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Sub

Non Judicial		Indian-Non Judicial Stamp Haryana Government		Date : 07/08/2023	
Certificate No.	G0G2023H837		Stamp Duty Paid : ₹ 101 <small>(Rs. Only)</small>		
GRN No.	105779992		Penalty : ₹ 0 <small>(Rs. Zero Only)</small>		
<u>Seller / First Party Detail</u>					
Name:	Clins Research				
H.No/Floor :	F104	Sector/Ward :	Na	LandMark :	Sector omega ii
City/Village :	Greater noida	District :	Gautambudhnagar	State :	Uttar pradesh
Phone:	95*****79				
<u>Buyer / Second Party Detail</u>					
Name :	Swami Vivekanand Subharti university				
H.No/Floor :	Nh58	Sector/Ward :	Na	LandMark :	Meerut bypass rd
City/Village:	Meerut	District :	Meerut	State :	Uttar pradesh
Phone :	95*****79				
Purpose :	Agreement				



The authenticity of this document can be verified by scanning this QRCode Through smart phone or on the website <https://egrashry.nic.in>

AGREEMENT FOR CLINICAL TRIALS

This agreement is made on 07th Day of August 2023 at Delhi by and between Clins Research, is a Company Registered under Companies Act,, having its Registered Office at F-104, Sector Omega II, Pari Chowk, Greater Noida - 201308-U.P. India. hereinafter referred as "Clins/First Party" through its "Managing Director, Ms. Beauty Saraswat" duly empowered, authorized and represented in this regard, which expression shall, unless it be repugnant to the context or meaning thereof be deemed to mean and include its representatives, successors and assignees of the ONE PART.

And

Swami Vivekanand Subharti University, having address at Subhartipuram, NH-58, Delhi-Haridwar, Meerut Bypass Rd, Meerut, Uttar Pradesh 250005, India. a Hospital runs and maintains by Swami Vivekanand Subharti University, a Society duly registered under the Registration of Society Act, XXI of 1860, hereinafter referred to as "Swami Vivekanand Subharti University/Second Party" through its Authorized

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Signatory duly empowered and authorized in this regard, which expression shall unless it be repugnant to the context or meaning thereof, be deemed to mean and include its representatives, successors and assignees of the **OTHER PART**.

The Period of Performance is **07th Day of August 2023** for a period of five years from such date of execution, unless otherwise decided between Parties.

The *Clins Research* and *Swami Vivekanand Subharti University*, are individually referred to as a "Party" and collectively as "Parties".

This consortium partner memorandum of understanding (hereinafter referred to as an "Agreement") is by and between the undersigned "**Director**" of the "*Clins Research*" and the "**Authorized Signatory**" of "*Swami Vivekanand Subharti University*" whereas both parties have developed this agreement in accordance to the Clinical Research Agreement dated **07th Day of August 2023** Signed between them. This Agreement will serve as wherein both parties agree to provide integrated workforce services for the Clinical Research Activities at Subhartipuram, NH-58, Delhi-Haridwar, Meerut Bypass Rd, Meerut, Uttar Pradesh 250005, India

1. PURPOSE OF THE AGREEMENT

This Agreement will serve to describe each party's role of services as agreed upon between them vide the agreement of Clinical Trial **07th Day of August 2023** and in accordance to the terms and conditions mentioned herein.

Clins Research specializes in managing Clinical Trial at Hospitals and works with Medical Research Companies to find a suitable facility for holding Clinical Trials in successful execution.

That the Swami Vivekanand Subharti University, is hosting the Clinical Trial(s) in *consortium* with Clins Research, wherein the Swami Vivekanand Subharti University, shall provide the necessary space with all amenities(Chair, Table, Almirah And electricity port) for conducting and facilitating such clinical trial.

2. GOAL AND PRIORITIES

(1) Collaborate on Strengthening of Clinical Research Studies, including the operation for successful execution

(2) Improve efficiency by eliminating redundancies and sharing best practices; and

Improve results by developing and implementing new and innovative approaches.

3. THE PARTIES:

a) The Swami Vivekanand Subharti University, is a hospital/Medical College/University engaged in the providing Healthcare & Medical consultation, diagnosis, treatment by Doctors and prevention of disease to the patients.

b) **Clins Research** is engaged in the activities of:

(i) Identifying entities such as Clinical Research Organizations and Pharmaceutical Companies (hereinafter "Sponsors") who requires to conduct clinical trials; and

(ii) Managing all activities pertaining to clinical trials(Including Clinical trial documentation, EDC, eCRF, CRF, Trained CRC, Pharmacist etc.) and matters connected thereto, including obtaining Ethics Committee Approvals, etc.;

c) Pursuant to discussions between the Parties and in accordance with the requirements of the Sponsors, the Swami Vivekanand Subharti University, undertakes to provide, assistance to enable the proper and efficient conduct of the clinical trials.

NOW, THEREFORE, this Agreement WITNESSETH and the Parties mutually agree to the following terms and conditions:

4. SERVICES SUPPORTED BY THE AGREEMENT:

At a minimum, the following services will be provided by each party as described below:

Clins Research shall, during the term of this Agreement,

a) Identify Sponsors who require clinical trials to be conducted at the Swami Vivekanand Subharti University, (hereinafter referred to as "Site") and promote the site activity to improve the Clinical Trials.

- b) Shall place the sufficient staff, trainees, and personnel to coordinate and for data compilation, etc.
- c) Shall assist the Swami Vivekanand Subharti University, in conducting such clinical trials in accordance with the protocols, New Drug Clinical Trial (NDCT) Rule, The International Council for Harmonization (ICH), and Good Clinical Practice (GCP).
- d) Shall conduct studies only after submission of applicable EC Review fees & it is approval by Institutional Ethics Committee(IEC), an ethical committee that reviews Clinical Trial insights and allows to conduct Trial at Swami Vivekanand Subharti University.
- e) Shall perform all procedures legally and ethically after due permissions from Drug Controller General of India (DCGI) and other necessary government/regulatory authorities as required are obtained.
- f) Shall not conduct any protocol-related procedures without obtaining duly signed informed consent of the patient/authorized person in every case/trial.
- g) Shall not indulge in any activity which will bring disrepute to the Swami Vivekanand Subharti University, from use of the Site will assure for indemnification to the second party in this regards.
- h) The Staff so assigned shall maintain the documents safely in their custody until the trial is completed.
- i) Shall provide Standard Operating Procedures (“SOP”) for the conduct of trial and studies in accordance with applicable regulations.
- j) In case any modification in the SOP Same will be notify to the EC of Swami Vivekanand Subharti University without any delay.
- k) Shall have a copy of agreements made between sponsors or its delegates and itself accessible to the Swami Vivekanand Subharti University, and conduct all such agreements in a transparent manner.
- l) Shall actively participate in its routine monitoring by the sponsor as well as audit if any.

Without prejudice to the generality of the foregoing, the Swami Vivekanand Subharti University, shall provide the following:

The Swami Vivekanand Subharti University, shall conduct the clinical trials as per law in accordance with the protocols specified by the Sponsors.

- a) Access to the concerned personnel of the Swami Vivekanand Subharti University, to whom Clins Research ensure such access to be necessary, for educating / training program.
- b) Execution of the required documentation and undertake other actions to ensure that the required permissions form the Ethics Committee authorities are obtained in a prompt and timely manner.
- c) Shall provide suitably qualified Investigator and Sub investigators who will devote the necessary time and be wholly and solely responsible for the medical care and safety of the patients.
- d) The Investigator or Sub Investigator should follow The International Council for Harmonization (ICH), Good Clinical Practice(GCP), Schedule Y, The Indian Council of Medical Research (ICMR) Guidelines and the protocol.
- e) The Swami Vivekanand Subharti University, shall provide sufficient space and other amenities (access of laboratory, departments, EC etc.) , as required for the conduct of the study.
- f) The Swami Vivekanand Subharti University, shall provide facilities for archival of the documents after the completion of the study as per requirements and archival fee as per applicable fees in SOP.
- g) Swami Vivekanand Subharti University, shall support schedulingan Ethics Committee meetings and signing a Clinical Trial Agreement with Other Ethics Committee Notifications.

The Parties shall jointly set up and serve on a regional advisory committee(s), along with representatives, to ensure the timely execution of deliverables and to support the programs as per the MOU;

5. MEMBERSHIP OF THE AGREEMENT:

- a) That this Consortium shall continue to be in existence and shall continue to function even after the ownership or hold on the Swami Vivekanand Subharti University,

changes and there is a merger, acquisition, sale, etc. That Clins Research shall proceed to function along with the new management of the Swami Vivekanand Subharti University, in the same capacity and the same terms. and vice-versa for Clins Research.

b) That Clins Research has the obligation and duty to complete all the projects in relation to the ongoing clinical trial and shall not be prevented from doing the same.

c) The Consortium may be dissolved at any time after the clinical trial is concluded, by unanimous decision of both Parties and any member of the consortium who by acts or omissions fails to observe the terms of this Memorandum may be liable to be removed from the Consortium or be penalized.

d) Parties/Members of the consortium undertake that, while they are members of the consortium, they will at all times act in good faith towards other members of the consortium; and will not enter into discussions with any other party or parties who may be considering making a bid for a contract/agreement/MOU for the Site, or who might be considered to be in competition with the consortium either presently or in the future, without the full knowledge and consent of the other Party.

6. TERM:

The term of this Agreement shall be for five years commencing on the date of the signing of the Agreement by both the Parties in subject to annual review.

The Agreement will renew after five years term unless cancelled by a written notice between the Parties 30 days prior to the end of the current term.

7. PAYMENT:

That Clins Research shall pay to the Swami Vivekanand Subharti University, for each study.

a) Institutional overhead (as per Institution norm that is shall be paid to Hospital as per Clinical Trial Agreement (CTA)).

- b) Principal Investigator (PI) fee, shall be paid to PI/Hospital as per Clinical Trial Agreement (CTA).
- c) Swami Vivekanand Subharti University, will generate GST Invoice as per CTA to Clins Research after the Site Monitoring completed by Sponsor or completed the subject visits and it should be clarified from accounts department of Swami Vivekanand Subharti University, as well as applicability of taxes, if Any.
- d) Swami Vivekanand Subharti University, shall generate GST invoice of PI fee & Institution fee & Lab (as per actual) Excluding of Subject Reimbursement .
- e) All payment shall be made by Clins Research within twenty (21) days of receiving Invoice from Swami Vivekanand Subharti University.
- f) The Clins Research shall be solely and wholly responsible for payment of wages to the employees/staff and for looking after their welfare and statutory requirements as per the Labour Law in force from time to time. The Clins Research shall maintain proper records of employee/staffs. The Swami Vivekanand Subharti University, shall not be responsible for any lapse on this account. The Clins Research will obtain police verification of antecedents of its employees prior to deputed him/her in the premises of the hospital. Individuals possessing adverse police verification report are not to be deployed in the Hospital. Also, personnel deployed by the Clins Research while on work inside the Hospital, shall be in proper uniform supplied by the Clins Research at its own cost. The Clins Research shall issue identity card, on its own name and trading style, to its personnel deputed for its work and they shall maintain courtesy and discipline in the Hospital without creating any nuisance or misbehave with any employee, patients, attendants and visitors of the Hospital, failing which the hospital may require Clins Research not to deploy such of its errant staff in the hospital and impose any penalty for the same. Further at night, sleeping in Swami Vivekanand Subharti University, premises will not be permitted and no extra personnel will be allowed to stay in the Swami Vivekanand Subharti University, premises except on duty staff of Clins Research.

The Swami Vivekanand Subharti University, shall not be liable to any claim or damages or compensation that might become payable to the employees/ staff of Clins Research in the event of an accident resulting in any possible injury or death

of an employee of Clins Research while performing his/her work within the premises of damage of any other kind. The Clins Research shall always keep Swami Vivekanand Subharti University, fully indemnified against all losses, damages, claims and actions taken against Swami Vivekanand Subharti University, by any authority/Government Department (The Ministry of Labor& Employment) in this regard.

- g) Travel reimbursement for all patients for the purpose of trials shall be borne by the Clins Research.
- h) Swami Vivekanand Subharti University, will issue a No Objection Certificate (NOC) for Each Study after Invoice Payment.

8. Confidentiality:

Each member of the consortium agrees that the content of discussions between individual members of the consortium and the members alone;

As the contents of the program are highly confidential and classified the same shall be attempted to be protected by both Parties mutually and not merely by Clins Research. It shall be the duty and obligation of the Swami Vivekanand Subharti University, to protect any such information relating to this program and the same shall be protected.

The content of documents relating to the program under the consortium and the information submitted therein shall be treated as confidential by all members of the consortium and no such information or document will be disclosed to any other individual or organization at any stage; and this obligation of confidentiality of the Consortium will remain binding indefinitely whether or not members shall have left the consortium or this agreement has lapsed.

That the Swami Vivekanand Subharti University and Clins Research shall not disclose or keep the terms and conditions of agreement confidential and shall not mention it to any one, directly & indirectly, intentionally or un-intentionally, impliedly or otherwise to anyone who is not a part of this Agreement.

That it is the sole responsibility and duty of the both parties to ensure the confidentiality with respect to process, result etc. of the clinical research project taking place at the Site.

9. Non-Compete and Non-Circumvention:

That the Swami Vivekanand Subharti University, agrees that:

- a) They Swami Vivekanand Subharti University, or any Clinical Trial related staff or Investigator of Swami Vivekanand Subharti University will not reach any of Clins Research Client directly or indirectly and shall interact with Clins Research alone for all such professional or transactional purpose and,
- b) Any such contact or attempt shall lead to a breach of this agreement.

10. Intellectual Property Rights:

The Parties acknowledge that nothing in this agreement shall affect ownership of any intellectual property rights and any Intellectual Property Rights arising from the trial or otherwise at the site, during the existence of this agreement, shall belong to Clins Research/Sponsor alone and Institutional Ethics Committee, Swami Vivekanand Subharti University.

11. Miscellaneous Provisions and Exhibits:

A. Mutual Respect of Organizational Practices

Parties agree to respect each other's organizational practices and management structures in the provisions of services under this Agreement and agree to work forward with uttermost co-operation and co-ordination and assist with respect to furtherance of the objectives of this MOU;

B. Indemnification/Insurance and Liability

By executing this Agreement, each party agrees to work together with respect to furtherance of the terms and conditions as have been agreed upon herein and as per the terms of the Clinical Trial Agreement;

However, the entities are not legally “partners” to the extent that term encompasses joint and several liabilities. Each legal entity under the Agreement is responsible for its own employees, representatives, agents and subcontractors.

That Clins Research shall take all necessary steps and actions required in order to ensure that no loss, damage, etc. shall occur to the Swami Vivekanand Subharti University. In the event that any such damage or loss or injury occurs during related Clinical Trial Project, the Sponsor takes the full and absolute responsibility of indemnifying Clins Research and undertakes all and absolute liability on their behalf towards SWAMI VIVEKANAND SUBHARTI UNIVERSITY, for any loss suffered at Swami Vivekanand Subharti University. As in Clinical trial, the Sponsor who indemnifies to stakeholders of any Clinical trial Project is the one who is wholly and solely liable for any claim, damages and death. Without indemnification Letter/Insurance from Sponsor no Clinical trial will be executed by Clins Research at Swami Vivekanand Subharti University.

C. Others

- The Clins Research shall obtain for self and for SWAMI VIVEKANAND SUBHARTI UNIVERSITY, necessary approval(s), permissions(s), registration(s), license(s) etc. which are/may be applicable and required in respect of executing the present contract for Clinical Research Trials under the laws of the State and Central Government already in existence or enforced in the future pertaining to the type of Clinical Research Trials to be conducted in the SWAMI VIVEKANAND SUBHARTI UNIVERSITY, under the subject agreement and shall submit a copy thereof to the Swami Vivekanand Subharti University. The Clins Research shall also keep all the requisite approval(s), permission(s), registration(s), license(s) etc, and/or under any other applicable law valid throughout the period of this agreement.
- The Clins Research shall inform and provide guidance, assistance to the SWAMI VIVEKANAND SUBHARTI UNIVERSITY, necessary approval(s), permission(s), registration(s), license(s) etc, which are/may be applicable and required in respect of executing the present agreement under the laws of the State and Central Government already in existence or enforce in the future.

- In case of any dispute or difference arising out of or in connection with the present agreement, at any point, shall be first discussed under mutual discussions of both the parties. In case of non-agreement same be referred to the Director General Medical of Swami Vivekanand Subharti University, Group of Hospitals and his decision shall be final and binding on both the parties.
- All the matters arising between the parties to the agreement shall be subject to the jurisdiction of Court Meerut/Tribunals, but only after the decision of the Director General Medical of Swami Vivekanand Subharti University, Group of Hospitals as mentioned above of this agreement.
- Prior to going to the court, hospital will schedule a mutual meeting about the issue arise from subject / hospital management for the resolution.
- Intelligent Protection Right: The first right on the data / result of the clinical Study/research will be of Sponsor only.

12. Modification Process:

This Agreement, together with the exhibits identified above, constitutes the entire agreement between the Parties and supersedes all prior written or oral understandings. This agreement and said exhibits may only be amended, supplemented, or modified by a duly executed written instrument. Both parties to this agreement will comply with all applicable requirements of Union, State and Local laws, executive orders, regulations and policies governing this program.

13. Exit from Agreement & Termination Clause:

Each Party shall have to previously give notice to the other Party 90 days in writing subsequent to which the issue of such notice or intention to terminate shall be discussed. The other Party shall be awarded an opportunity wherein the matter shall be discussed and a solution to resolve the issue be discussed. Termination of this Agreement shall be done only exceptional circumstances wherein both Parties are mutually agreeable to the same. The agreement shall not, however be terminated on the basis of a mere disagreement or a simple dispute between the Parties with regard to functioning, etc.

If the Agreement is terminated by either Party, steps shall be taken to ensure that the termination does not affect any prior obligation, project or activity already in progress.

Any notice to be given shall be deemed validly given if delivered personally, sent by express delivery service, registered or certified mail, postage prepaid, return receipt requested shall be provided to both parties and the same shall be sent to the registered address of the respective Parties mentioned hereinabove.

Any notice to be given to any party, shall be deemed given on the date of actual receipt by the addressee if delivered personally, on the date of deposit with express delivery service or the postal authorities if sent in either such manner.

14. SIGNATURE OF PARTIES:

NAME	Ms. Beauty Saraswat	NAME	Syed Zafar Hussain
DESIGNATION	Managing Director	DESIGNATION	Registrar (S).
ORGANIZATION WITH ADDRESS	Clins Research, #F-104, Sector Omega II, Pari Chowk, Greater Noida – 201310, India.	ORGANIZATION WITH ADDRESS	Swami Vivekanand Subharti University, Subhartipuram, NH-58, Delhi-Haridwar, Meerut Bypass Rd, Meerut, Uttar Pradesh 250005, India
SIGN WITH DATE AND SEAL	<p><i>Saraswat</i> 07/Aug/2023</p> 	SIGN WITH DATE AND SEAL	<p><i>[Signature]</i> 07/8/2023</p> 
NAME OF WITNESS	Ravindra Lal Singh	NAME OF WITNESS	
DESIGNATION	Site Start-up manager	DESIGNATION	

SIGN WITH DATE

Ravinder
7th Aug 2023

SIGN WITH DATE