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Certificate No.	:	**IN-DL86787903446716W**
Certificate Issued Date	:	14-Nov-2024 03:53 PM
Account Reference	:	IMPACC (IV)/ dl777003/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL77700320595321826017W
Purchased by	:	GEORGE INSTITUTE FOR GLOBAL HEALTH
Description of Document	:	Article 5 General Agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	GEORGE INSTITUTE FOR GLOBAL HEALTH
Second Party	:	Not Applicable
Stamp Duty Paid By	:	GEORGE INSTITUTE FOR GLOBAL HEALTH
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

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 Surgeon
HIMS, UKMC : 2671

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

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.

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4.6 The Institution and Investigator shall have a right to use the Study results for non-commercial research and teaching purposes only after the Multi -Centre Publication of the result of the Study or with the prior written permission of GIGH.

5. PUBLICATION

5.1 Institution and Investigator each acknowledge and agree that unless approved by the committee ("**Steering Committee**") appointed by GIGH to oversee the multi-centre Study, there shall be no publication, report, release, disclosure or likewise of any preliminary or final Study findings or results prior to release of the first publication of Study findings or results ("**Multi-Centre Publication**"). Attribution and authorship in the Multi-Centre Publication shall be given in accordance with academic standards and/or as per the International Committee for Medical Journal Editors (ICMJE).

5.2 The Steering Committee and GIGH may at any time disclose or publish all information as they may reasonably decide where such disclosure or publication relates to the safety of the Participants, patients in general, or the general public.

5.3 Proposals for all publications, abstracts, and other presentations arising from the Study shall be submitted for approval to the Steering Committee through GIGH at least four (4) weeks prior to the date it is intended to be submitted for publication. The Steering Committee or a subcommittee thereof, may recommend changes prior to approval.

5.4 No Party shall use the name of any other Party in any advertising or promotional material without having received the prior written consent of such other Party, provided that:

(i) a Party may acknowledge, in general terms, the existence of this Agreement;

(ii) GIGH (or its affiliates) may state on its website or in any Study material that Institution is a participating site of the Study and Investigator is the investigator of the Study at the Study Site; and

(iii) Institution may acknowledge receipt of financial support from GIGH for the Study at the Study Site.

6. PAYMENTS

6.1 The full & final amounts/fees (inclusive of taxes) and terms of payment payable by GIGH to the Institution for performance of the Study are set forth in the Payment Schedule and Payment Rule Form that is attached hereto as Exhibit C (hereinafter referred to as the "PRF").

6.2 Institution and Investigator each agree and undertake not to seek any payment from any third party or Participant for any services provided to a Participant in connection with such Participant's participation in the Study or the costs incurred in connection therewith.

6.3 Institution shall be responsible for the payment of any or all taxes applicable on the income received pursuant to this Agreement, including, without limitation, for paying any GST or similar tax imposed by the taxation authorities in any jurisdiction.

6.4 Institution and Investigator shall inform GIGH in writing not later than one (1) month of any discrepancies that may exist in the payment(s) received. Institution and Investigator shall have waived, all rights to receive further compensation in connection with the Study, if such discrepancies is not raised within the said period.

6.5 Institution warrants that the Payee as per Exhibit C, wherever different from the Institution name, is part of or an affiliate of the Institution and that the Institution shall remain responsible for all obligations under this Agreement.

7. CONFIDENTIALITY & PRIVACY

7.1 The Parties acknowledge and agree that they shall not disclose or publish Confidential Information to any third party, other than in accordance with this clause 7. For the purpose of this Agreement, "**Confidential**

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Information" shall mean any confidential or proprietary information, including without limitation, any derivatives thereof, which is confidential and proprietary in nature, including, but not limited to, intellectual property; internal practices and procedures; feedback relating to any results of the Participant,; deliverables information, all information collected in the course of, resulting from, or arising directly out of the conduct of the Study, whether at the Study Site or elsewhere, the Protocol, and information related to the Protocol and Study materials, know-how, trade secrets, ideas, concepts, technical and operational information, scientific or technical processes or techniques, methodology, processes, sequences, structure and organisation of the Study; other information relating to disclosing Party's business, including, without limitation, the terms and conditions of this Agreement; and any third-party confidential information. ;
Confidential Information shall not include information:

a) which is published in accordance with the Publication Section of this Agreement,
b) which a Receiving Party can demonstrate through contemporaneous written records was in its possession prior to disclosure by the Disclosing Party,
c) which is in the public domain or which later becomes part of the public domain other than by breach of this Agreement by a Receiving Party,
d) which is lawfully disclosed to a Receiving Party by a third party not obligated to the Disclosing Party to keep the information confidential, and
e) which is required to be disclosed by law, or by order of a court of competent jurisdiction to the extent necessary.
f) which is used or disclosed for absolute performance of the Study or performance of the obligations under this Agreement to the extent necessary.

7.2 The obligations of confidentiality under this clause 7 shall be binding for the term of this Agreement and shall survive for a period of ten (10) years after expiry or termination of this Agreement.

7.3 Each Party agrees to comply with all applicable privacy laws and regulations regarding the collection, use, disclosure, holding and protection of personal and/or health information.

7.4 In the event that GIGH shall come into contact with Participants' medical records, GIGH shall hold in confidence the identity of the Participants and shall comply with Applicable Laws regarding the confidentiality of such records.

8. RELATIONSHIP OF PARTIES

8.1 This Agreement does not create, and no provision of this Agreement shall be interpreted to create, a relationship of employer and employee, principal and agent, joint venture, or partnership between the parties. Neither Party (including any employee, agent or authorised representative thereof) shall have the power to bind or designate the other Party nor any persons affiliated with such Party in any manner whatsoever.

8.2 No employee, agent or authorised representative of the Institution and/or Investigator or personnel of the Study Team shall be considered, an employee of GIGH. Institution shall indemnify and hold harmless GIGH (and its affiliates) against all claims and demands that may be made by any of the above mentioned parties against GIGH.

9. NOTICES

9.1 Any notice, consent, approval or other communication (each a "**notice**") under this Agreement shall be in writing and shall be delivered to the recipient Party by hand or by sending to the address or email specified below (or as subsequently varied by notice):

If to GIGH:	If to Institute:	If to Investigator:
Amit Khanna George Institute for Global Health 308 Elegance Tower	Name: Commander Challa Venkateshwar **Himalayan Institute of Medical Sciences**	Name: **Dr Hemant Nautiyal** Address: **Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Swami**

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Plot No. 8, Jasola District Centre New Delhi 110025 , India Email: akhanna@georgeinstitute .org.in	Address: **Swami Rama Himalayan University, Swami Rama Nagar, Jollygrant, Dehradun, Uttarakhand, India (248016)** Email : **principal.hims@srhu.edu.in** **reg@srhu.edu.in**	**Rama Nagar, Jollygrant, Dehradun, Uttarakhand, India (248016)** Email: **drnauty1@gmail.com**

9.2 A notice given in accordance with clause 9.1 is taken to be received: (i) if hand delivered on the day of delivery; (ii) if sent by courier upon the day of the courier's delivery (as verified by the courier's records); (iii) if sent by certified or registered mail, upon the day of the postal service's delivery (as verified by the postal service's records); or (iv) if sent by email, upon confirmed successful transmission at the sender's location; but if delivery or receipt is not on a business day or is after 5:00 P.M. on a business day, notice is taken to be received in the next business day.

10. TERMINATION

10.1 GIGH may terminate this Agreement with immediate effect by written notice (hereinafter referred to as the "**Termination Notice**") to Institution and Investigator if:

(i) any regulatory authority requires the Study to be discontinued or materially altered; Investigator or Institution is Disqualified (as defined by clause 1.7 of this Agreement);

(ii) GIGH does not approve of the proposed replacement investigator;

(iii) GIGH fails or ceases to receive research funding for the Study;

(iv) Institution and Investigator do not randomize at least 12 Participant within one (1) months of receiving an authorisation letter from GIGH (as provided by clause 1.4 of this Agreement);

(v) Institution or Investigator, or Study Team, fail to perform, or performs improperly, any obligation of it under this Agreement (hereinafter referred to as the "**Default**"), provided that GIGH shall first have: (i) notified Institution and Investigator of such Default; and (ii) permitted the Party in Default a period of three working days (hereinafter referred to as the "**Cure Period**"), to cure the Default, which Cure Period shall be stated in the notice from GIGH; or

(vi) It comes to the attention of GIGH that Institution or Investigator has fabricated, falsified or plagiarized data pertaining to the Study or has otherwise breached or compromised the scientific integrity of the Study or caused harm to Participants.

10.2 GIGH may terminate this Agreement for whatever reason by giving thirty (30) days' prior written notice to the other Party.

10.3 Institution and Investigator may terminate this Agreement by written notice, which shall be effective immediately if :

(i) the IRB/IEC or any regulatory authority requires that Institution and/or Investigator cease a material part or all of their activities in connection with the Study; or

(ii) GIGH fails to perform, or performs improperly, any of its material obligations under this Agreement (hereinafter referred to as "**GIGH Default**"), provided that the Institution and/or Investigator shall first have: (i) notified GIGH of such GIGH Default; and (ii) permitted GIGH a period of thirty (30) days to cure the GIGH Default, which Cure Period shall be stated in the notice from the Institution and/or Investigator.

10.4 In the event of termination, the Parties shall promptly do all that is reasonably necessary to close-out the Study and shall cooperate to ensure the continued safety of the Participants. Each Party will, upon request of a Party, return or destroy any Confidential Information of that Party.

10.5 If this Agreement is terminated under clause 10.1, GIGH shall pay Institution for any work completed up to the date of Termination and for closing-out activities in accordance with generally accepted standards

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of good clinical practice, including ICH-GCP. Investigator and Institution acknowledge that they shall not be entitled to any further or additional payments from GIGH (or its affiliates).

10.6 Clauses 1 (Performance of the Study), 4 (Ownership of Data, Results, Intellectual Property), 5 (Publication), 7 (Confidentiality & Privacy), 10.4 (Termination), 11 (Indemnities, Limitation of Liability & Insurance) and 14.4 (Arbitration) of this Agreement, and any other clauses or provisions giving operational effect thereto, and any other clause or provision that should by its nature, shall survive on expiry or termination of this Agreement.

11. INDEMNITIES, LIMITATION OF LIABILITY & INSURANCE

11.1 GIGH shall hold harmless the Institution and the Investigator and their respective officers, directors and employees (hereinafter individually referred to as an "**Indemnified Party**" and collectively referred to as the "**Indemnified Parties**"), as applicable, from all claims made by third parties and against any and all liabilities, losses, damages and expenses (hereinafter collectively referred to as "**Losses**") that one or more of the Indemnified Parties may sustain due to any injury, (including death), suffered by any Participant resulting only from the administration of the Study drug described in the Protocol, when used in accordance with the approved labelling, the Protocol and any written instructions of GIGH, provided that the Indemnified Party has (i) used reasonable medical judgment in the conduct of the Study, (ii) otherwise acted in conformity with generally accepted standards of the medical community in which they practice and (iii) duly complied with all Applicable Laws and regulations and all ethical and professional standards relating to the protection of Participants, including with respect to ensuring appropriate IRB approval and oversight, obtaining effective informed consent and maintaining patient privacy in accordance with the Protocol and the instructions/guidance/advice issued by GIGH, from time to time.

11.2 Each Party ("**Indemnifying Party**") agrees and undertakes to indemnify, hold harmless and defend the other Party ("**Indemnified Party**") from and against any and all **Losses** arising as a result of or arising directly out of (a) breach by the Indemnifying Party of any provision of this Agreement or (b) the Indemnifying Party's negligence or wilful default in relation to performance or non-performance of any of its obligations under this Agreement.

11.3 Each Party's obligation to indemnify the other as set forth above is conditional on the Indemnified Party: (a) providing written notice to the Indemnifying Party of any Losses for which it is seeking an indemnity hereunder within ten (10) business days from the date of knowledge of such Losses; (b) permitting the Indemnifying Party to assume full responsibility to investigate, prepare for and defend any such Losses; (c) assisting the Indemnifying Party at their own expense, in the investigation and defence of any such Losses; and (d) not compromising or settling such Losses without the Indemnifying Party's prior written approval. In turn, the Indemnifying Party will not make any settlement which adversely affects in a material manner the reputation of an Indemnified Party without such Indemnified Party's prior approval, which approval shall not be unreasonably withheld.

11.4 Notwithstanding the above or anything contained to the contrary in this Agreement:

(i) neither Party shall be liable to the other for any punitive or consequential loss, including, without limitation, any loss of business, revenue, profit, reputation or goodwill;

(ii) the Parties shall take all reasonable steps to mitigate any loss, damage, claim, action or expense (including legal expense) they may suffer in terms of this Agreement; and

(iii) GIGH's liability whether in terms of this Agreement, tort (including gross negligence), strict liability, indemnity or otherwise and for any and all claims arising out of or in connection with this Agreement shall be limited in aggregate, whether in relation to a single event or a series of events, and whether each event is related or not, to a maximum of the fees paid to the Institution and/or the Investigator under this Agreement till the date such liability arose/the per subject and aggregate limit of GIGH's Clinical Trials Liability insurance cover, whichever is lower.

11.5 GIGH has made an arrangement of Clinical Trials Liability insurance cover adequate to cover the risks as specified under the aforementioned provisions of this Article. However, it is understood and agreed that

the maintenance of such insurance cover will not relieve either Party of its other obligations under this Agreement.

11.6 Institution and Investigator may secure and maintain insurance coverage for medical professionals and/or medical malpractice liability, general liability and employee's compensation as per the Applicable Laws or regulations.

12. ENTIRE AGREEMENT, AMENDMENT

12.1 All exhibits, schedules attached hereto, including the Protocol referenced herein, shall be incorporated by reference, and will form part of this Agreement. No part of this Agreement may be modified except where agreed to in writing by the Parties. No oral explanation or information or previous communication provided by any Party to any other Party affects the meaning or interpretation of this Agreement, or constitutes any collateral agreement, warranty or understanding between the Parties.

12.2 In the event of any inconsistency between the terms of this Agreement and the Protocol, the terms of this Agreement will prevail.

13. ASSIGNMENT& SUBCONTRACTING

13.1 The Institution or Investigator shall not assign or transfer or sub-contract the performance any of its rights or obligations under this Agreement or any part thereof without the prior written consent of GIGH, such consent not to be unreasonably withheld or delayed.

14. CONCLUDING PROVISIONS

14.1 Any clause or provision of this Agreement which is prohibited or unenforceable is ineffective to the extent of the prohibition or unenforceability, but the validity or enforceability of the remaining clauses of this Agreement will not be affected.

14.2 The obligations of a Party under this Agreement shall be suspended during the period and to the extent that such Party is prevented or hindered from complying by causes or circumstances: (i) beyond its reasonable control not due to its own fault or negligence; (ii) which are not reasonably foreseeable; and (iii) which the Party is by exercise of reasonable diligence, unable to prevent, including (a) act of God; (b) industrial dispute of any kind; (c) act of public enemy, war (whether declared or undeclared), blockade, revolution, riot, insurrection, malicious damage, civil commotion; (d) natural disaster/ pandemic/epidemic, medical emergency; € order of any court or authority, restraint, restriction, requirements, prevention, frustration or hindrance by or of any person, government or competent authority; and (f) embargo, unavailability or shortage of essential equipment, chemicals or other materials, goods, labour or services, lack of transportation or communication, breakage of facilities or machinery (each hereinafter a "**Force Majeure Event**"). A Party relying on this clause 14.2 must promptly provide notice to the other Parties of the occurrence or cessation of any Force Majeure Event as soon as practicable. Where such Majeure Event continues for more than three (3) calendar months, the other Parties have the right to promptly terminate the Agreement by written notice to the affected Party, and clauses 10.4 and 10.6 of this Agreement will apply.

14.3 This Agreement shall be construed, interpreted and applied in accordance with, and shall be governed by, the laws applicable in India within the jurisdiction of New Delhi courts.

14.4 The Parties agree to first attempt to resolve any dispute or difference arising out of or in connection with this Agreement or in respect of any defined legal relationship associated therewith or derived therefrom (hereinafter referred to as the "**Dispute**"). However, if the Parties are unable to resolve the Dispute within fourteen (14) days after first commencing good faith negotiations, the Parties agree to submit such Dispute for arbitration under Arbitration and Conciliation Act, 1996. The dispute or difference shall be referred to the sole arbitrator mutually appointed by the Parties the language for the arbitration proceedings shall

be English, and the place of arbitration proceedings shall be New Delhi courts/ where the cause of action arises. Each Party to the Dispute will be responsible for its own costs and expenses, and arbitration fees will be shared equally between the Parties to the Dispute. The decision of the arbitrator shall be final and binding between the Parties. The Parties agree to continue to perform this Agreement despite the existence of a Dispute or any proceedings under this clause 14.4. Nothing in this clause prevents a Party from obtaining urgent injunctive relief from any court, including with respect to the protection of its confidential or proprietary information.

14.5 No right under this Agreement is waived or deemed to be waived except by notice in writing signed by the Party waiving the right. Likewise, a single or partial exercise of any right, power or remedy will not preclude any other or further exercise of that or any other right, power or remedy.

The Parties hereto have caused this Agreement to be duly executed, as of the day and year first above written.

On Behalf of GIGH:

Signature Date: 18/2/25

Name: Amit Khanna
Designation: Director, Finance & Operations

Signature Date: 17FEB25

Name: Vivekanand Jha
Designation: Executive Director

INSTITUTION:

Signature Date: 07 Mar 2025

Name: Commander Challa Venkateshwar
Designation: Registrar

INVESTIGATOR:

Signature Date: 25/02/25

Name: Dr Hemant Nautiyal
Designation: Prof & Head of General Surgery

GIGH Representative Initials | Institution Representative Initials | Investigator Initials

Exhibit A

Enclosed: Effects of Advanced Trauma Life Support ® Training Compared to Standard Care on Adult Trauma Patient Outcomes: A Cluster Randomised Trial

STUDY PROTOCOL-V1.1.0_2024-05-09

EXHIBIT B
INVESTIGATOR CONFIRMATION

Study Name: Effects of Advanced Trauma Life Support ® Training Compared to Standard Care on Adult Trauma Patient outcomes: A Cluster Randomised Trial (Advance Trauma)

Investigator: Dr Hemant Kumar Nautiyal

I, the Investigator, confirm that I have received the Effects of Advanced Trauma Life Support ® Training Compared to Standard Care on Adult Trauma Patient outcomes: A Cluster Randomised Trial (Advance Trauma). I represent that I have read and fully understand the Protocol and other study related obligations. I will provide copies of the Protocol, and all information furnished by GIGH, to the Study Team and to discuss this material with them and ensure they are fully informed and understand the Protocol.

I agree and undertake to abide by the contents of the latest IRB/IEC approved Protocol and any amendments there to that are communicated to me.

Signature _____ Date 25/02/25

Name: Dr Hemant Kumar Nautiyal

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

GIGH Representative Initials _____ Institution Representative Initials _____ Investigator Initials _____

EXHIBIT C
PAYMENT SCHEDULE AND PAYMENT RULE FORM

STUDY: Effects of Advanced Trauma Life Support ® Training Compared to Standard Care on Adult Trauma Patient outcomes: A Cluster Randomised Trial

COUNTRY: INDIA

Expected Recruitment: 150 participants with adult trauma patients presenting to the emergency department of a participating hospital. Are expected to be recruited at the Institution.

Payment distribution will be as shown below, without any additional cost. All amounts mentioned below are inclusive of all taxes. All payments made to the payee are subject to Tax Deducted at Source (TDS) as per the applicable existing tax laws and GIGH will deduct the tax at the time of making payments unless a valid certificate for Tax Exemption is made available from the tax authority in a timely manner.

Data collection will be considered complete following verification of all data entry into the eCRF and resolution of all queries.

A fees of INR 30000(Thirty thousand only) per month shall be paid to Institution by GIGH for the recruitment of 12 participants per month and complete verification of all the appliable study forms upon verification of all data collected through the eCRF (Screening, Consent, Lar Attempt form, Baseline, Prehospital, Emergency Department, Hospital, Surgery, Imaging, Transfusion, Injury, Individual Mortality Status, Quality of Life (EQ5D5L), Disability (WHODAS), return to work and end of study form. In case, there are less than 12 participant recruitment consecutively for 3 months then the decision for termination of the site will be made from the George Institute.

*Payments will be processed on a quarterly basis as per the above schedule if all study visit data has been entered and queries resolved adequately.

GIGH shall conduct a training programme for the Institution and Investigator knows as ALTS Training Programme which will be completely sponsored by GIGH.

GIGH Representative Initials | Institution Representative Initials | Investigator Initials

Payments will be made to the following party:

(ALL INFORMATION BELOW MUST BE PRINTED)

Payable to:	SWAMI RAMA HIMALAYAN UNIVERSITY
PAN No. of Institution:	AAAJH0463L
Account Number:	33082676422
Bank Name & Address:	State Bank of India, Jolly Grant, Dehradun
IFSC Code:	SBIN0010580
Mailing Address:	SWAMI RAMA HIMALAYAN UNIVERSITY, SWAMI RAMA NAGAR, JOLLY GRANT, DEHRADUN. PIN CODE: 248016

Signature of the authorized signatory of the Institution: _____

Name of authorized signatory: Commander Challa Venkateshwar

Phone: 7055309532 **Email address:** reg@srhu.edu.in, principal.hims@srhu.edu.in

Date: _____