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Purchased by	:	GEORGE INSTITUTE FOR GLOBAL HEALTH
Description of Document	:	Article 5 General Agreement
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Swami Rama Himalayan University Director Research

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This stamp paper forms an integral part of the CTA executed by and between George Institute for Global Health and Swami Rama Himalayan University and Dr. Hemant Kumar Nautiyal.

GEORGE INSTITUTE FOR GLOBAL HEALTH

Swami Rama Himalayan University Registrar

Dr. HEMANT NAUTIYAL
Professor and Head
Advanced Laparoscopic
Bariatric and Metabolic Surgery
HIMS, UKMC : 2671

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CLINICAL TRIAL/RESEARCH ACTIVITY AGREEMENT

This Clinical Trial Agreement (hereinafter the "**Agreement**") is executed at New Delhi with effect from 28 January 2025 (hereinafter referred to as the "**Effective Date**") between;

GEORGE INSTITUTE FOR GLOBAL HEALTH (CIN U74900TG2007NPL055085), a company registered under section 25 the Companies Act, 1956 (India), having its office at 308, Third Floor, Elegance Tower Plot No. 8, Jasola District Centre, New Delhi 110025 (hereinafter referred to as "**GIGH**", which expression shall, unless repugnant to the meaning or context thereof, be deemed to include its agents, representatives, administrators, and assignees, as applicable) of the First Part;

AND

Swami Rama Himalayan University, having PAN AAAJH0463L and having registered address at Swami Rama Nagar, Jollygrant, Dehradun, Uttarakhand, India (248016), a University registered under section 2(f) of UGC Act,1956 and enacted vide Uttarakhand Act no. 12 of year 2013, for its unit **Himalayan Institute of Medical Sciences** through its Registrar Commander Challa Venkateshwar (hereinafter referred to as the "**Institution**," which expression shall, unless repugnant to the meaning or context thereof, be deemed to include its agents, representatives, administrators, and assignees, as applicable) of the Second Part;

AND

Dr Hemant Kumar Nautiyal the Investigator at the Institution, with office at Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Swami Rama Nagar, Jollygrant, Dehradun, Uttarakhand, India (248016) (hereinafter referred to as the "Investigator," which expression shall, unless repugnant to the meaning or context thereof, be deemed to mean and include his/her heirs, representatives and assigns) of the Third Part;

(Each of GIGH, the Institution, and the Investigator may hereinafter be referred individually as a "**Party**" and collectively as the "**Parties**.")

WHEREAS GIGH, as a sponsor is conducting a study, known as the Effects of Advanced Trauma Life Support ® Training Compared to Standard Care on Adult Trauma Patient Outcomes: A Cluster Randomised Trial (hereinafter referred to as the "**Study**").

AND WHEREAS GIGH wishes the Study to be conducted in terms of the protocol (including amendments made thereto from time to time), attached hereto as Exhibit A (hereinafter referred to as the "**Protocol**");

AND WHEREAS GIGH may also conduct sub-studies from time to time (hereinafter referred to as each "**Sub-Study**") in conjunction with the Study, and upon written notification of a Sub-Study, all applicable references in this Agreement to 'Study' shall include such Sub-Study and all references in this Agreement to 'Protocol' shall include the protocol related to such Sub-Study;

AND WHEREAS Investigator and Institution possess the resources and expertise to carry out the Study at the site (s) of the Institution (hereinafter individually referred to, for the purposes of this Agreement, as the "**Study Site**"), and wish to assist GIGH in conducting the Study;

NOW THIS AGREEMENT WITNESSETH AND HEREBY RECORD THE RIGHTS AND OBLIGATIONS AGREED UPON IN CONNECTION WITH THE PERFORMANCE OF THE STUDY BY AND BETWEEN THE UNDERSIGNED PARTIES AS FOLLOWS:

1. PERFORMANCE OF THE STUDY

1.1. Institution and Investigator shall carry out and conduct the Study at the Study Site in strict conformance with:

(i) the terms of this Agreement, the Protocol and the written instructions or any advice issued by GIGH;

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Dr. HEMANT NAUTIYAL Professor and Head Advanced Laparoscopic and Metabolic Surgeon UMC : 2671

(ii) generally accepted standards of good clinical practice, New Drugs and Clinical Trials Rules, 2019 and National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 and Applicable laws and, if applicable, international treaties and regulations, as amended from time to time.

(iii) all applicable Study documents which are duly approved by the governing Institutional Review Board/Independent Ethics Committee Board (hereinafter referred to as the **"IRB/ IEC"**);

1.2. Institution and Investigator represent and agree that:

(i) they have, and at all times during the course of the Study shall have, personnel with appropriate training, information, licenses, approvals, and certifications as are necessary to safely, adequately and lawfully perform, conduct and coordinate the Study in accordance with the Applicable Laws;

(ii) Investigator has not been debarred pursuant to any Applicable Laws or by any regulatory authority; and neither the Institution nor the Investigator have been disqualified from participating in a clinical study by any regulatory authority.

(iii) Investigator is currently, and shall throughout the performance of the Study, be authorised to perform his/her duties under this Agreement; and

1.3. Investigator shall obtain written approval from the Study Site's IRB/IEC for the Protocol. Investigator shall ensure verbal and/or written consent, as per IRB/IEC approval, are obtained from each human subject (hereinafter referred to as the **"Participant"**) or their authorized legal representative(s). Consent shall be obtained in the format specified by GIGH in sample "Consenting Documents". Additional information may be added to the sample Consent Documents after obtaining approval from GIGH, if required by the IRB/IEC and Institution. The Institution /Investigator shall, where required, maintain each Participant's audio-visual recordings of consenting process in the Participant's permanent record in addition to the written consent. Such audio-visual recording and related documentation must be preserved adhering to the principles of confidentiality by the Investigator.

1.4. It is anticipated that up to 4320 participants will be recruited from approximately 30 centres in India. The Investigator shall start recruiting Participants only after receiving written authorisation from GIGH to start recruitment, which shall be provided after receipt of all relevant documentation at GIGH. GIGH reserves the right to limit the recruitment of further Participants or cease the recruitment at the Study Site, on reaching the recruitment target or even otherwise. Upon written notice, the recruitment shall be ceased immediately.

1.5. Institution and Investigator undertake that there are no other agreements or understandings with third parties or any conflict in the performance of the Study or the acceptance by a regulatory authority of the data collected by the Study Site.

1.6. Institution and Investigator agree to provide to GIGH, any documentation required by regulatory authorities and/or under Applicable Laws, including but not limited to any documentation or information that relates to disclosure of Institution and Investigator's interests, including any financial interests of the Institution/Investigator, in the Study.

1.7. Institution agrees that they shall promptly notify GIGH in the event of any debarment, conviction, threat, disqualification or indictment of Investigator or any person who has provided services under this Agreement, during the term of this Agreement or three (3) years following its expiration or earlier termination.

1.8. Investigator may appoint other individuals as may be deemed appropriate and approved by the Institution (**Study Team**") to assist in the conduct of the Study in accordance with the Protocol. Investigator shall be solely responsible for the Study and for leading the Study Team, which shall be bound by the same obligations as Investigator under this Agreement.

1.9. All correspondence from any regulatory authority or the IRB/IEC in relation to the study shall be shared with GIGH immediately. Institution and/or Investigator shall take appropriate action in this regard including actions in accordance with the lawful instructions and advice of GIGH.

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1.10. Institution and Investigator shall prepare and maintain complete and up to date accurate medical records, accounts, medical notes, reports, and data including all supportive documentation for each Participant (hereinafter referred to as the "**Source Documents**") in accordance with the operating procedures required by GIGH and the Applicable Laws. Such information shall be recorded into the database via the corresponding electronic Case Report Forms (eCRFs) found in the web-based management system for each Participant, if and as required by the Protocol. Investigator shall ensure no information that would personally identify a Participant be provided to GIGH. GIGH shall be consulted before any Source Documents are destroyed.

1.11. The Institution and Investigator shall immediately inform GIGH of any Adverse Events and/or Serious Adverse Events ("**SAE**"), as defined in the Protocol provided by GIGH.

1.12. Investigator and/or the Institution shall submit periodic reports to GIGH regarding progress of the Study, in GIGH's agreed form and manner.

1.13. Institution and Investigator shall cooperate and permit, upon the request of GIGH or an official of any regulatory authority, such party to examine and inspect Institution's facilities and equipment required for performance of the Study and inspect and copy all data, reports, work products and results relating to the Study. If the Institution or the Investigator is notified of an inspection by a regulatory authority, the same shall be immediately informed to GIGH. GIGH or any person designated by them shall also be authorized to participate, to the extent permitted under Applicable Laws. Information arising out of the inspections shall also be shared with GIGH as per the Applicable Law. Institution and/or the Investigator shall bear their own cost and/or expense in relation with any audits and/or inspections instructed by any regulatory authority

1.14. GIGH to send the DSMB report (if applicable) and its timely submission to EC.

1.15. In the event that Investigator leaves Institution or otherwise becomes unavailable during the term of this Agreement, Institution shall make reasonable efforts to find a replacement investigator of similar expertise and qualifications who is acceptable to both Institution and GIGH. Replacement Investigator shall be bound by all the terms and conditions hereunder and, where required by GIGH, a new agreement will be executed between Institution, the replacement investigator and GIGH.

1.16. From time to time, GIGH may modify the Protocol by written notice to Institution and Investigator. Except where the modification is necessary to eliminate an immediate hazard to Participants or involves only logistical or administrative aspects of the trial, any modification may not be implemented before approval by the IRB/IEC.

1.17. Neither Institution nor Investigator shall conduct any other study, investigation or trial on the Participants recruited for the Study without prior intimation to GIGH

1.18. GIGH represents and warrants that:

i. It has the absolute right and authority to provide any or all material and information ("**Materials**") as per the Protocol for the purpose of the Agreement.

ii. The signatory to the present Agreement is having the right and full authority to enter into this Agreement and the Agreement so executed is binding in nature.

2. PERFORMANCE PERIOD

2.1 This Agreement commences from the Effective Date. Unless terminated early, this Agreement terminates on Study Completion.

3. DUTIES AND RESPONSIBILITIES OF THE PARTIES

3.1 In addition to applicable provisions of clause 1 of this Agreement, GIGH shall be responsible for:

(i) obtaining the necessary approvals or authorisations for the conduct of the Study in India, and coordinate the Study in India;

(ii) making timely payments to the Institution subject always to approvals mentioned in clause 3.1(i) above;

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(iii) overall conduct of the study including monitoring and evaluation of study sites in India; and

(iv) Advise and provide information to the Institution and to the IRB/IEC as and when necessary and update the appropriate Regulatory Authorities of:

a) Any SAEs/adverse events/risk information; or

b) The cessation elsewhere of any relevant trial of the Study drug or intervention (or closely related products); or

c) The withdrawal of the Study drug (or closely related products) from any other market for safety reasons; or

d) Any other information available to justify any variations to the Study Protocol and the nature, scope and duration of the Study.

3.2 In addition to applicable provisions of clause 1 of this Agreement, Institution and Investigator shall be responsible for:

(i) obtaining the necessary consents, approvals or authorisations for the conduct of the Study at the Study Site;

(ii) obtaining and maintaining approvals or communications from the IRB/IEC;

(iii) ensuring the protection of the rights, safety and well-being of Participants, and the scientific integrity of the Study;

(iv) submitting the requisite documentation to the relevant regulatory authorities from time to time during and after the conclusion of the Study;

(v) providing Investigator with materials, access to personnel, facilities and information as may be reasonably required to satisfactorily perform the Study;

(vi) exercising due care and skill and work in a competent and professional manner in carrying out their obligations under this Agreement;

(vii) ensure that the equipment used for conduct of the Study are properly maintained;

(viii) monitoring to ensure that no unlawful or unethical activity arises during the conduct of the Study at the Study Site; and

(ix) any agreement concluded, or arrangement reached with the Study Team appointed by them, if any, shall be subject to the provisions of this Agreement.

(x) Institution shall be responsible for maintaining the Master list of identifiable data which could be linked to the stored data for any future reference. Storage of hard copy is responsibility of the Institution.

4. OWNERSHIP OF DATA, RESULTS, INTELLECTUAL PROPERTY

4.1 The Parties acknowledge and agree that GIGH shall have all right, title and interest in and to all data and results of the Study, including without limitation all inventions, patents, tests, applications, creations, research data, intellectual property, processes, methods, software, tangible research products, formulas and techniques, improvements thereto, and know-how related and Confidential Information that may be developed, produced, created, furnished or disclosed by any Party made during the conduct of the Study, or arising from the performance of the Study which shall be communicated immediately to GIGH.

4.2 The ownership of any or all intellectual properties owned by the Parties before the execution date of this Agreement by the Institution (**"Background IP"**) shall remain with such Party.

4.3 If GIGH and/or its assignee desires to file patent applications as a result of discoveries made during the Study, the Institution and Investigator shall assist in the preparation of such patent applications.

4.4 Each party will not use the other party's/ies' Background IP in any publicity, advertising or news release without the prior written consent of the other party/ies. However, the Intellectual Properties may be used for the proper performance of the services under this Agreement.

4.5 The parties will not infringe the Intellectual Property Rights of a third party or misappropriate any Know How or Intellectual Property Rights of a third party.

Swami Rama Himalayan University Director Research

Swami Rama Himalayan University Registrar

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