also agrees that it is not acting as an agent or employee of CRO/Sponsor.

12 GOVERNING LAW AND DISPUTE RESOLUTION

The provisions and implementation of this Agreement shall be governed by the laws of India.

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, then said 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. The arbitration shall be conducted in accordance with provisions of the Arbitration and Conciliation Act, 1996, or any modification or any succeeding Act, at Meerut Uttar Pradesh. 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.

Head of Swami Vivekanand Subharti University, (SVSU)

Name:

Designation: Registrar

Signature & Date: 19.02.2024

Seal:

Director (Somaya Research and Health Services LLP)

Name: PRITI PAL

Designation: DIRECTOR

Signature & Date: 17/2/2024

Seal:

Head of Swami Vivekanand Subharti University, (SVSU)

Somaya Research and Health Services LLP

Witness: Gaurav Verma

Name: Gaurav Verma

Signature & Date: 19-2-2024

Seal:

Witness:

Name: Shubham Pomaz

Signature & Date: Shubham 17/10/24

Seal: